

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 8, 2019

Findings Date: November 8, 2019

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: G-11764-19

Facility: Fresenius Medical Care High Point

FID #: 150332

County: Guilford

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

Project: Add no more than 4 dialysis stations for a total of no more than 14 stations upon project completion

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. (hereinafter referred to as “the applicant” or BMA) proposes to add four dialysis stations to Fresenius Medical Care High Point (FMC High Point), an existing facility, for a total of 14 dialysis stations upon completion of this project.

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 62, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 20 stations in Guilford County, but because there are facilities with a reported utilization of less than 80%, there is no county need determination for new dialysis stations for Guilford County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for FMC High Point in the July 2019 SDR is 3.6 patients per station per week, or 90%, based on 36 in-center dialysis patients and 10 certified dialysis stations [$36 / 10 = 3.6$; $3.6 / 4 = 0.9000$ or 90%]. Therefore, FMC High Point is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates up to six additional stations may be needed at this facility, as illustrated in the following the table:

FMC High Point		
OCTOBER 1 REVIEW-JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		90.00%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		36
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		30
Step	Description	Result
	Difference (SDR2 - SDR1)	6
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.4000
(ii)	Divide the result of Step (i) by 12	0.0333
(iii)	Multiply the result of Step (ii) by 12	0.4000
(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	50.4000
(v)	Divide the result of Step (iv) by 3.2 patients per station	15.7500
	and subtract the number of certified and pending stations to determine the number of stations needed	5.7500

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC High Point is six, based on rounding allowed in

Step (v). 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; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.3 (a and d), pages 11 and 13, respectively; Section N.2(b), page 53; Section O, pages 55-58; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.3 (b and d), pages 11 - 13; Section C.7, pages 20-21; Section L, pages 47-50; Section N.2(c), page 53; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.3 (c and d), pages 12-13; Section N.2(a), pages 52-53; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to add four dialysis stations to FMC High Point for a total of 14 dialysis stations upon completion of this project.

The following table, summarized from data on page 7 of the application and Table B of the July 2019 SDR, illustrates the current and projected number of dialysis stations at FMC High Point.

FMC High Point

# of Stations	Description	Project ID #
10	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
4	# of stations to be added as part of this project	G-11764-19
	# of stations to be deleted as part of this project	
	# of stations previously approved to be added but not yet certified	
	# of stations previously approved to be deleted but not yet certified	
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
14	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add four dialysis stations at FMC High Point for a total of 14 stations, upon the completion of each of the projects listed above.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Guilford County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 16, the applicant provides the patient origin for FMC High Point patients as of December 31, 2018, as summarized in the table below.

**FMC High Point
 1/1/2018/-12/31/2018**

COUNTY	# OF PATIENTS	% OF PATIENTS
Guilford	26	72.2%
Davidson	3	8.3%
Durham	1	2.8%
Forsyth	2	5.6%
Randolph	1	2.8%
Virginia	1	2.8%
Other States	2	5.6%
Total	36	100.0%

Totals may not sum due to rounding

The applicant provides the following patient origin to represent the second full operating year following project completion, in Section C, page 17.

**FMC High Point
Projected Patient Origin
CY2022 [CY2021]**

COUNTY	# OF PATIENTS	% OF PATIENTS
Guilford	35.2	77.9%
Davidson	3.0	6.6%
Forsyth	6.0	13.3%
Randolph	1.0	2.2%
Total	45.2	100.0%

Totals may not sum due to rounding

However, the table provided by the applicant provides the number of patients (45.2) as of the end of the first full operating, CY2021. Using the same percent of patients per county, the following reflects the patient origin for the second full operating year, CY2022.

