

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: December 11, 2014

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10329-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Durham / Add four dialysis stations for a total of 18 dialysis stations upon completion of this project and Project I.D. #J-10248-14 (add 2 dialysis stations) / Durham County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Durham (FMC South Durham) proposes to add four dialysis stations for a total of 18 certified dialysis stations upon completion of this project and Project I.D. #J-10248-14 (add two dialysis stations).

Need Determination

The 2014 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 July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Durham 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 South Durham in the July 2014 SDR is 3.92 patients per

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station. This utilization rate was calculated based on 47 in-center dialysis patients and 12 certified dialysis stations as of December 31, 2013 (47 patients / 12 stations = 3.92 patients per station). Application of the facility need methodology indicates that six additional stations are needed for this facility, as illustrated in the following table:

2014 SMFP Facility Need Methodology

Required SDR Utilization		80%
FMC South Durham Utilization Rate as of 12/31/2013		97.92%
Certified Stations		12
Pending Stations		2
Total Existing and Pending Stations		14
In-Center Patients as of 6/30/2013 (SDR1, January 2014 SDR)		40
In-Center Patients as of 12/31/2013 (SDR2, July 2014 SDR)		47
Step	Description	
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center Change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/2013	0.3500
(ii)	Divide the result of Step (i) by 12	0.0292
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/2012 until December 31, 2013) for the July 2014 SDR	0.3500
(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	63.4500
(v)	Divide the result of Step (iv) by 3.2 patients per station and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	5.8281

As shown in the table above, based on the facility need methodology for dialysis stations, which allows for rounding to the nearest whole number only in step (v), the potential number of stations needed at FMC South Durham is six. 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 only four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: *Basic Principles*, page 38, of the 2014 SMFP is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant, a subsidiary of Fresenius Medical Care Holdings, Inc., describes how its proposal will promote safety and quality in Section I, pages 4-8, and Section II, pages 12, 19-20, and 26-28. The applicant states in Section I, pages 4-5,

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 will promote equitable access in Section II, pages 20-21, Section III, pages 31-35, Section V, pages 41-42, Section VI.1, pages 43-45, and referenced exhibits. The applicant states in Section II, pages 20-21, that the majority of its dialysis patients are covered by Medicare and Medicaid and projects that greater than 89% of its in-center dialysis treatments will be covered by government payors.

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 will maximize health care value for resources expended in Section II, page 21, Section III, pages 31-35, and Section V, pages 41-42. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize healthcare value.

Conclusion

The applicant adequately demonstrates that the proposal will promote quality and safety, equitable access, and maximize healthcare value. Additionally, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2014 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

The applicant, FMC South Durham, proposes to add four in-center dialysis stations to its existing facility, pursuant to a facility need determination, for a facility total of 18 stations upon completion of this project and Project I.D. #J-10248-14 (add two stations). The two additional stations conditionally approved in Project I.D. #J-10248-14 were certified on September 3, 2014 and the project is now complete. Therefore, FMC South Durham currently has 14 certified dialysis stations.

Population to be Served

In Section II, page 13, and in Section III.7, page 32, the applicant provides the historical and projected patient origin for FMC South Durham, respectively, as follows:

Historical and Projected Patient Origin

	June 30, 2014	Operating Year 1 CY2016	Operating Year 2 CY2017	County Patients as a Percent of Total	
County	In-Center Patients	In-Center Patients	In-Center Patients	Operating Year 1	Operating Year 2
Durham	41.0	52.1	57.3	89.7%	90.5%
Wake	4.0	4.0	4.0	6.9%	6.3%
Orange	2.0	2.0	2.0	3.4%	3.2%
Total	47.0	58.1	63.3	100.0%	100.0%

The applicant adequately identified the population FMC South Durham proposes to serve.

