

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 15, 2020

Findings Date: June 15, 2020

Project Analyst: Celia C. Inman

Co-Signer: Fatimah Wilson

Project ID #: G-11875-20

Facility: FMC of East Greensboro

FID #: 001324

County: Guilford

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

Project: Add no more than 8 dialysis stations pursuant to facility need for a total of no more than 51 dialysis 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. (BMA), the applicant, proposes to add no more than eight dialysis stations pursuant to facility need for a total of no more than 51 stations at FMC of East Greensboro (FMCEG) upon project completion.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Guilford County. However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center, as reported in the 2020 SMFP, is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for FMCEG on page 157 of the 2020 SMFP, is 90.38% or 3.6 patients per station per week, based on 141 in-center dialysis patients and 39 certified dialysis stations [$141 / 39 = 3.62$; $3.62 / 4 = 0.9038$].

As shown in Table 9E, page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMCEG is up to twelve additional stations; thus, the applicant is eligible apply to apply to add up to twelve additional stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

In Section B.2, page 11, the applicant provides a Facility Need Methodology table, pursuant to Condition 2, as summarized below:

Facility Need Methodology Condition 2	Response
SMFP in effect on the day the review begins	2020 SMFP
County	Guilford
FID # / Facility Name	FID #001324 / FMC of East Greensboro
Total number of stations needed pursuant to Condition 2 of the Facility Need Methodology	12
Is this the first application submitted in this calendar year in response to this need determination?	Yes
If not, provide the Project ID#(s) for applications submitted earlier this calendar year	NA
How many stations were previously applied for and / or approved in those applications?	0
Number of stations the applicant proposes to develop or add in this application	8

The applicant proposes to add no more than eight new stations at FMCEG, which is consistent with the 2020 SMFP calculated facility need determination for up to twelve dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

Policy GEN-3: Basic Principles, pages 30-31 of the 2020 SMFP, 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.”

In Sections B, C, L, N and O, the applicant explains why it believes its application is conforming to Policy GEN-3, as discussed below.

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5(a and d), pages 14-15 and 16-17, respectively; Section N.2(b), page 51; Section O, pages 53-56; 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. 5 (b and d), pages 15-16 and 16-17, respectively; Section C.7, pages 22-23; Section L, pages 45-47; Section N.2(c), page 51; 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.5(c and d), pages 16-17, and in Section N, pages 50-51. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how FMCEG’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. 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 the application is conforming to this criterion based on the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology in the 2020 SMFP.
- The applicant adequately demonstrates it is consistent with Policy GEN-3 because the applicant shows how FMCEG’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

(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 no more than eight dialysis stations pursuant to facility need for a total of no more than 51 stations upon project completion.

The following table, summarized from data on page 7 of the application and page 157 of the 2020 SMFP, shows the projected number of stations at FMCEG upon project completion.

FMC East of Greensboro		
Stations	Description	Project ID #
39	Total # of existing certified stations in the SMFP in effect on the day the review will begin	
+8	# of stations to be added as part of this project (add eight stations and relocate two stations from HPKC)	G-11875-20
+4	# of stations previously approved to be added but not yet certified per the 2020 SMFP	G-11395-17*
51	Total stations upon completion of proposed project and previously approved projects	

*Project ID #G-11395-17 (add four stations) – stations were certified effective November 25, 2019

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” FMC of East Greensboro is located in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

In Section C, pages 19-20, the applicant provides FMCEG’s current patient origin and projected patient origin for the second full operating year following project completion, January 1, 2023 – December 31, 2023 (CY2023), as summarized in the following table:

County	CY2019		CY2023	
	IC Patients	% of Total	IC Patients	% of Total
Guilford	121.0	93.08%	149.3	95.52%
Forsyth	3.0	2.31%	3	1.92%
Hyde	1.0	0.77%	1	0.64%
Randolph	2.0	1.54%	2	1.28%
Rockingham	1.0	0.77%	1	0.64%
Georgia	1.0	0.77%	0	0.00%
Other States	1.0	0.77%	0	0.00%
Total	130.0	100.00%	158.4 [156.3]*	100.00%

Totals may not sum due to rounding

*The total for CY2023 patients provided in the applicant’s table appears to be a typographical error based on the applicant’s methodology table provided on page 21 and the fact that the percentages in the applicant’s table agree with the percentages using the correct total number of patients.

As the applicant’s tables on pages 19-20 and above show, the applicant offers only in-center dialysis. In Section I, page 38, the applicant states that it does not offer home hemodialysis training and support services at the FMCEG facility.