**FMC High Point
Projected Patient Origin
CY2022**

COUNTY	# OF PATIENTS	% OF PATIENTS
Guilford	37.4	77.9%
Davidson	3.2	6.6%
Forsyth	6.4	13.3%
Randolph	1.1	2.2%
Total	48.0	100.0%

Totals may not sum due to rounding

In Section C, pages 17-18, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

The applicant proposes to add four dialysis stations to FMC High Point for a total of 14 dialysis stations upon completion of this project. In Section C.4, page 19, the applicant states that the need the proposed population has for the proposed services is a function of the individual patient need for dialysis care and treatment.

In Section Q, pages 67-68, the applicant describes its need methodology and assumptions for projecting utilization at FMC High Point, summarized as follows:

- The applicant provides a table on page 67 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

**FMC High Point
In-Center Patients**

COUNTY	12/31/18	6/30/2019
Guilford	26	29
Davidson	3	3
Durham	1	0
Forsyth	2	6
Randolph	1	1
Virginia	1	0
Other States	2	0
Total	36	39

- The applicant states that the FMC High Point patient census as of June 30, 2019 is the beginning census for projecting utilization and that census was submitted to the Agency on the ESRD Data Collection form in August 2019.
- The applicant states that it assumes the 10 patients from Davidson, Forsyth, and Randolph counties dialyzing at FMC High Point on June 30, 2019 will continue dialyzing at the facility by patient choice. The utilization will remain constant.
- The applicant assumes the Guilford County patient population who dialyze at FMC High Point will increase at a growth rate of 8.0% based upon facility performance. The applicant states that this growth rate is reasonable based on the growth of 40% achieved in Step (i) in the facility need methodology, even though Guilford County's Five Year Average Annual Change Rate (AACR) published in the July 2019 SDR is 5.4%. However, the applicant provides the facility utilization as of June 30, 2019; thus, the facility growth from June 30, 2018 through June 30, 2019 can be accurately calculated at 30% ($39 - 30 = 9/30 = 30\%$). The Guilford County patient growth for the last six months was an increase of 11.5% ($29 - 26 = 3/26 = 0.115$), which would be 23% if annualized. Therefore, the 8% annual growth rate for Guilford County patients is not unreasonable.
- Services will be offered as of December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

Projected Utilization

In Section Q, page 68, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the following table.

FMC HIGH POINT IN-CENTER PATIENTS

Begin with facility census of Guilford County patients as of June 30, 2019.	29
Project this population forward six months to December 31, 2019, using the annual growth rate of 8% (4% for six months).	$29 \times 1.04 = 30.2$
Project Guilford County patients forward one year to December 31, 2020, using the annual growth rate of 8%.	$30.2 \times 1.08 = 32.6$
Add patients from Davidson, Forsyth and Randolph counties projected to continue to dialyze at FMC High Point. This is the starting census on December 31, 2020.	$32.6 + 10 = 42.6$
Project Guilford County patients forward one year to December 31, 2021, using the annual growth rate of 8%.	$32.6 \times 1.08 = 35.2$
Add patients from Davidson, Forsyth and Randolph counties projected to continue to dialyze at FMC High Point. This is the census on December 31, 2021 at the end of OY1.	$35.2 + 10 = 45.2$
Project Guilford County patients forward one year to December 31, 2022, using the annual growth rate of 8%.	$35.2 \times 1.08 = 38.0$
Add patients from Davidson, Forsyth and Randolph counties projected to continue to dialyze at FMC High Point. This is the census on December 31, 2022 at the end of OY2.	$38.0 + 10 = 48.0$

Source: Table in Section Q, page 68

At the end of OY1 (CY2021) FMC High Point is projected to serve 45.2 in-center patients on 14 stations; and at the end of OY2 (CY2022) the facility is projected to serve 48 in-center patients on 14 stations.

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

- OY1: 3.23 patients per station per week, or 80.7% utilization [$45.2 \text{ patients} / 14 \text{ stations} = 3.23$; $3.23 / 4 = 0.8071$].
- OY 2: 3.43 patients per station per week, or 85.7% utilization [$48 \text{ patients} / 14 \text{ stations} = 3.43$; $3.43 / 4 = 0.8571$].