Demonstration of Need

In Section III.2, page 29, the applicant applies the facility need methodology in the 2014 SMFP utilizing data from the January and July 2014 SDRs, and proposes to add four dialysis stations to FMC South Durham for a total of 18 stations. The 18 stations include two stations that were certified on September 3, 2014 (Project I.D. #J-10248-14). The applicant provides its assumptions and methodology, on pages 30-33, to project utilization and the need for four additional dialysis stations, summarized as follows:

- Based on the data reported in Table A, page 11 of the July 2014 SDR, FMC South Durham had 47 in-center patients as of December 31, 2013. In addition, there were 12 certified dialysis stations and two conditionally approved dialysis stations pending certification from Project I.D. #J-10248-14. The two conditionally approved stations were certified on September 3, 2014, therefore FMC South Durham currently has 14 certified in-center dialysis stations.
- BMA does not use the Five Year Average Annual Change Rate (AACR) of 2.4% published in the July 2014 SDR to project growth in the number of in-center patients at the facility from Durham County. The applicant identifies the facility growth rate of 35% as calculated in the Facility Need Methodology, but uses a growth rate of 10.0% for in-center patients from Durham County only to project utilization (see Section III.2, Facility Need Methodology). The Project Analyst determined that the three-year Compound Annual Growth Rate (CAGR) for FMC South Durham was 37.7% from December 31, 2010 – December 31, 2013, the dates for which data was available for the facility. Therefore, the Project Analyst concluded that the applicant's utilization of a 10% annual growth rate was reasonable.

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- FMC South Durham is projected to have 58.1 in-center patients by the end of Operating Year One (January 1, 2016 - December 31, 2016) and 63.3 in-center patients by the end of Operating Year Two (January 1, 2017 – December 31, 2017). The applicant illustrates this in Section II, page 14, as follows:

FMC South Durham	In-Center Patients
BMA begins with facility census of Durham County residents as of December 31, 2013.	41 patients
The census is increased by one half of the 10.0% for six months to December 31, 2014.	$\{41 \times (0.10/12 \times 6)\} + 41 = 43.0$
The census is increased by 10.0% for one year to December 31, 2015, the projected completion date for this project.	$(43.0 \times 0.10) + 43.1 = 47.3$
BMA adds the six patients from Wake and Orange Counties. This is the projected beginning census for this project.	$47.3 + 6 = 53.3$
The census of Durham County residents is increased by 10.0% for one year to December 31, 2016.	$(47.3 \times 0.10) + 47.3 = 52.0$
BMA adds the six patients from Wake and Orange Counties for the projected ending census for Operating Year 1.	$52.0 + 6 = 58.0$
The census of Durham County residents is increased by 10.0% for one year to December 31, 2017.	$(52.0 \times 0.10) + 52.0 = 57.2$
BMA adds the six patients from Wake and Orange Counties for the projected ending census for Operating Year 2.	$57.2 + 6 = 63.2$

The applicant states, on page 14,

“BMA also recognizes the CON Section has previously indicated that patients are not partial patients, but rather are whole. In financial projections and utilization projections for this application, BMA has rounded down to the whole number.”

Therefore, for Operating Year One, 58 in-center patients would be dialyzing on 18 stations for a projected utilization rate of 3.2 patients per station (58 in-center patients/18 stations = 3.2) which

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meets the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for four additional dialysis stations at the FMC South Durham facility.

Access

In Section VI.1(a), page 43, the applicant states that BMA “*has a long history of providing dialysis services to the underserved populations of North Carolina.*” It further states that each of its 100 facilities in 42 North Carolina Counties has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. On page 44, the applicant projects that greater than 89% of its in-center patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at FMC South Durham, and demonstrates the extent to which all residents of the area, and, in particular, 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.

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In Section III.9, pages 33-35, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

- 1) Maintain the Status Quo – The applicant states that if it did not apply for the additional stations, FMC South Durham would not be able to accommodate the expected growth of the facility. The applicant states, “*Patients choose a dialysis facility for a variety of reasons, such as access to transportation, or shift schedules which are compatible with the patient life style. ...Failure to expand potentially denies patients a choice of dialysis at FMC South Durham.*”

- 2) Apply for Fewer Stations – The applicant states that this alternative does not address the growing patient census at FMC South Durham, and that the application of the Facility Need Methodology demonstrates a growth rate of 35% for the facility. Therefore, applying for fewer stations would not be the most effective alternative. The applicant also stated that it would not be appropriate to consider a relocation of stations from another Durham county facility due to utilization of the facilities.