In Section C, pages 20-21, the applicant provides the assumptions, methodology, and support documentation used to project FMCEG’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant describes the need, stating:

“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the

proposed project. BMA has identified the population to be served as 148.7 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 72.88% or 2.92 patients per station.”

The information is reasonable and adequately supported for the following reasons:

- The applicant demonstrates the need for the additional stations at FMCEG based on its existing and future patient population.
- The existing operational Guilford County facilities are operating at above 76% capacity per the 2020 SMFP.
- The applicant provides supporting documentation in its projected utilization in Section Q Form C.

Projected Utilization

In Section Q, page 67, the applicant provides its projected utilization methodology, based on its stated assumptions, as summarized in the following table.

Begin with facility census of Guilford County patients as of December 31, 2019.	121
Project this population forward one year to December 31, 2020, using the Guilford County Five-Year AACR of 5.4%.	$121 \times 1.054 = 127.5$
Project Guilford County patients forward one year to December 31, 2021, using the Guilford County Five-Year AACR of 5.4%.	$101.1 \times 1.054 = 134.4$
Project Guilford County patients forward one year to December 31, 2022, using the Guilford County Five-Year AACR of 5.4%.	$105.3 \times 1.054 = 141.7$
Add the seven patients from Forsyth, Hyde, Randolph and Rockingham counties. This is the ending for OY1, CY2022.	$141.7 + 7 = 148.7$
Project Guilford County patients forward one year to December 31, 2023, using the Guilford County Five-Year AACR of 5.4%.	$141.7 \times 1.054 = 149.3$
Add the seven patients from Forsyth, Hyde, Randolph and Rockingham counties. This is the ending for OY2, CY2023.	$149.3 + 7 = 156.3$

Source: Table in Section Q

As the table above shows, using conventional rounding, the methodology used by the applicant achieves a projection of 149 in-center patients by the end of the first operating year, OY1 (CY2022), for a utilization rate of 2.9 patients per station per week or 73% (149 patients / 51 stations = 2.92 patients per station / 4 = 0.7304). By the end of OY2 (CY2023), following the applicant’s methodology and assumptions, FMCEG will have 156 in-center patients dialyzing at the center for a utilization rate of 76.5% (156 / 51 = 3.06 / 4 = .7647). The projected utilization of 2.9 patients per station per week for CY2022 satisfies the 2.8 in-center patients per station per week threshold for the first full year following project completion as required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Guilford County as published in the 2020 SMFP to project growth of Guilford County residents.

Access

In Section C.7, pages 22-23, 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.”

The applicant projects payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table from Section L.3(b), page 47.

**Projected Payor Mix
CY2023**

Payor Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-Pay	1.28%	0.00%	0.00%
Commercial Insurance*	7.32%	0.00%	0.00%
Medicare*	54.44%	0.00%	0.00%
Medicaid*	12.15%	0.00%	0.00%
Other: Medicare / Commercial	20.56%	0.00%	0.00%
Other: Misc. including VA	4.25%	0.00%	0.00%
Total	100.00%	0.00%	0.00%

In Section L, page 47, the applicant provides the assumptions for projecting payor mix, stating that the projected payor mix is based upon FMCEG’s recent history of treatment volumes of payor mix. 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 a reduction, elimination, or relocation of a facility or service.

- (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 no more than eight dialysis stations pursuant to facility need for a total of no more than 51 stations upon project completion.

In Section E, page 28, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- Status Quo – the applicant states that not applying to expand the facility was deemed unacceptable due to the growth experienced by FMCEG. Thus, this alternative was not considered an effective alternative.
- Apply for fewer stations pursuant to the Facility Need Methodology – the applicant states that the facility physical plant can be expanded to accommodate a maximum of eight dialysis stations and will require extensive renovations.

Thus, it is more cost effective to spread that cost among eight dialysis stations as opposed to fewer stations.

- Apply for more stations pursuant to the Facility Need Methodology – BMA considered this alternative; however, the facility physical plant capacity is limited and cannot accommodate more than eight additional stations.

On page 28, the applicant states that the growth of the patient census at FMCEG is sufficient reason to apply for eight stations.

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

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

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. 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 2020 SMFP, Bio-Medical Applications of North Carolina, Inc. shall develop no more than eight additional in-center dialysis stations at FMC of East Greensboro for a total on no more than 51 in-center dialysis 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 no more than eight dialysis stations pursuant to facility need for a total of no more than 51 stations upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 69, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Construction/Renovation Costs	\$280,566
Architect Fees	\$25,251
Non-Medical Equipment/Furniture	\$74,890
Contingency	\$45,873
Total Capital Costs	\$426,579

The applicant provides the assumptions used to project the capital cost in Section Q, page 70.