The projected utilization of 3.23 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- FMC High Point was operating at 90% capacity as of December 31, 2018, as reported in the July 2019 SDR.
- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the patient population using the facility growth rate adjusted down to 8%.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C.7, pages 20-21, the applicant states:

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

...

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

In Section L, page 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**FMC High Point
Projected Payor Mix CY 2022**

Payor Source	# of Patients	% of Total
Self-pay	0.40	0.84%
Insurance*	3.32	6.92%
Medicare*	31.04	64.67%
Medicaid*	0.76	1.58%
Medicare/Commercial	12.31	25.65%
Miscellaneous (Incl. VA)	0.16	0.34%
Total	47.99	100.00%

Totals may not sum due to rounding

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add four dialysis stations to FMC High Point for a total of 14 dialysis stations upon completion of this project.

In Section E, page 26, the applicant states it considered the following three alternatives related to serving the needs of the patients in the area:

1. Maintain the status quo – the applicant states this was not a reasonable alternative because it fails to recognize the growth of the ESRD patient population residing in High Point and the western Guilford County area. The applicant states that failure to add stations will result in higher utilization rates at the facility and fewer opportunities for patient admission.
2. Apply for fewer than four stations – the applicant states that applying for fewer stations would only serve to increase projected utilization rates at the facility; thus BMA would be forced to file yet another application to add stations at FMC High Point.
3. Relocate stations from another BMA facility in Guilford County – the applicant discusses that each Guilford County facility is well utilized. The applicant states that it would not be appropriate to relocate stations from these facilities given the individual circumstances as listed in the application for each facility.

On page 27, the applicant states that it elected to add four stations because this proposal is the most cost-effective approach to providing the necessary services for the patient population projected to be served at FMC High Point.

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

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. 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 July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than four additional dialysis station at Fresenius Medical Care High Point for a total on no more than 14 dialysis stations, 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 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 FMC High Point for a total of 14 dialysis stations upon completion of this project.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 71, the applicant projects a total capital cost of \$15,000 for furniture and non-medical equipment.

In Section Q, page 72, the applicant provides the assumptions used to project the capital cost.

In Sections F.3, page 29, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 28, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans		
Accumulated reserves or OE *	\$15,000	\$15,000
Bonds		
Other (Specify)		
Total Financing	\$15,000	\$15,000

* OE = Owner's Equity

Exhibit F-2 contains a letter dated September 16, 2019 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings (FMCH), the parent company for BMA, for the capital costs of the project. The letter also documents that the 2018 Consolidated Balance Sheet for FMCH reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

FMC High Point Projected Revenue and Operating Expenses

	OY 1 CY2021	OY 2 CY2022
Total Treatments	6,493.61	6,894.69
Total Gross Revenue (charges)	\$40,851,271	\$43,374,519
Total Net Revenue	\$2,044,298	\$2,170,567
Average Net Revenue per Treatment	\$314.82	\$314.82
Total Operating Expenses (costs)	\$1,956,871	\$2,091,064

Average Operating Expense per Treatment	\$301.35	\$303.29
Net Income / Profit	\$87,427	\$79,503

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q 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, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add four dialysis stations to FMC High Point for a total of 14 dialysis stations upon completion of this project.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” 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 2019 SDR, there are nine existing and approved 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	85.27%	3.4107
BMA of South Greensboro (FMC)	49	99.49%	3.9796
BMA of Southwest Greensboro (FMC)	33	76.52%	3.0606
FMC of East Greensboro (FMC)	39	90.38%	3.6154
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
Fresenius Medical Care High Point (FMC)	10	90.00%	3.6000
High Point Kidney Center (WFUHS)	41	91.46%	3.6585
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.1622
Triad Dialysis Center (WFUHS)	27	87.04%	3.4815

Source: July 2019 SDR, Table B.

