

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2017

Findings Date: December 18, 2017

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: G-11395-17

Facility: FMC of East Greensboro

FID #: 001324

County: Guilford

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

Project: Add four dialysis stations for a total of 43 dialysis stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Department 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to add four stations at its existing FMC of East Greensboro (FMC East Greensboro) facility for a total of 43 stations upon project completion.

This application is one of three Guilford County ESRD applications filed on September 15, 2017 for the October 1, 2017 review cycle:

- G-11395-17 / FMC of East Greensboro / add four dialysis stations pursuant to Facility Need Methodology
- G-11398-17 / Northwest Greensboro Kidney Center / add four dialysis stations pursuant to Facility Need Methodology

- G-11412-17 / Guilford County Dialysis / develop a new 10-station dialysis facility by relocating 10 dialysis stations from facilities in Rockingham County

The Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”) received a request from Fresenius Kidney Care Director of Operations, Certificate of Need, Jim Swann on October 6, 2017, to consider the three applications as competitive. The request is dated October 5, 2017.

However, the request was received after the review had begun on October 1, 2017. Furthermore, Chapter 14 of the State Medical Facilities Plan (SMFP) includes a County Need Methodology and a Facility Need Methodology for determining the need for additional dialysis stations. These need methodologies are mutually exclusive. If a need is generated pursuant to the County Need Methodology, facilities located in that county cannot apply for additional stations pursuant to the Facility Need Methodology. If no need is generated pursuant to the County Need Methodology, then facilities located in that county may apply pursuant to the Facility Need Methodology if utilization was 80% or greater. When reviewing an application filed pursuant to the Facility Need Methodology, the Agency does not consider whether or not there is a deficit or surplus of stations in that county. If the Agency did so, then no applicant proposing additional stations pursuant to the Facility Need Methodology could be approved if the County Need Methodology showed a surplus of stations. This would contradict the intent of the Facility Need Methodology. Therefore, the request was denied; therefore, the applications are not being reviewed as part of a competitive batch. Furthermore, during the review period, Project ID #G-11412-17 / Guilford County Dialysis was withdrawn by the applicant.

Need Determination

The 2017 SMFP provides a County Need Methodology and a Facility Need Methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the County Need Methodology shows there is no county need determination for Guilford 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 FMC East Greensboro in the July 2017 SDR is 3.41 patients per station per week. This utilization rate was calculated based on 133 in-center dialysis patients and 39 certified dialysis stations as of December 31, 2016 (133 patients / 39 stations = 3.41 patients per station per week). Application of the facility need methodology indicates up to four 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		85.26%
Certified Stations		39
Pending Stations		0
Total Existing and Pending Stations		39
In-Center Patients as of 12/31/16 (SDR2)		133
In-Center Patients as of 6/30/16 (SDR1)		130
Step	Description	Result
	Difference (SDR2 – SDR1)	3
(i)	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0462
(ii)	Divide the result of step (i) by 12	0.0038
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0462
(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	139.1385
(v)	Divide the result of step (iv) by 3.2 patients per station	43.4808
	and subtract the number of certified and pending stations to determine the number of stations needed	4.4808

As shown in the table above, based on the Facility Need Methodology for dialysis stations, the potential number of stations needed is four 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 four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

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

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 53-55, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 9, Section L, pages 46-50, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 10-11, and Section N, page 52. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

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

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

This determination is based on a review of the:

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

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

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

C

The applicant proposes to add four dialysis stations to its existing facility for a total of 43 stations at FMC East Greensboro upon project completion. There are no current projects under development at FMC East Greensboro that affect the number of certified and pending stations at the facility.

Patient Origin

On page 373, the 2017 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 Guilford County. Facilities may also serve residents of counties not included in their service area.