In Section F, pages 30-31, the applicant states that there will be no start-up or initial operating costs because FMCEG is an operational facility.

Availability of Funds

In Section F, page 29, the applicant states that the capital cost, respectively, will be funded by Bio-Medical Applications of North Carolina, Inc., as shown in the table below.

Sources of Capital Financing	
Type	Bio-Medical Applications of North Carolina, Inc.
Loans	
Accumulated reserves or OE *	\$426,579
Bonds	
Other (Specify)	
Total Financing	\$426,579

* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated March 16, 2020, 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.

The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q Form F-2 Income Statement, the applicant project that revenues will exceed operating expenses in the first two operating years of this project, as summarized in the table below.

FMC of East Greensboro Revenue and Expenses		
	CY2022	CY2023
In-Center Patients*	145	153
In-Center Treatments	21,467	22,571
Gross Patient Revenue	\$135,051,598	\$141,992,441
Adjustment from Gross	\$128,517,290	\$135,122,308
Net Patient Revenue	\$6,534,308	\$6,870,132
Average Net Revenue per Treatment	\$304	\$304
Total Operating Expenses	\$5,559,682	\$5,424,840
Average Operating Expense per Treatment	\$259	\$240
Net Income	\$974,626	\$1,445,293

Totals may not sum due to rounding

*Average number of patients during the year ((beginning patients + ending patients) / 2)

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 availability of sufficient funds for the capital needs of the proposal.

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

C

The applicant proposes to add no more than eight dialysis stations pursuant to facility need for a total of no more than 51 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* FMCEG is located in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

According to Table B, pages 156-157 of the 2020 SMFP, there are ten existing or approved dialysis facilities in Guilford County, as summarized below:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	85.27%	3.4
BMA of South Greensboro (FMC)	49	99.49%	4.0
BMA of Southwest Greensboro (FMC)	33	76.52%	3.1
Central Greensboro Dialysis (TRCNC proposed new site)	0	0.00%	0.0
FMC of East Greensboro (FMC)	39	90.38%	3.6
Fresenius Kidney Care Garber-Olin (FMC proposed new site)	0	0.00%	0.0
FMC High Point (FMC)	10	90.00%	3.6
High Point Kidney Center (WFUHS)	41	91.46%	3.7
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.2
Triad Dialysis Center (WFUHS)	27	87.04%	3.5

Source: 2020 SMFP, Table B.

Per the 2020 SMFP and the table above, Fresenius related entities own and operate seven of the ten 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 and a DaVita related facility has been approved for development. With the exception of the approved but undeveloped facilities, each of the existing dialysis facilities is well-utilized, operating above 3.0 patients per station.

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. The applicant states:

“This is a proposal to add eight dialysis stations to an existing dialysis facility. The Stations are needed by the patient population projected to be served by the facility. . . . The applicant has not projected to serve patients currently served in another facility, or served by another provider. The stations are needed at FMC of East Greensboro to support the growing patient census at the facility.”

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:

- The proposal is consistent with the facility need methodology.
- The applicant adequately demonstrates that the proposed addition of stations at the existing facility is needed in addition to the operational facilities in Guilford County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q Form H Staffing, page 81, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions, as summarized in the following table.

POSITION	FTE Positions as of January 2020	FTE POSITIONS CY2022	FTE POSITIONS CY2023
FMC Clinic Manager	1.00	1.00	1.00
RN	7.00	8.00	8.00
Patient Care Technician	15.00	17.00	17.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration	2.00	2.00	2.00
FMC Director Operations	0.20	0.20	0.20
In-Service	0.25	0.25	0.25
Chief Technician	0.20	0.20	0.20
Total	28.65	31.65	31.65

Source: Section Q Form H of the application.

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 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 37, the applicant identifies the current medical director for the facility as Dr. Ryan Sanford. In Exhibit H-4, the applicant provides a letter from Ryan Sanford, 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.1, pages 38-39, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 38, as summarized below.

**FMC of East Greensboro
 Ancillary and Support Services**

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

Source: Table in Section I, page 38

In Section I, page 39, the applicant describes FMCEG’s relationships with other local health care and social service providers.

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 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.

C

The applicant proposes to add eight dialysis stations to FMCEG for a total of 51 dialysis stations upon completion of this project.

