ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date:	December 13, 2016
Findings Date:	December 13, 2016
Project Analyst:	Celia C. Inman
Team Leader:	Fatimah Wilson
Project ID #:	F-11236-16
Facility:	BMA West Charlotte
FID #:	955792
County:	Mecklenburg
Applicant(s):	Bio-Medical Applications of North Carolina, Inc.
Project:	Add two dialysis stations for a total of 29 dialysis stations upon completion of this project, Project ID #F-11099-15 (relocate 4 stations to FMC Aldersgate) and Project ID #F-11144-16 (add 2 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA West Charlotte (the applicant) proposes to add two dialysis stations for a total of 29 certified dialysis stations upon completion of this project, Project ID #F-11099-15 (relocate four stations to FMC Aldersgate) and Project ID #F-11144-16 (add two stations).

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 July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 13 stations in Mecklenburg County and thus, no need for additional dialysis

stations in Mecklenburg County, based on the county need methodology. 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 BMA West Charlotte in the July 2016 SDR is 3.48 patients per station per week. This utilization rate was calculated based on 101 in-center dialysis patients and 29 certified dialysis stations as of December 31, 2015 (101 patients / 29 stations = 3.48 patients per station).

Application of the facility need methodology indicates that up to five additional stations are needed for this facility, as illustrated in the following table:

October 1 REVIEW-July 2016 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		81.90%
Certified Stations		29
Pending Stations	(May 3, 2016 / Project ID #F-11144-16 / add 2)	2
Total Existing and Pending Stations		**31**
In-Center Patients as of 12/31/15- July 2016 SDR (SDR2)		101
In-Center Patients as of 6/30/15 – Jan 2016 SDR (SDR1)		95
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1263
(ii)	Divide the result of Step (i) by 12	0.0105
(iii)	Multiply the result of Step (ii) by 12	0.1263
(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	113.7579
(v)	Divide the result of Step (iv) by 3.2 patients per station	35.5493
	and subtract the number of certified and pending stations to determine the number of stations needed	**4.5493**

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 BMA West Charlotte is five. 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 two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles, page 39, of the 2016 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. (FMC), describes how its proposal will promote safety and quality in Section A.11, pages 4-8, Section B.4, pages 12, and 14-16, Section N.1, page 57, and Section O.1, pages 59-62. 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 B.4, pages 13 and 14-16, Section C.3, page 19, Section L.1, pages 51-55, and Section N.1, page 57. The applicant states in Section B.4, page 13, *"the first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers."* The applicant further states that the majority of its dialysis patients are covered by Medicare and/or Medicaid and projects that greater than 86% of its in-center dialysis treatments will be reimbursed by some form of Medicare and/or Medicaid. 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 B.4, pages 14-16, and Section N.1, pages 57-58. 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

The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3: Basic Principles* and adequately demonstrates that the application is consistent with the facility need determination in the July 2016 SDR. 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 proposes to add two dialysis stations to its existing facility for a total of 29 certified dialysis stations upon completion of the proposed project, Project ID #F-11099-15 (relocate four stations to FMC Aldersgate) and Project ID #F-11144-16 (add two stations).

The following table, summarized from page 4 of the application, illustrates the current projects under development which impact the number of dialysis stations at BMA West Charlotte.

Stations	Description	Project ID #
29	Total existing certified stations as of the July 2016 SDR	
+2	Stations to be added as part of this project	F-11236-16
+2	Stations previously approved to be added, but not yet certified	F-11144-16
-4	Stations previously approved to be relocated from BMA West Charlotte	F-11099-15
29	Total stations upon completion of above projects	

Patient Origin

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. BMA West Charlotte is located in Mecklenburg County; thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 21, the applicant provides a table showing the historical patient origin for BMA West Charlotte, as follows:

BMA West Charlotte
Historical Patient Origin
As of June 30, 2016

County	Number of In-Center Dialysis Patients
Mecklenburg	97
Totals	97

The applicant states, *"BMA West Charlotte is not certified to provide home training and support for patients dialyzing at home."*