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

**FMC East Greensboro Historical Patient Origin
 As of June 30, 2017**

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Guilford	129	0	0
Rockingham	1	0	0
Other States	1	0	0
TOTAL	131	0	0

In Section C.1, page 13, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

**FMC East Greensboro
 Projected Patient Origin by County**

County	Operating Year 1 1/1/19 –12/31/19	Operating Year 2 1/1/20-12/31/20	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	OY1	OY2
Guilford	138.9	147.1	99.3%	99.4%
Rockingham	1.0	1.0	0.7%	0.6%
Total	139.9	148.1	100.0%	100.0%

Totals may not sum due to rounding

The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients. Exhibit I-1 contains a Home Training agreement between FMC East Greensboro and Greensboro Kidney Center (BMA Greensboro).

In Section C.1, pages 13-16, the applicant provides the assumptions and methodology used to project utilization and patient origin. The applicant states that projected utilization is based on the existing facility's experience along with the letters from 21 patients dialyzing at another BMA facility expressing their intent to transfer their care to FMC East Greensboro upon completion of its expansion.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, pages 5-6, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the July 2017 SDR, and it proposes to add four dialysis stations to FMC East Greensboro for a total of 43 stations at that facility following completion of this project. The applicant used the following assumptions, as outlined in Section C.1, pages 13-17:

- 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).
- The applicant assumes that the FMC East Greensboro Guilford County patients will increase at a rate of 6.67%. On pages 13-14, the applicant states that the facility census increased by 28 patients since December 31, 2014 and provides data showing an increase in census from 95 patients in December 31, 2011 to 133 patients at December 31, 2016, a five year compound annual growth rate (CAGR) of 7%, higher than the July 2017 SDR's published Guilford County Five Year Average Annual Change Rate (AACR) of 4.7% and higher than the proposed 6.67% rate.
- The applicant assumes 18 of 21, or 85% of the dialysis patients providing letters of intent to transfer their care from another BMA facility to FMC East Greensboro will actually transfer their care to FMC East Greensboro upon completion of its expansion.
- The applicant assumes the Rockingham County patient will continue treatment at the facility, but will not increase and will be added to the census projection at appropriate points in time. The applicant assumes the patient from out-of-state was a transient patient and will not be projected forward.
- Project ID #G-11303-17 to develop FKC Garber-Olin projected 30 patients dialyzing at FMC East Greensboro would transfer their care to FKC Garber-Olin upon its

completion as of December 31, 2018. The applicant assumes those 30 patients will transfer their care from FMC East Greensboro.

Projected Utilization

In Section C.1, page 15, the applicant provides the methodology used to project utilization, as summarized below:

FMC East Greensboro	In-Center
Begin with the Guilford County patients dialyzing at FMC East Greensboro, as of June 30, 2017.	129
Project the Guilford County patient population forward six months to December 31, 2017, using half the annual increase of 6.67% ($6.67\% / 12 \times 6 = 3.33\%$).	$129.0 \times 1.0333 = 133.3$
Project the Guilford County patient population forward twelve months to December 31, 2018, using an annual increase of 6.67%.	$133.3 \times 1.067 = 142.2$
Subtract the 30 patients transferring their care to FKC Garber-Olin (Project ID #G-11303-17).	$142.2 - 30 = 112.2$
Add the 18 Guilford County patients who expressed intent to transfer to FMC East Greensboro upon project completion.	$112.2 + 18 = 130.2$
Add the 1 Rockingham County patient to establish the projected beginning census for the first year of operation.	$130.2 + 1 = 131.2$
Project the Guilford County patient population forward twelve months to December 31, 2019, using an annual increase of 6.67%.	$130.2 \times 1.067 = 138.9$
Add the patient from Rockingham County. This is the end of OY1.	$138.9 + 1 = 139.9$
Project the Guilford County patient population forward twelve months to December 31, 2020 (end of OY2), using the an annual increase of 6.67%	$138.9 \times 1.067 = 147.1$ [148.1]
Add the patient from Rockingham County. This is the end of OY2.	$147.1 + 1 = 148.1$ [148.1 + 1 = 149.1]

Note: The Project Analyst's calculations, using the applicant's assumptions, resulted in a total of 149 patients, one more than the applicant projected; thus, the applicant's projection is conservative, comparably.

