ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:	June 8, 2016
Findings Date:	June 8, 2016
Project Analyst:	Julie Halatek
Team Leader:	Lisa Pittman
Project ID #:	G-11143-16
Facility:	FMC of East Greensboro
FID #:	001324
County:	Guilford
Applicant:	Bio-Medical Applications of North Carolina, Inc.
Project:	Add four dialysis stations for a total of 39 certified dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC of East Greensboro (FMC-EG) proposes to add four dialysis stations for a total of 39 certified dialysis stations upon project completion.

Need Determination

The 2016 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of eight dialysis stations in Guilford County; therefore, based on the county need methodology, there is no need for additional

stations in Guilford County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for FMC-EG in the January 2016 SDR is 3.4 patients per station, which is at least 3.2 patients per week. This utilization rate was calculated based on 119 in-center dialysis patients and 35 certified dialysis stations as of June 30, 2015 (119 patients / 35 stations = 3.4 patients per station per week).

April 1 Review – January 2016 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		85.0%
Certified Stations		35
Pending Stations		0
Total Existing and Pending Stations		**35**
In-Center Patients as of 6/30/15 (January 2016 SDR) (SDR2)		119
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR1)		105
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	14
	Multiply the difference by 2 for the projected net in-center change	28
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.2667
(ii)	Divide the result of Step (i) by 12	0.0222
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/15 until the end of calendar year 2015)	0.1333
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	134.8667
(v)	Divide the result of Step (iv) by 3.2 patients per station	42.1458
	and subtract the number of certified and pending stations to determine the number of stations needed*	**7**

*Note: According to Step Two of the facility need methodology in the January 2016 SDR, "*Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)*(v). *In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.*

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles on page 39 of the 2016 SMFP. Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote*

safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 12-13, Section O, pages 60-66, and referenced exhibits. The information provided by the applicant is reasonable and adequately 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 would promote equitable access in Section B.4(b), pages 13-14, Section L, pages 53-57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 14-16, and Section N, page 59. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need methodology in the January 2016 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial

and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC of East Greensboro (FMC-EG) proposes to add four dialysis stations for a total of 39 certified dialysis stations upon project completion.

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 23, the applicant provides the historical patient origin for FMC-EG patients as of December 31, 2015, which is summarized in the following table:

FMC-EG Dialysis Patients by County/State 12/31/2015	
County/State	**Number of Patients**
Guilford	121
Alamance	1
Johnston	1
SC, VA, Other	3
Total	**126**

In Section C.1, page 19, the applicant provides the projected patient origin for FMC-EG for in-center patients for the first two operating years (OY) following completion of the project, as shown below.

FMC-EG Dialysis Patients by County/State – OYs 1 & 2				
County	**OY1 – CY 2017**	**OY2 – CY 2018**	**Patients as % of Total**	
	In-Center	**In-Center**	**OY1**	**OY2**
Guilford	127.3	130.2	99.2%	99.2%
Alamance	1	1	0.8%	0.8%
Total	**128.3**	**131.2**	**100.0%**	**100.0%**

The applicant provides the assumptions and methodology used to project patient origin on pages 19-21. The applicant adequately identifies the population to be served.

Analysis of Need

FMC-EG proposes to add four dialysis stations for a total of 39 certified dialysis stations upon project completion. In Section C, pages 19-21, the applicant states the need for the proposed project is based on the following factors:

- The first two full OYs of the project are expected to be CY 2017 and CY 2018.

- On December 31, 2015, FMC-EG was providing dialysis treatment for 126 in-center patients, including 121 patients who reside in Guilford County, one patient who resides in Alamance County, and three patients who reside in other states.

- The applicant assumes the Guilford County ESRD patient population utilizing the facility will increase at the rate of three percent per year, the Five Year Average Annual Change Rate (AACR) for Guilford County as published in the January 2016 SDR. The applicant states that no growth was calculated for the patients residing outside of Guilford County.

- The applicant assumes that the patients residing in other states are transient patients, dialyzing at FMC-EG for a short period of time, and does not include those patients in projections.

- The applicant states that FMC-EG has a need for the four additional stations due to current utilization of the existing stations, the facility need methodology which shows the potential need for four additional stations, and because the projected patient population at the end of the first operating year corresponds with a utilization rate of approximately 82.75 percent.

Projected Utilization

In Section C.1, pages 19-21, the applicant provides the assumptions and methodology it uses to determine the need for additional dialysis stations at the facility. The applicant's assumptions and methodology are summarized below:

- The Guilford County patient population will grow at a rate of three percent (the Five Year AACR for Guilford County as published in the January 2016 SDR) through the end of the second year of operation.