In Section C.1, page 17, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

BMA West Charlotte
Projected Patient Origin by County

County	Operating Year 1 1/1/18 –12/31/18	Operating Year 2 1/1/19-12/31/19	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Mecklenburg	100.8	105.8	100.0%	100.0%
Total	**100.8**	**105.8**	**100.0%**	**100.0%**

In Section C.1, pages 17-18, the applicant provides the assumptions and methodology used to project patient origin, based on existing patient origin. The applicant states on page 18 that it rounds down to the whole patient for projected utilization.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to add two dialysis stations to BMA West Charlotte for a total of 29 stations upon completion of the proposed project, Project ID #F-11099-15 (relocate four stations to FMC Aldersgate) and Project ID #F-11144-16 (add two stations) pursuant to the 2016 SMFP Facility Need Methodology.

Projected Utilization

As of December 31, 2015, as reported in the July 2016 SDR, the utilization rate at BMA West Charlotte was 87.07% or 3.48 patients per station per week based on 101 in-center patients utilizing 29 certified dialysis stations.

In Section C.1, pages 17-18, the applicant provides the following assumptions used to project utilization:

- The applicant projects that the growth rate for Mecklenburg County patients dialyzing at BMA West Charlotte will be commensurate with the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 5.0% as reported in the July 2016 SDR.
- The applicant states that five patients at BMA West Charlotte were projected to transfer their care to FMC Aldersgate (Project ID #F-11099-15), a new dialysis facility, upon its certification on June 30, 2017. BMA will subtract the five patients on June 30, 2017.
- The applicant states that one patient at FMA [BMA] West Charlotte was projected to transfer their care to Fresenius Kidney Center Southeast Mecklenburg County (FKCSMC) in Project ID #F-11207-16, a new dialysis facility. BMA subtracts the patient as of December 31, 2017 to reach the starting census for the project.
- The applicant states that the project will be completed on December 31, 2017. Operating Year 1 (OY1) is the period from January 1 through December 31, 2018. Operating Year 2 (OY2) is the period from January 1 through December 31, 2019

In Section C.1, page 18, the applicant provides the following methodology used to project utilization:

BMA West Charlotte	**In-Center**
Beginning facility census of Mecklenburg County patients dialyzing at BMA West Charlotte on June 30, 2016.	97
BMA projects the patient population forward six months to December 31, 2016, using one-half the Mecklenburg County Five Year AACR of 5.0%.	(97 x 0.050 / 12 x 6) + 97 = 99.4
BMA projects the patient population forward six months to June 30, 2017, using one-half the Mecklenburg County Five Year AACR of 5.0%.	(99.4 x 0.05 / 12 x 6) + 99.4 = 101.9
BMA subtracts the five Mecklenburg County patients projected to transfer to FMC Aldersgate.	101.9 – 5 = 96.9
BMA projects the patient population forward six months to December 31, 2017, using one-half the Mecklenburg County Five Year AACR of 5.0%.	(96.9 x 0.05 / 12 x 6) + 96.9 = 99.3
BMA subtracts the one patient projected to transfer to FKCSMC to reach the starting census as of December 31, 2017.	99.3 – 1 = 98.3
BMA projects patient population forward one year to December 31, 2018, the end of Operating Year One, using the Mecklenburg County Five Year AACR of 5.0%.(Applicant's calculation erroneously projects forward for only 6 months, not 12 months.)	(98.3 x 0.050) + 98.3 = 100.8[103.2]
BMA projects patient population forward one year to December 31, 2019, the end of Operating Year Two, using the Mecklenburg County Five Year AACR of 5.0%.	(100.8[103.2] x 0.050) + 100.8[103.2] = 105.8[108.4]

The applicant's calculations are presented in the table above, followed by the Project Analyst's calculations (based on the applicant's methodology) in brackets. In addition to the inaccurate calculations, during the expedited review of Project ID #F-11207-16 (see

assumption above for the transfer of one patient), the start date for the development of Fresenius Kidney Center Southeast Mecklenburg County was extended to January 1, 2019; therefore, the one patient transferred in the table above, as of December 31, 2017, will not actually be removed from the BMA West Charlotte census until December 31, 2018, which coincides with the end of the first operating year for the proposed project. Clearly, the applicant's inaccurate calculations and the one-year delay in the transfer of the one patient to FKCSMC result in a conservative utilization projection by the applicant. Based on the corrected methodology and calculations, the projected utilization at the end of OY1 would be 103 patients, as opposed to the 100 patients, as projected.