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 FMC South Durham proposal is the least costly or most effective alternative to meet the 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 South Durham 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 South Durham shall develop and operate no more than four additional dialysis stations for a total of no more than 18 certified stations upon completion of this project and Project I.D. #J-10248-14 (add two stations), which shall include any isolation or home hemodialysis stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Durham shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 18 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Durham shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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.

In Section VIII.1, page 51, the applicant projects a capital cost of \$267,400 for the proposed project, funded through accumulated reserves. The applicant indicates that \$237,000 of the cost will be for the replacement of the water treatment system which is needed due to the increase in dialysis stations. The remaining costs are for patient chairs and patient TVs, \$3,400 and \$7,000, respectively, plus \$20,000 for contractor fees. In Section IX, page 55, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since it is an existing facility.

Exhibit 24 includes a letter, dated September 15, 2014, from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

"This is to inform you that Fresenius Medical Care Holdings, Inc is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.

BMA is submitting a Certificate of Need Application to add four dialysis stations to its FMC South Durham facility in Durham County. ... As Vice President, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$267,400 as may be needed for this project."

In Exhibit 4, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2013 and 2012. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$275,719,000 with \$16,597,314,000 in total assets and \$8,521,824,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

In Section X.1, page 56, the applicant projects the following charges per treatment for each payment source:

Payor	In-Center Charge
Private Pay	\$1,425.00
Commercial	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
VA	\$231.12
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
Other: Self/Indigent	\$1,425.00

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The applicant states, on page 56, that the commercial charge listed does not reflect actual reimbursement rates.

In Section X.2, page 58, and X.4, page 63, the applicant reports projected revenues and expenses as follows:

FMC South Durham		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,923,590	\$3,138,770
Total Operating Costs	\$2,440,053	\$2,591,809
Net Profit	\$483,538	\$546,961

The applicant projects that revenue will exceed operating expenses in each of the first two operating years of the project. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable. See Section X, pages 56-64, of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues (charges) and operating costs. 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.

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FMC South Durham proposes to add four in-center dialysis stations for a total of 18 dialysis stations upon project completion. As of December 31, 2013, FMC South Durham served 47 patients weekly on 12 stations, which is 3.92 patients per station or 97.9% of capacity. On September 3, 2014, two additional stations were certified for a total of 14 dialysis stations (Project I.D. #J-10248-14). The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 30-33 of the application. The growth projections are based on a 10.0% annual growth rate of FMC South Durham's in-center dialysis patients residing in Durham County, with the addition of, and no increase in, the number of in-center patients from Orange and Wake Counties. The discussion regarding projected utilization in Criterion 3 is incorporated herein by reference. At the end of Operating Year Two, the projected utilization for FMC South Durham will be 3.50 in-center patients per station (63 patients / 18 dialysis stations = 3.50), for a utilization rate of 87.5% of capacity.

According to the July 2014 SDR, there were eight operational dialysis facilities in Durham County. The applicant operates four dialysis centers in Durham County, Duke University Hospital operates one, and DVA Healthcare Renal Care, Inc. (DaVita) operates three, as illustrated in the following table:

Durham County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/2013	% Utilization	Patients Per Station
Duke Hospital Dialysis	16	79.69%	3.19
Durham Dialysis (DaVita)	24	94.79%	3.79
Durham West Dialysis (DaVita)	29	84.48%	3.38
FMC Dialysis Briggs Avenue	29	68.97%	2.76
FMC Dialysis West Pettigrew	20	76.25%	3.05
FMC South Durham Dialysis	12	97.92%	3.92
Freedom Lake Dialysis Unit (BMA)	22	81.82%	3.27
Southpoint Dialysis (DaVita)	12	97.92%	3.92
East Durham Dialysis*	0	0.00%	0.00
Totals (Averages for % Utilization and Patients per Station)**	164	85.23%	3.41

Source: July 2014 SDR, Table A, page 11.

*According to the July 2014 SDR, Table A, page 11, East Durham Dialysis is a "Proposed new site consisting of existing stations".

**Totals do not include data for East Durham Dialysis.

As shown in the table above, as of December 31, 2013, five of the eight operational Durham County dialysis facilities were operating above 80% utilization (3.2 patients per station), and seven were operating above 75% utilization (3.0 patients per station).