Per the July 2019 SDR, as of December 31, 2018, Fresenius related entities own and operate seven of the nine existing and proposed dialysis facilities in Guilford County with a total of 224 certified stations. Wake Forest University Health Sciences owns and operates two facilities. With the exception of the approved but undeveloped facility, each of the existing dialysis facilities is well-utilized, operating above 3.0 patients per station.

The applicant provides the same data as above in Section G, page 33. On page 34, the applicant provides the same data for the Fresenius facilities submitted on the Fresenius ESRD Data Collection Forms in August 2019, still showing seven facilities as of June 30, 2019, but with a total of 235 certified stations following the opening or the approved Garber-Olin facility and the relocation of stations at other facilities, as summarized below.

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	44	100.00%	4.0000
BMA of South Greensboro (FMC)	48	88.02%	3.5208
BMA of Southwest Greensboro (FMC)	33	80.30%	3.2121
FMC of East Greensboro (FMC)	39	91.03%	3.6410
Fresenius Kidney Care Garber-Olin (FMC)	24	44.79%	1.7917
Fresenius Medical Care High Point (FMC)	10	97.50%	3.9000
Northwest Greensboro Kidney Center (FMC)	37	73.65%	2.9459

The applicant provides a table on page 35 which shows the total number of patients by county dialyzing at each BMA Guilford County facility for a grand total of 784 patients served at BMA Guilford County facilities as of June 30, 2019.

In Section G, page 34, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Guilford County based on the utilization as of June 30, 2019. The applicant states:

“This is an application to add four dialysis stations to FMC High Point. All of the BMA facilities in Guilford County are well utilized. The overall utilization by 784 dialysis patients on 235 certified dialysis stations is 3.3362 patients per station.

BMA is not proposing to duplicate services, but to ensure a sufficient number of stations remain available for the patients of the area. The July 2019 SDR reports a deficit of 20 stations for Guilford County. Adding stations will not duplicate services.”

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

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

Conclusion

The Agency reviewed the:

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

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

- (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 Form H Staffing, page 82, the applicant provides a table illustrating current and projected OY2 staffing in full time equivalents (FTEs) for FMC High Point, as summarized below.

POSITION	FTE Positions as of 6/30/19	FTE POSITIONS OY1	FTE POSITIONS OY2
FMC Clinic Manager	1.00	1.00	1.00
RN	1.00	1.75	2.00
Patient Care Technician	3.00	3.75	4.50
Dietician	0.30	0.40	0.40
Social Worker	0.30	0.40	0.40
Equipment Technician	0.40	0.40	0.40
Administration	0.50	0.50	0.50
FMC Director Operations	0.15	0.15	0.15
In-Service	0.15	0.10	0.10
Chief Technician	0.15	0.10	0.10
Total	6.95	8.55	9.55

Source: Section Q Form H

The assumptions and methodology used to project existing staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 38, the applicant identifies the current medical director for the facility as Dr. James Lin. In Exhibit H-4, the applicant provides a letter from James Lin, MD indicating his intent in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section I, page 40, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	Referral to BMA Greensboro Kidney Center
Home training	
HH	
PD Accessible follow-up program	
Psychological counseling	Presbyterian Crossroad Counseling
Isolation – hepatitis	BMA on site
Nutritional counseling	BMA on site
Social Work services	BMA on site
Acute dialysis in an acute care setting	Referral to Cone Health
Emergency care	BMA staff until ambulance transport to hospital
Blood bank services	Cone Health
Diagnostic and evaluation services	Cone Health; Greensboro Diagnostic
X-ray services	Cone Health; Greensboro Diagnostic
Laboratory services	BMA on site / Spectra
Pediatric nephrology	Referral to UNC Healthcare
Vascular surgery	Referral to Carolina Kidney Vascular; Vein and Vascular Specialists
Transplantation services	Referral to UNC Healthcare
Vocational rehabilitation & counseling	Guilford County Vocational Rehabilitation
Transportation	Specialty Community Area Transportation; Greensboro Transit Authority; Guilford County Transportation

Source: Table in Section I, page 40

In Section I, page 40, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

NA

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

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

NA

The applicant is not 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 or 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, page 48, the applicant provides the historical payor mix during CY2018 for its existing services, as shown in the table below.