- The applicant assumes no increase for the resident of Alamance County who utilizes the facility but assumes that patient will continue to dialyze at FMC-EG and is added to the calculations when appropriate.

- The project is scheduled for completion on December 31, 2016. OY1 is CY 2017. OY2 is CY 2018.

In Section C.1, pages 19-21, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

FMC-EG	In-Center Dialysis
Starting point of calculations is Guilford County patients dialyzing at FMC-EG on December 31, 2015.	121
Guilford County patient population is projected forward by one year to December 31, 2016. Projection is based on the AACR for Guilford County (3.0%).	121 X 1.03 = 124.6
Guilford County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (3.0%).	124.6 X 1.03 = 128.3
The one patient from Alamance County is added. This is the projected census on December 31, 2017 (OY1)).	128.3 + 1 + 129.3
Guilford County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (3.0%).	128.3 X 1.03 = 132.2
The one patient from Alamance County is added. This is the projected census on December 31, 2018 (OY2).	132.2 + 1 = 133.2

Note: On pages 19-21, the applicant's projections are slightly lower than in the table above. This appears to be due to a calculation error by the applicant at the beginning of its calculations. The correct calculations are shown in the table above.

The applicant projects to serve 129.3 in-center patients on 39 stations, which is 3.32 patients per station per week (129.3 patients / 39 stations = 3.32), by the end of OY1 and 133.2 in-center patients on 39 stations, which is 3.42 patients per station per week (133.2 patients / 39 stations = 3.42), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The January 2016 SDR indicates that FMC-EG's utilization rate was 85 percent (3.4 patients per station) as of June 30, 2015. In this application, the applicant projects the Guilford County in-center patient census will increase annually by three percent, which is consistent with the Guilford County AACR published in the January 2016 SDR. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

In Section C.1, page 19, the applicant states:

> *"This facility does not include a home therapies program. BMA has an existing home program at the BMA Greensboro facility. The existing FMC East Greensboro facility does not have sufficient space to accommodate a home therapies program. BMA believes it is most cost effective to not add home therapies at this location."*

Access

In Section L.1, pages 53-54, the applicant states that FMC-EG provides dialysis services to all residents in its service area without qualifications and serves patients without

regard to income, race, color, ethnic origin, gender, age, or physical or mental conditions. The applicant projects 86 percent of its patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at FMC-EG, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section E.1, page 27, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that this alternative was dismissed due to the growth rate of the patient population at FMC-EG.

- Apply for More Than Four Stations – The applicant states that it could have applied for up to seven stations, per the facility need methodology, but that the facility does not have physical space to accommodate more than four additional stations without expending significant resources. The applicant states the four additional stations will help meet the growing demand for services at FMC-EG.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of East Greensboro shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of East Greensboro shall develop and operate no more than four additional dialysis stations for a total of no more than 39 certified stations which shall include any isolation or home hemodialysis stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of East Greensboro shall install plumbing and electrical wiring through the walls for no more than 39 dialysis stations which shall include any isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of East Greensboro shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 for a total of 39 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In the table in Section F.1, page 29, the applicant states that the projected capital cost is $17,300, which includes $3,000 for water treatment equipment and $14,300 for other equipment.

The applicant states that FMC-EG is an existing dialysis facility with an ongoing operation; therefore, in Sections F.10-12, page 32, it does not project any working capital needs.

Availability of Funds

In Section F.2, page 30, the applicant states that cash reserves/owner's equity is being used to finance the proposed project.

Exhibit F-1 contains a March 15, 2016 letter from the Vice President and Assistant Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, stating that the company is submitting a certificate of need application to add four stations to FMC-EG. The letter states that Fresenius Medical Care Holdings, Inc. has committed cash reserves in the amount of $17,300 for the project's capital expenditure.