In addition, the applicant states, on page 34, that it has "evaluated utilization of its existing facilities in aggregate" and found that its overall utilization is greater than 80% and that it is providing dialysis services to over half of the Durham County dialysis patients on less than half of the available dialysis stations. The applicant states, "...it is obvious that there are no other alternatives..." and further, "It would not be appropriate to consider a relocation of certified stations from another BMA facility in Durham due to the utilization of BMA facilities."

The applicant adequately demonstrates the need to develop four additional dialysis stations at the existing FMC South Durham facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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- (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.

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The following table shows current and projected staffing for FMC South Durham, as provided by the applicant in Section VII.1, page 48:

FMC South Durham			
Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	1.75	0.75	2.50
Tech.	5.00	0.50	5.50
Clinical Manager	1.00	0.00	1.00
Medical Director	Contracted Position		
Admin. (FMC Dir. Ops.)	0.20	0.00	0.20
Dietician	0.50	0.16	0.66
Social Worker	0.50	0.16	0.66
Chief Tech.	0.10	0.00	0.10
Equipment Tech.	0.75	0.00	0.75
In-Service	0.20	0.00	0.20
Clerical	1.00	0.00	1.00
Total	11.00	1.57	12.57

As shown in the above table, the applicant proposes to employ a total of 12.57 full-time equivalent (FTE) positions to staff FMC South Durham upon completion of the proposed project. In VII, page 50, the applicant states there will be five direct care staff for each of the facility's two daytime shifts. In addition, in Section V.4, page 40, the applicant states that Tomasz Gawecki, M.D., a nephrologist with Durham Nephrology Associates, will serve as Medical Director of the facility. Exhibit 21 contains a letter from Dr. Gawecki stating his intention to continue as the Medical Director for FMC South Durham. The information provided in Section VII is reasonable and credible. The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a medical director, for the provision of dialysis 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.

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In Section V.1, page 38, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 15 includes an agreement with Spectra Laboratories to provide laboratory services and Exhibit 26 includes transplant agreements with Duke University Medical Center and The University of North Carolina Hospitals. In addition, the applicant provides a copy of an affiliation agreement with Duke Regional Hospital in Exhibit 25 in which the hospital agrees to provide any necessary inpatient services to patients at FMC South Durham. Exhibit 21 includes a letter of support from Dr. Tomasz Gawecki, the Medical Director of the facility, in which he also asserts support for the project on behalf of the entire practice of Durham Nephrology Associates. Moreover, the applicant states, in Section V.5, page 41, that it has relationships with area health care facilities and health professionals in the community. 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 system. Therefore, 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

- (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;

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In Section VI.1(a), page 43, the applicant states,

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has eight facilities under development or pending CON approval. 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.

...

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

In Section VI.1(b), page 44, the applicant provides the current in-center dialysis payor mix at FMC South Durham as of December 31, 2013, as shown in the table below:

FMC South Durham In-Center Patients	
Source of Payment	Percentage
Private Pay	0.00%
Commercial Insurance	10.30%
Medicare	71.40%
Medicaid	9.50%
Medicare/Commercial	8.80%
Other: Self/Indigent	0.00%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Durham County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Durham County	15.6%	5.7%	20.1%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina’s

Network 6 were under the age of 35 (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2013 – 12/31/2013*, page 99).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%

¹ <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

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Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age Groups		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.3%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African American	9,559	62.1%
White	5,447	35.4%
Other	383	2.5%
Total	15,389	100.0%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services. 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

³ www.esrdnetwork6.org/publications/reports.html

The applicant states, in Section VI.1, page 45, that while it does not have any obligation under federal regulations to provide uncompensated care or community service, it “*will treat all patients the same regardless of race and handicap status.*” In addition, it states,

“In accepting payments from Medicare, Title XVII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6 (a), page 46, the applicant states there have been no civil rights access complaints filed within the last five years for any of its BMA North Carolina facilities. 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 VI.1(c), page 44, the applicant provides the projected payor mix for the proposed services at FMC South Durham, as follows:

FMC South Durham In-Center Patients	
Source of Payment	Percentage
Private Pay	0.00%
Commercial Insurance	10.30%
Medicare	71.40%
Medicaid	9.50%
Medicare/Commercial	8.80%
Other: Self/Indigent	0.00%
Total	100.00%

The applicant projects no change from the current payor mix for in-center dialysis services, which is 89.7% Medicare and Medicaid. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. 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 VI.5, page 46, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC South Durham will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that FMC South Durham will provide a range of means by which a person can access the 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 V.3, page 39, the applicant states that it welcomes all health related training programs to its facility and includes a copy of a letter to Durham Technical Community College, in Exhibit 19, inviting the college to utilize FMC South Durham as a clinical training site for its nursing students.