Therefore, based on the table above, the applicant projects that at the end of OY1, 139.9 patients, rounded down to 139 patients will be dialyzing on 43 stations for a projected utilization rate of 3.23 patients per station per week ($139 \text{ in-center patients} / 43 \text{ stations} = 3.23$) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

In Section C.2, page 15, the applicant states:

“In this application, BMA has projected a patient population of 139.9 rounded down to 139 patients, to be dialyzing at the FMC East Greensboro facility at the end of the first year. Failure to add the four stations will lead to higher utilization rates at the facility. Utilization by 139 patients on 43 dialysis stations is calculated to be 3.2325 patients per station, or 80.81% utilization.”

Projected utilization appears to be based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1, page 47, the applicant states:

“It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L.1(b), page 47, the applicant projects that 81% of its in-center patients will be covered by some combination of Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed increase in stations, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

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

- 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,
- use of established methodologies and assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services,
- documentation from patients willing to transfer their care to the facility due to the facility location being closer to their homes or more convenient to access,
- projected utilization supported by a facility growth rate higher than the county CAGR from 2014 to 2016, which is expected to continue for the future, and
- use of 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, and
- information which was publicly available during the review and used by the Agency.

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

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

NA

The proposed project does not involve the reduction or elimination of a service, or the relocation of a facility or a 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 the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant states that it has projected a patient population at the facility which results in greater than 80% utilization; therefore, the applicant determined that failure to develop additional capacity would result in higher utilization rates and potentially restrict patient admission.
2. Apply for fewer stations – the applicant states that fewer stations would result in higher utilization rates, and spreading the cost of internal expansion over fewer stations would be less cost effective.

Thus, after considering the above alternatives, the applicant concludes that its proposal to add four dialysis stations is the most effective alternative.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application 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, and
- the data cited is reasonable to use to support the assumptions made with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of East Greensboro 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. d/b/a FMC of East Greensboro shall develop no more than four additional dialysis stations for a total of no more than 43 certified stations at FMC of East Greensboro upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of East Greensboro shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of East Greensboro shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add four dialysis stations to its existing facility for a total of 43 stations at FMC East Greensboro upon project completion.

Capital and Working Capital Costs

In Section F.1, page 23, the applicant provides the capital cost of the project as summarized in the following table:

**FMC East Greensboro
Project Capital Costs**

		Total Capital Costs
Construction Project Costs		
Construction Contract	\$95,816	
Sub-Total Construction Costs		\$95,816
Miscellaneous Project Costs		
Water Treatment Equipment	\$3,000	
Equipment/Furniture	\$12,000	
Architect & Engineering Fees	\$8,623	
Other: Contingency/Generator	\$5,750	
Sub-Total Miscellaneous Costs		\$29,373
Total Capital Cost		\$125,189

Totals may not sum due to rounding

In Sections F.10 and F.11, page 26, the applicant states that FMC East Greensboro is an existing facility, thus the project will not involve start-up and initial operating expenses.

Availability of Funds

In Exhibit F-1, the applicant provides a letter dated September 15, 2017 from the Senior Vice President & Treasurer of the parent company, Fresenius Medical Care Holdings, Inc. (FMC), authorizing the project and committing cash reserves for the capital expenditure in the amount of \$125,189. Exhibit F-2 contains the FMC and Subsidiaries Consolidated Financial Statements, as of December 31, 2016, showing cash and cash equivalents of \$357,899,000, total assets of \$20,135,661,000 and net assets (total assets less total liabilities) of \$10,533,297,000. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides 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	Operating Year 2
Total Treatments	20,007	21,340
Total Gross Revenues (Charges)	\$ 79,787,916	\$ 85,103,920
Total Net Revenue	\$ 6,797,517	\$ 7,250,413
Total Operating Expenses (Costs)	\$ 5,069,264	\$ 5,310,627
Net Income	\$ 1,728,253	\$ 1,939,786

Note: The applicant incorrectly labels Form B, page 66. Column D should be labeled Column C. Column E should be labeled Column D as Interim Year from 1/1/18-12/31/18. Column F should be labeled Column E as Year 1 from 1/1/19-12/31/19. The final column is correctly labeled Column F as Year 2 from 1/1/2020- 12/31/2020.