In Section K.2, page 41, the applicant states that the proposed project involves 1,500 square feet of existing space to be renovated.

In Section K.3(a), page 41, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Section Q and Exhibit K.2.

On page 42, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states:

“This project will not increase costs or charges to the public for the proposed services.”

The applicant provides supporting documentation in Section Q.

On pages 42-43, the applicant addresses applicable energy saving features that will be incorporated into the proposed project.

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.

- (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

The applicant proposes to add no more than eight dialysis stations pursuant to facility need for a total of no more than 51 stations upon project completion.

In Section L, page 46, the applicant provides the historical payor mix during CY2019 for its existing services, as summarized in the table below.

**FMC of East Greensboro
Historical Payor Mix CY2019**

Payor Source	# of Patients	% of Total
Self-pay	1.70	1.28%
Insurance*	9.50	7.32%
Medicare*	70.70	54.44%
Medicaid*	15.80	12.15%
Medicare/Commercial	26.70	20.56%
Miscellaneous (Incl. VA)	5.50	4.25%
Total	130.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 45, the applicant provides comparison of the demographical information on FMCEG patients and the service area patients during CY2019, as summarized below.

	Percentage of Total FMCEG Patients Served during the Last Full OY	Percentage of the Population of the Service Area
Female	45.7%	52.7%
Male	54.3%	47.3%
Unknown		
64 and Younger	65.2%	84.8%
65 and Older	34.8%	15.2%
American Indian	0.0%	0.8%
Asian	0.0%	5.4%
Black or African-American	87.0%	35.1%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	12.3%	49.8%
Other Race	0.7%	8.8%
Declined / Unavailable	0.0%	

* 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 46, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons under any federal regulations.

In Section L, page 47, 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 47, 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 of East Greensboro
Projected Payor Mix CY 2022**

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	2.00	1.28%
Insurance*	11.40	7.32%
Medicare*	85.10	54.44%
Medicaid*	19.00	12.15%
Medicare/Commercial	32.10	20.56%
Miscellaneous (Incl. VA)	6.60	4.25%
Total	156.30	100.00%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 1% of total in-center services will be provided to self-pay patients, 75% to Medicare patients (includes Medicare and Medicare/Commercial), and 12% to Medicaid patients.

On page 47, 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 of East Greensboro.

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.5, page 48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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 49, 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-2.

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 no more than eight dialysis stations pursuant to facility need for a total of no more than 51 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” FMCEG is located in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

According to Table B of the 2020 SMFP, there are ten existing or approved dialysis facilities in Guilford County. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	85.27%	3.4
BMA of South Greensboro (FMC)	49	99.49%	4.0
BMA of Southwest Greensboro (FMC)	33	76.52%	3.1
Central Greensboro Dialysis (TRCNC proposed new site)	0	0.00%	0.0
FMC of East Greensboro (FMC)	39	90.38%	3.6
Fresenius Kidney Care Garber-Olin (FMC proposed new site)	0	0.00%	0.0
FMC High Point (FMC)	10	90.00%	3.6
High Point Kidney Center (WFUHS)	41	91.46%	3.7
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.2
Triad Dialysis Center (WFUHS)	27	87.04%	3.5

Source: 2020 SMFP, Table B.

Fresenius related entities own and operate seven of the ten existing and proposed dialysis facilities in Guilford County. Wake Forest University Health Sciences owns and operates two facilities and a proposed DaVita related facility has been approved. 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.

Regarding the expected effects of the proposal on competition in the service area and how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services, in Section N, pages 50-51, 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.

...

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

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.

- (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, pages 59-64, the applicant identifies the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies more than 100 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 56, 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.

Therefore, the application is conforming to this criterion.

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

C

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

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- The applicant is not proposing to establish a new ESRD facility.

- (b) An applicant proposing to increase the number of dialysis stations in:
 - (1) an existing dialysis facility; or
 - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section Q, page 65-67, the methodology proposed by the applicant achieves a projection of 149 in-center patients by the end of the first operating year, OY1 (CY2022), for a utilization rate of 2.9 patients per station per week or 73% (148.7 patients / 51 stations = 2.92 patients per station / 4 = 0.7304). The projected utilization of 2.9 patients per station per week for CY2022 satisfies

the 2.8 in-center patients per station per week threshold for the first full year following project completion as required by 10A NCAC 14C .2203(b).

- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section Q, pages 66-67, the applicant provides the assumptions and methodology used to project utilization of the facility.