The information provided in Section V.3 is reasonable and credible and supports a finding of conformity 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

According to the July 2014 SDR, there were eight operational dialysis facilities in Durham County. The applicant operates four dialysis centers in Durham County, Duke University Hospital operates one, and DVA Healthcare Renal Care, Inc. (DaVita) operates three, as illustrated in the following table:

Durham County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/2013	% Utilization	Patients Per Station
Duke Hospital Dialysis	16	79.69%	3.19
Durham Dialysis (DaVita)	24	94.79%	3.79
Durham West Dialysis (DaVita)	29	84.48%	3.38
FMC Dialysis Briggs Avenue	29	68.97%	2.76
FMC Dialysis West Pettigrew	20	76.25%	3.05
FMC South Durham Dialysis	12	97.92%	3.92
Freedom Lake Dialysis Unit (BMA)	22	81.82%	3.27
Southpoint Dialysis (DaVita)	12	97.92%	3.92
East Durham Dialysis*	0	0.00%	0.00
Totals (Averages for % Utilization and Patients per Station)**	164	85.23%	3.41

Source: July 2014 SDR, Table A, page 11.

*According to the July 2014 SDR, Table A, page 11, East Durham Dialysis is a "Proposed new site consisting of existing stations".

**Totals do not include data for East Durham Dialysis.

As shown in the table above, as of December 31, 2013, five of the eight operational Durham County dialysis facilities were operating above 80% utilization (3.2 patients per station), and seven were operating above 75% utilization (3.0 patients per station).

FMC South Durham proposes to add four dialysis stations to its existing facility for a total of eighteen stations upon completion of this project. On September 3, 2014, two conditionally approved stations were certified at FMC South Durham, for a total of 14 certified stations (Project I.D. #J-10248-14). In Section V.7, pages 41-42, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states that there are eight dialysis facilities operating in Durham County as indicated in the July 2014 SDR and that two other dialysis providers provide dialysis services within the county, namely DaVita Dialysis and Duke University Hospital. The applicant states that patients therefore have a choice of where to receive

their dialysis care. In addition, in regard to cost-effectiveness, the applicant states on page 42, “*BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.*” In regard to quality, the applicant states, on page 42, that FMC South Durham will have “*added value*” from its relationship with five nephrologists from Durham Nephrology Associates who will provide care to patients at the facility. In addition, the applicant states, on page 42, that over 89% of its proposed patients for FMC South Durham will be Medicare or Medicaid patients.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following:

- ◆ The applicant adequately demonstrates the need to add four dialysis stations at the FMC South Durham facility and that it is a cost-effective alternative. See the discussion regarding need in Criterion (3) and cost effectiveness in Criteria (4) and (5) which is incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will continue to provide quality services. See the discussion regarding quality in Criterion (1) which is incorporated herein by reference; and
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. See the discussion regarding access in Criterion (13a) which is incorporated herein by reference.

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

According to the files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, on February 26, 2014 FMC Dialysis West Pettigrew, one of FMC’s dialysis facilities in Durham County, was surveyed as a result of a complaint and was determined to be in noncompliance with Medicare Conditions of Participation. The Medicare Conditions of Participation were corrected and the facility was determined to be in compliance

on March 27, 2014. FMC's three other dialysis facilities in Durham County, including FMC South Durham, operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

.2202(a)(1) Utilization rates;

)

-C- See Section III.2, page 29, which indicates the facility had a 97.92% utilization rate as of December 31, 2013.

.2202(a)(2) Mortality rates;

)

-C- In Section IV.2, page 36, the applicant reports 2011, 2012 and 2013 facility mortality rates of 3.8%, 14.7% and 12.8%, respectively.