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, and
- documentation of sufficient funding for the capital needs of the project is provided and is credible.

This determination is based on a review of the:

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

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

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

C

The applicant proposes to add four dialysis stations to its existing FMC East Greensboro facility, for a total of 43 stations upon project completion.

On page 373, the 2017 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.*” The facility is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are four operational dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	79.91%	3.1964
BMA of South Greensboro (FMC)*	59	77.12%	3.0847
BMA of Southwest Greensboro (FMC)**	33	85.61%	3.4242
FMC of East Greensboro (FMC)	39	85.26%	3.4103
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
FMC High Point (FMC Proposed Site)	0	0.00%	0.0000
High Point Kidney Center (WFUHS)***	40	93.75%	3.7500
Northwest Greensboro Kidney Center (FMC)	33	81.06%	3.2424
Triad Dialysis Center (WFUHS)	27	77.78%	3.1111

Source: July 2017 SDR, Table B.

* Project ID #G-11055-15 approved the relocation of 10 stations from BMA of South Greensboro to develop FMC High Point in Guilford County, leaving a total of 49 stations at BMA of South Greensboro upon project completion.

**BMA of Southwest Greensboro was approved to relocate four stations to Northwest Greensboro Kidney Center in Project ID #G-11287-17. This certificate of need was relinquished by the applicant on September 5, 2017.

*** Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Point Kidney Center upon project completion.

Fresenius related entities own and operate seven of the nine existing and proposed dialysis facilities in Guilford County. With the exception of the two proposed projects, each of the existing FMC dialysis facilities is well-utilized, operating above 3.0 patients per station.

According to Table D in the July 2017 SDR, there is a deficit of ten dialysis stations in Guilford County. The county need methodology, as discussed on page 376 of the 2017 SMFP, requires a deficit of 10 stations or greater and the utilization of all facilities in the county to be

80% or greater to identify a county need for an additional facility. Therefore, based on the utilizations in the July 2017 SDR for Guilford County facilities, the deficit does not result in a county need determination.

The applicant is proposing to add four stations based on facility need and demonstrates the facility was serving 133 patients weekly on 39 stations, which is 3.4 patients per station or 85% of capacity, as of December 31, 2016. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 13-16 of the application. The growth projections are based on a projected 6.67% average annual growth rate in the number of in-center dialysis patients (Guilford County residents only) at the FMC East Greensboro facility. At the end of Operating Year One, FMC East Greensboro projects utilization will be 3.23 in-center patients per station (139 patients / 43 dialysis stations = 3.23), which is 81% of capacity. The applicant adequately demonstrates the need to develop four additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Guilford County. The discussion on analysis of need 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, and
- 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, and
- information which was publicly available during the review and used by the Agency.

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

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

C

In Section H.1, page 33, the applicant provides the projected staffing for FMC in OY2 by full-time equivalent (FTE) positions, as shown in the table below:

FMC of East Greensboro Proposed FTE Positions and Salaries OY2			
Position	Total FTE Positions	OY2 Projected Annual Salary per FTE	OY2 Total Projected Salary
Registered Nurse	5.00	\$ 72,732	\$ 363,660
Patient Care Technician	14.00	\$ 32,957	\$ 461,398
Dietitian	1.00	\$ 65,913	\$ 65,913
Social Worker	1.00	\$ 56,822	\$ 56,822
Clinical Manager	1.00	\$ 77,278	\$ 77,278
Administrator	0.20	\$ 106,825	\$ 21,365
In-Service	0.30	\$ 72,732	\$ 21,820
Clerical	2.00	\$ 36,366	\$ 72,732
Chief Tech	0.25	\$ 61,368	\$ 15,342
Equipment Tech	1.00	\$ 40,912	\$ 40,912
Total FTEs	25.75		

Notes: The Medical Director is an independent contractor, not an employee.