In Section F.8(b), page 31, the applicant states:

> "*The 2014 Consolidated Balance Sheet reflects more than $341 million in cash, and total assets exceeding $18 billion. It is obvious that FMC has the resources necessary for all projects. This application will not interfere with the financing of any other projects currently filed, or being filed by BMA. The amount shown in the financial statements is more than adequate to finance all CON projects proposed, and under development.*"

Exhibit F-2 includes the most recent audited financial statements for Fresenius Medical Care Holdings, Inc. for years ended December 31, 2013 and 2014. As of December 31, 2014, Fresenius Medical Care Holdings, Inc. had $195,280,000 in cash and cash equivalents, $18,507,042,000 in total assets and $9,460,268,000 in net assets. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B) in Section R, page 75, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FMC-EG	**Operating Year 1 CY 2017**	**Operating Year 2 CY 2018**
Gross Patient Revenue	$74,467,924	$76,238,596
Deductions from Gross Patient Revenue	($68,355,881)	($69,981,170)
Net Patient Revenue	$6,112,043	$6,257,426
Total Operating Expenses	$4,795,560	$4,912,653
Net Income/Profit	**$1,316,484**	**$1,344,773**

The applicant's projections of treatments and revenues are reasonable based on the number of patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 39, the applicant provides projected staffing and salaries. Form A in Section R, page 72, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC of East Greensboro (FMC-EG) proposes to add four dialysis stations for a total of 39 certified dialysis stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The January 2016 SDR indicates there are seven dialysis facilities in Guilford County, as shown below. Five facilities are BMA facilities and two facilities are Wake Forest University Health Sciences (WFUHS) facilities.

Guilford County Dialysis Facilities			
Dialysis Facilities	**Certified Stations 6/30/2015**	**Percent Utilization**	**Patients per Station**
BMA of Greensboro (BMA)	56	75.45%	3.02
BMA of South Greensboro (BMA)	59	75.42%	3.02
BMA of Southwest Greensboro (BMA)	31	78.23%	3.13
FMC of East Greensboro (BMA)	35	85.00%	3.40
High Point Kidney Center (WFUHS)	42	91.07%	3.64
Northwest Greensboro Kidney Center (BMA)	33	71.97%	2.88
Triad Dialysis Center (WFUHS)	22	84.09%	3.36

As illustrated above, each Guilford County facility is utilized above 70 percent as of June 30, 2015. As of that date, FMC-EG was serving 119 patients weekly on 35 stations, which is 3.4 patients per station per week or 85 percent of capacity (119 patients / 35 stations = 3.4; 3.4 / 4 = 0.85 or 85%). At the end of Operating Year One, the applicant projects that FMC-EG will be serving 129.3 patients weekly on 39 stations, which is 3.32 in-center patients per station per week or 83 percent of capacity (129.3 patients / 39 stations = 3.32; 3.32 / 4 = 0.83 or 83%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates the need to add four additional dialysis stations based on the number of in-center patients it currently serves and proposes to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Guilford County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 39, the applicant provides the following table to illustrate the projected staffing for FMC-EG at the end of OY2.

FMC-EG – Proposed Facility Staffing	
Position	**Projected # of FTEs**
Medical Director*	
RN	5.00
Technician	13.00
Clinical Manager	1.00
Administrator	0.20
Dietician	1.00
Social Worker	1.00
Chief Tech	0.15
Equipment Tech	1.00
In-Service	0.20
Clerical	1.75
Total	**24.30**

*The Medical Director is a contract position and is not an employee of the facility.

The following table shows the applicant's projected number of direct care staff FTEs at FMC-EG for OY2, as shown on page 42 of the application.

FMC-EG – Projected Direct Care Staff Hours – OY2					
Direct Care Positions	**# FTEs*** [a]	**Hours / Year / FTE** [b]	**Total Annual FTE Hours** [c] = [a] x [b]	**Total Annual Hours of Operation **** [d]	**FTE Hours / Hours of Operation** [e] = [c] ÷ [d]
RN	5.00	2,080	10,400	3,120	3.33
Technician (PCT)	13.00	2,080	27,040	3,120	8.67
Total	**18.00**	**2,080**	**37,440**	**3,120**	**12.00**

* FTEs should match the direct care Total FTE Positions [a + c] listed in the Facility Staffing table in Section H, Question 1.
** Total annual hours of operation from the Proposed Hours of Operation table in Section H, Question 6.

The applicant states that the Medical Director is not directly employed by the facility but provides services on a contractual basis. In Section I.3, page 44, the applicant identifies Dr. Kellie A. Goldsborough as the current Medical Director for the facility. Exhibit I-6 contains a copy of a letter from Dr. Goldsborough supporting the proposed project.

In Section H.3, page 40, the applicant describes its experience and process for recruiting and retaining staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I, pages 43-46, the applicant discusses the providers of the necessary ancillary and support services for the proposed facility. The applicant discusses coordination with the existing health care system on pages 43-45. Exhibits I-1 through I-6 contain documents from BMA of Greensboro, Spectra Laboratories, Moses Cone Memorial Hospital, North Carolina Baptist Hospital, and Dr. Kellie A. Goldsborough, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information found in Section I and referenced Exhibits is reasonable and supports a finding of conformity with 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

(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

(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

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 57, the applicant reports that 86 percent of the patients who received treatments at FMC-EG had some or all of their services paid for by Medicare or Medicaid in CY 2015. The historical payor mix for patients dialyzing at FMC-EG is shown in the table below.