.2202(a)(3) The number of patients that are home trained and the number of patients on Home dialysis;

)

-NA- In Section IV.3, page 36, the applicant states that FMC South Durham does not operate a home dialysis program.

.2202(a)(4) The number of transplants performed or referred;

-)
- C- In Section IV.4, page 36, the applicant states that FMC South Durham referred six patients for transplant evaluation in 2013 and none of its patients received a transplant in 2013.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-)
- C- In Section IV.5, page 36, the applicant states that FMC South Durham has two patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus Non-dialysis related;*
-)
- C- See Section IV.6, page 37, the applicant reports a total of 107 hospital admissions in 2013; 82 were non-dialysis related and 25 were dialysis-related.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
-)
- C- In Section IV.7, page 37, the applicant reports that in 2013 there were no patients with Hepatitis B, and no patients converted to Hepatitis B in 2013. The applicant states, on page 37, “BMA does not identify patients with AIDS or other infectious disease.”
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*
- NA- FMC South Durham is an existing facility.
- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically Re-evaluated for transplantation, and,*

- (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- FMC South Durham is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- FMC South Durham is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 12 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- FMC South Durham is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Sections II.1, page 12; VII.2, page 49; XI.6(e), page 68; XI.6(g), page 69 and Exhibit 12.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, page 32, FMC South Durham provided projected patient origin based on historical experience for the first two years of operation following completion of the project.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- FMC South Durham is an existing facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II.1, page 15, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- FMC South Durham is an existing facility.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Sections II.1, page 14 and III.7, page 32, the applicant projects to serve 58.1 in-center patients by the end of Operating Year 1, which is 3.2 patients per station ($58.1 / 18 = 3.2$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 12-14 and Section III.7, pages 31-33, the applicant provides the assumptions and methodology used to project utilization of FMC South Durham. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- .2204(1) Diagnostic and evaluation services;*
- C- The applicant states, in Section V.1, page 38, that Duke Regional Hospital will provide diagnostic and evaluation services.
- .2204(2) Maintenance dialysis;*
- C- The applicant states, in Section V.1, page 38, that FMC South Durham will provide maintenance dialysis services.
- .2204(3) Accessible self-care training;*
- C- In Section V.1, page 38, the applicant states that FMC West Pettigrew will provide self-care training.
- .2204(4) Accessible follow-up program for support of patients dialyzing at home;*
- C- In Section V.1, page 39, the applicant states that FMC West Pettigrew will provide follow-up support of patients dialyzing at home.
- .2204(5) X-ray services;*

- C- In Section V.1, page 38, the applicant states that x-ray services will be provided by Duke Regional Hospital.
- .2204(6) *Laboratory services;*
- C- In Section V.1, page 38, and Exhibit 15, the applicant states that SPECTRA Laboratories, Inc. will provide laboratory services.
- .2204(7) *Blood bank services;*
- C- In Section V.1, page 38, the applicant states that blood bank services will be provided by Duke Regional Hospital.
- .2204(8) *Emergency care;*
- C- In Section V.1, page 38, the applicant states that emergency care will be provided by FMC South Durham facility staff and the hospital.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- In Section V.1, page 38, the applicant states that acute dialysis will be provided by Duke Regional Hospital.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- In Section V.1, page 38, the applicant states that vascular surgery will be provided by Regional Vascular Associates and Duke Regional Hospital
- .2204(11) *Transplantation services;*
- C- In Section V.1, page 38, the applicant states that transplantation services will be provided by Duke University Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- In Section V.1, page 38, the applicant states that Durham Vocational Rehabilitation will provide these services.
- .2204(13) *Transportation*
- C- In Section V.1, page 38, the applicant states that transportation will be provided by Access, H2GO, and Red Cross.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- In Section VII.1, page 48, the applicant provides the proposed staffing. In Section VII.2, page 49, the applicant states the facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding proposed staffing in Criterion (7) is incorporated herein by reference.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- In Section VII.5, page 49, the applicant states that all staff receive a 10-week

training program and are required to maintain CPR certification. The applicant provides an outline of its training program in Exhibit 9 and an outline of its continuing education programs in Exhibit 10.