In Exhibit I.5, the applicant provides a letter from Ryan Sanford, MD, dated August 17, 2017, indicating support for the project and a willingness to continue to serve as Medical Director of the facility. In Section H.3, page 57, the applicant states it does not anticipate any difficulties in filling staff positions as it will use aggressive recruiting and advertising efforts, coupled with a range of benefits and competitive salaries to attract qualified staff.

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

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

This determination is based on a review of the:

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

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

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

C

In Section I.1, page 36, the applicant lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting, blood bank services, diagnostic/evaluation, and X-ray will be referred to Cone Health. Exhibit I-3 includes a back-up hospital agreement between the applicant and Cone Health. Exhibit I-4 contains transplant services agreements for both North Carolina Baptist Hospital and Carolinas Medical Center with the applicant. Exhibit I-1 contains an agreement for home training services at Greensboro Kidney Center (BMA of Greensboro). Exhibit I-2 contains an agreement for lab services between Spectra and FMC. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 37-39, stating that Fresenius has relationships with the medical community in the area, including area physicians and hospitals. On page 37, the applicant identifies Dr. Kellie Goldsborough as the Medical Director for the facility and states a letter from Dr. Goldsborough is included in Exhibit I-6. However, Exhibit I-5 contains a letter from Dr. Ryan Sanford documenting he is the Medical Director for FMC of East Greensboro. Dr. Sanford's curriculum vitae is included in Exhibit I-6.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare system.

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

- agreements for the provision of necessary ancillary services required for the provision of the proposed services,
- agreements for the referral and transfer of dialysis patients for inpatient hospital services and transplant services, and
- identified relationships with the medical community, including physicians and hospitals.

This determination is based on a review of the:

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

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

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

NA

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

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

NA

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

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

NA

The proposed project does not involve construction of new space and any renovations will be minor. The estimated square footage in the facility will not change pursuant to his project. Therefore Criterion (12) is not applicable to this review.

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

C

In Section L.7, page 50, the applicant reports that 81.6% of the patients who received treatments at FMC East Greensboro had some or all of their services paid for by Medicare or Medicaid in CY2016. The table below shows the historical (CY2016) payment source for the facility:

Payment Source	Patients by Percent of Total
Self Pay/Indigent/Charity	0.44%
Medicare	54.38%
Medicaid	10.65%
Commercial Insurance	12.52%
Medicare/Commercial	16.55%
Miscellaneous (including VA)	5.47%
Total	100.00%

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
Guilford	14%	52%	49%	16%	7%	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 based on reasonable and adequately supported assumptions regarding:

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

This determination is based on a review of the:

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

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

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

(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), pages 48-49, 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 accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 49, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

The applicant adequately demonstrates 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.

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

- the facility’s historical payor mix, and
- the existence of any civil rights access complaints against the existing facility.

This determination is based on a review of the:

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

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

- (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(b), page 47, the applicant provides the projected payor mix for the FMC East Greensboro facility as shown in the table below:

Projected Payor Mix, OY2

Payment Source	Patients by Percent of Total
Self Pay/Indigent/Charity	1.66%
Medicare	54.79%
Medicaid	9.68%
Commercial Insurance	12.18%
Medicare/Commercial	16.20%
Miscellaneous (including VA)	5.49%
Total	100.00%

As shown in the table above, the applicant projects that over 80.67% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. The projected payor mix is comparable to the 2016 payor mix for FMC East Greensboro, as shown in Criterion (13)(a).

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

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

The applicant adequately demonstrates that medically underserved populations would have access to the proposed services. This determination is based on a review of the:

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

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

- (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 East Greensboro will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that FMC East Greensboro provides a range of means by which a person can access its services.

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

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

This determination is based on a review of the:

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

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

- (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 health related education programs are welcomed at the facility. Exhibit M-1 includes a letter from the applicant to the Dean of Health Programs at Guilford Technical Community College, dated September 14, 2017, inviting the school to include the facility in its clinical rotations for its nursing students.

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

This determination is based on a review of the:

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

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

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

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

C

The applicant proposes to add four additional dialysis stations to the existing FMC East Greensboro facility for a total of 43 dialysis stations upon completion of the project.