FMC-EG Historical Payor Mix – CY 2015	
Payment Source	**% Total Patients**
Private Pay	0.6%
Commercial Insurance	9.1%
Medicare	58.9%
Medicaid	8.3%
Miscellaneous (including VA)	4.3%
Other Medicare Commercial	18.8%
Total	**100.0%**

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

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Guilford	14%	53%	48%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."*

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	**% of Dialysis Population**
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

http://www.esrdnetwork6.org/utils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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

In Section L.3, page 55, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section L.6, page 56, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1(b), page 54, the applicant projects that 86 percent of the patients who will receive treatments at FMC-EG in the second operating year (CY 2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility.

FMC-EG Projected Payor Mix – OY2	
Payment Source	**% Total Patients**
Private Pay	0.6%
Commercial Insurance	9.1%
Medicare	58.9%
Medicaid	8.3%
Miscellaneous (including VA)	4.3%
Other Medicare Commercial	18.8%
Total	**100.0%**

The applicant's projected OY2 payor mix for the facility is the same as the historical payor mix reported by the applicant in Section L.7, page 57. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC-EG. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, pages 55-56, the applicant describes the range of means by which a person will have access to the dialysis services at FMC-EG, including admissions from nephrologists with medical privileges at the facility or via referral from a different provider to a nephrologist with medical privileges. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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.2, page 58, the applicant states that FMC-EG has sent a letter to Guilford Technical Community College inviting the school to include the FMC-EG facility in clinical rotations for nursing students. Exhibit M-1 contains the referenced letter, dated March 15, 2016, from the applicant to Guilford Technical Community College. The

information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC of East Greensboro (FMC-EG) proposes to add four dialysis stations for a total of 39 certified dialysis stations upon project completion.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to add four dialysis stations to the existing FMC-EG in Guilford County. The January 2016 SDR indicates there are seven dialysis facilities in Guilford County, as shown below. Five facilities are BMA facilities and two facilities are Wake Forest University Health Sciences (WFUHS) facilities.

Guilford County Dialysis Facilities			
Dialysis Facilities	**Certified Stations 6/30/2015**	**Percent Utilization**	**Patients per Station**
BMA of Greensboro (BMA)	56	75.45%	3.02
BMA of South Greensboro (BMA)	59	75.42%	3.02
BMA of Southwest Greensboro (BMA)	31	78.23%	3.13
FMC of East Greensboro (BMA)	35	85.00%	3.40
High Point Kidney Center (WFUHS)	42	91.07%	3.64
Northwest Greensboro Kidney Center (BMA)	33	71.97%	2.88
Triad Dialysis Center (WFUHS)	22	84.09%	3.36

As illustrated above, each Guilford County facility is utilized above 70 percent as of June 30, 2015. As of that date, FMC-EG was serving 119 patients weekly on 35 stations, which is 3.4 patients per station per week or 85 percent of capacity (119 patients / 35 stations = 3.4; 3.4 / 4 = 0.85 or 85%). At the end of Operating Year One, the applicant projects that FMC-EG will be serving 129.3 patients weekly on 39 stations, which is 3.32 in-center patients per station per week or 83 percent of capacity (129.3 patients / 39 stations = 3.32; 3.32 / 4 = 0.83 or 83%). This meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

In Section N.1, page 59, the applicant discusses how the proposed project would have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

> *"BMA does not expect this proposal to have effect on the competitive climate in Guilford County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC East Greensboro facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Guilford County five year average annual change rate of 3.0% as published within the January 2016 SDR.*
>
> *…*
>
> *BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 86% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.*
>
> *BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment."*

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

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.

- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3), and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O.3, page 64, the applicant states that there are more than 100 dialysis facilities owned by, operated by, or affiliated with the applicant or its parent company, Fresenius Medical Care Holdings, Inc. In Exhibit O-2, the applicant identifies two kidney disease treatment centers located in North Carolina, owned and operated by the applicant or its parent company, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 66, the applicant states both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The 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 to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMC-EG 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 C.1, pages 19-21, the applicant documents the need for the project and demonstrates that it will serve a total of 129.3 in-center patients on 39 stations at the end of the first operating year, which is 3.32 patients per station per week or a utilization rate of 83 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 19-21, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.