**FMC High Point
Historical Payor Mix CY2018**

Payor Source	# of Patients	% of Total
Self-pay	0.30	0.84%
Commercial Insurance*	2.49	6.92%
Medicare*	23.28	64.67%
Medicaid*	0.57	1.58%
Medicare/Commercial	9.23	25.65%
Miscellaneous (Incl. VA)	0.12	0.34%
Total	36	100.00%

*Including any managed care plans

Total may not sum due to rounding

In Section L.1(a), page 47, the applicant provides comparison of the demographical information on FMC High Point patients and the service area patients during CY2018, as summarized below.

	Percentage of Total FMC High Point Patients Served during the Last Full OY	Percentage of the Population of the Service Area
Female	47.5%	52.7%
Male	52.5%	47.3%
Unknown		
64 and Younger	67.5%	84.8%
65 and Older	32.5%	15.2%
American Indian		0.8%
Asian	2.5%	5.4%
Black or African-American	60.0%	35.1%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	35.0%	49.8%
Other Race	0.0%	8.8%
Declined / Unavailable	2.5%	

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 48, that it has no obligation in any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 49, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 49, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**FMC High Point
Projected Payor Mix CY 2022**

Payor Source	# of Patients	% of Total
Self-pay	0.40	0.84%
Commercial Insurance	3.32	6.92%
Medicare*	31.04	64.67%
Medicaid*	0.76	1.58%
Medicare/Commercial*	12.31	25.65%
Miscellaneous (Incl. VA)	0.16	0.34%
Total	47.99[48.00]	100.00%

Totals may not sum due to rounding

*Including any managed care

As shown in the table above, during the second year of operation, the applicant projects that 0.4% of total services will be provided to self-pay patients, 90.32% to Medicare patients (includes Medicare and Medicare/Commercial), and 1.58% to Medicaid patients.

On pages 49-50, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of FMC High Point.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section M, page 51, 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.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

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

C

The applicant proposes to add four dialysis stations to FMC High Point for a total of 14 dialysis stations upon completion of this project.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” 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 2019 SDR, there are nine existing and approved 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	85.27%	3.4107
BMA of South Greensboro (FMC)	49	99.49%	3.9796
BMA of Southwest Greensboro (FMC)	33	76.52%	3.0606
FMC of East Greensboro (FMC)	39	90.38%	3.6154
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
Fresenius Medical Care High Point (FMC)	10	90.00%	3.6000
High Point Kidney Center (WFUHS)	41	91.46%	3.6585
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.1622
Triad Dialysis Center (WFUHS)	27	87.04%	3.4815

Source: July 2019 SDR, Table B.

Fresenius related entities own and operate seven of the nine existing and proposed dialysis facilities in Guilford County. Wake Forest University Health Sciences owns and operates two facilities. With the exception of the approved but undeveloped facility, each of the existing dialysis facilities is well-utilized, operating above 3.0 patients per station.

According to Table D in the July 2019 SDR, there is a deficit of 20 dialysis stations in Guilford County. The applicant proposes to add four dialysis stations to the existing facility in Guilford County.

In Section N, pages 52-53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Guilford County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with patients currently dialyzing at the facility.

...

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

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.

...

It is corporate 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.”

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 B, F, and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies 127 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality

of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- FMC High Point is an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section Q Form C, page 66, the applicant projects that FMC High Point will serve 45.2 in-center patients on 14 stations, or a rate of 3.23 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 3.2 patient per station per week. 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 Q, pages 13 - 15, and Section Q, pages 67-68, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.