On page 373, the 2017 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.*” The facility is located in Guilford County; thus, the service area for this facility consists of

Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the July 2017 SDR, there are seven operational dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	79.91%	3.1964
BMA of South Greensboro (FMC)*	59	77.12%	3.0847
BMA of Southwest Greensboro (FMC)**	33	85.61%	3.4242
FMC of East Greensboro (FMC)	39	85.26%	3.4103
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
FMC High Point (FMC Proposed Site)	0	0.00%	0.0000
High Point Kidney Center (WFUHS)***	40	93.75%	3.7500
Northwest Greensboro Kidney Center (FMC)	33	81.06%	3.2424
Triad Dialysis Center (WFUHS)	27	77.78%	3.1111

Source: July 2017 SDR, Table B.

* Project ID #G-11055-15 approved the relocation of 10 stations from BMA of South Greensboro to develop FMC High Point in Guilford County, leaving a total of 49 stations at BMA of South Greensboro upon project completion.

**BMA of Southwest Greensboro was approved to relocate four stations to Northwest Greensboro Kidney Center in Project ID #G-11287-17. This certificate of need was relinquished by the applicant on September 5, 2017.

*** Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Point Kidney Center upon project completion.

Fresenius related entities own and operate seven of the nine existing and proposed dialysis facilities in Guilford County. With the exception of the two proposed projects, each of the existing FMC dialysis facilities is reasonably well-utilized, operating above 3.0 patients per station.

According to Table D in the July 2017 SDR, there is a deficit of ten dialysis stations in Guilford County. The county need methodology, as discussed on page 376 of the 2017 SMFP, requires a deficit of 10 stations or greater and the utilization of all facilities in the county to be 80% or greater to identify a county need for an additional facility.

The applicant is proposing to add four stations based on facility need and demonstrates the facility was serving 133 patients weekly on 39 stations, which is 3.4 patients per station or 85% of capacity, as of December 31, 2016. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 13-16 of the application.

The growth projections are based on a projected 6.67% average annual growth rate in the number of in-center dialysis patients (Guilford County residents only) at the FMC East Greensboro facility. At the end of Operating Year One, FMC East Greensboro projects utilization will be 3.23 in-center patients per station (139 patients / 43 dialysis stations = 3.23), which is 81% of capacity. The applicant adequately demonstrates the need to develop four additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

In Section N.1, page 52, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

“BMA does not expect this proposal to have effect on the competitive climate in Guilford County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC East Greensboro facility begins with patients currently served by BMA, and a growth of that patient population at a rate of 6.67% annual [sic], based on recent facility history.”

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 80% of the patients at FMC East Greensboro will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 52, that its proposal will *“enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

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

The discussion regarding need and projected utilization found in Criterion (3), the discussion regarding alternatives found in Criterion (4), the discussion regarding costs and charges found in Criterion (5), the discussions regarding access found in Criteria (3) and (13), and the discussion regarding quality found in Criterion (20) are incorporated herein by reference.

The applicant adequately demonstrates 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.

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

- the need for the proposed project and that it is an effective alternative,
- the access of the proposed population to existing dialysis services,
- the projected utilization based upon reasonable and supported assumptions,
- the projected costs and charges associated with the proposed project, and
- the provision of quality care.

This determination is based on a review of the:

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

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

- (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

Bio-Medical Applications of North Carolina, Inc. owns and operates more than 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. Two BMA facilities incurred immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. The applicant summarizes the deficiencies cited, the resolutions, and provides documentation in Exhibits O-3 and O-4, including correspondence from Licensure and the Centers for Medicare and Medicaid Services. On page 57, the applicant states that both facilities were back in full compliance with all CMS Guidelines upon the submittal of the application. Based on a review of the 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, and
- the applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

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

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

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMC of East Greensboro is an existing facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, page 13, the applicant projects to serve 139 in-center patients by the end of Operating Year 1, which is 3.23 patients per station ($139 / 43 = 3.23$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 13-17. The

discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.