The applicant states on page 18, that it has rounded down to 100 patients to be dialyzing at the BMA West Charlotte facility at the end Operating Year One. Therefore, the applicant projects that 100 patients will be dialyzing on 29 stations for a projected utilization rate of 3.45 patients per station per week (100 in-center patients/ 29 stations = 3.448) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b). At 103 in-center patients, as correctly calculated, the utilization rate would be 3.55 patients per station per week. The Project Analyst will use the more conservative utilization, as projected by the applicant, throughout the review.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for two additional dialysis stations at BMA West Charlotte.

Access

In Section L.1, page 51, the applicant states:

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

In Section L.1, page 52, the applicant projects that over 86.0% of its in-center patients will be covered by either 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; adequately demonstrates the need the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions; and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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 25, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant dismissed this alternative based on the fact that the facility is projected to exceed 80% utilization at the end of the first operating year. The applicant states, *"Failure to develop additional capacity at the facility will result in higher utilization rates at the facility and potentially restrict patient admissions."*

2. Apply for Fewer Stations - the applicant states that the facility need calculations demonstrate that up to five additional stations are needed and that the facility is projected to continue to experience growth. The applicant further states that if two stations are not added, the facility will exceed 100% utilization; therefore, the applicant rejected this alternative.

3. Apply for More Stations – the applicant states that expanding the facility beyond 29 stations would have involved significant capital costs. BMA is able to add two stations without any capital investment due to the approval of a relocation of four stations from BMA West Charlotte (Project ID #F-11099-15). Therefore, the applicant rejected this alternative.

4. Apply to Offer Home Therapies – the applicant states that it could have proposed to provide home therapies at this location, however there is insufficient space to do so. Therefore, the applicant rejected this alternative.

5. Apply to Relocate Stations from Other BMA Facilities in Mecklenburg County - the applicant states that all BMA facilities in Mecklenburg County are operating above the 80% utilization rate; therefore, the applicant rejected this alternative.

Thus, after considering the above alternatives, the applicant concluded that its proposal to add two dialysis stations to BMA West Charlotte is the most effective alternative to meet the identified facility need.

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

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, 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 BMA West Charlotte shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA West Charlotte shall develop no more than two additional stations for a total of no more than 29 certified stations upon completion of Project I.D. #F-11099-15 (relocate four stations to FMC Aldersgate), Project ID #F-11144-16 (add two stations), and this project, which shall include any home hemodialysis or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA West Charlotte shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add two dialysis stations for a total of 29 dialysis stations at BMA West Charlotte upon completion of the proposed project, Project ID #F-11099-15 (relocate four stations to FMC Aldersgate) and Project ID #F-11144-16 (add two stations).

Capital and Working Capital Costs

In Section F.1, page 26, the applicant states that there will be no capital costs for the project. In Section F.9, pages 29-30, the applicant states that the dialysis machines will be leased.

In Sections F.10 and F.11, page 30, the applicant states that there will be no initial start-up expenses or initial operating expenses because BMA West Charlotte is an existing facility.

Availability of Funds

In Exhibit F-1, the applicant provides a letter dated September 15, 2016 from the Assistant Treasurer of the parent company, Fresenius Medical Care Holdings, Inc. (FMC), authorizing the project and confirming that the project will not require any capital expenditure. Exhibit F-2 contains the FMC and Subsidiaries Consolidated Financial Statements, as of December 31, 2015, showing cash and cash equivalents of $249,300,000, total assets of $19,332,539,000 and net assets (total assets less total liabilities) of $8,915,722,000. The applicant adequately demonstrates the availability of funds for the operating needs of the project.

Financial Feasibility

In Section R, Form C, page 76, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Self Pay/Indigent/ Charity	$168.52
Medicare	$247.53
Medicaid	$182.82
Commercial Insurance	$1,164.86
Medicare/Commercial	$295.02
VA	$337.13

In Section R, page 78, the applicant states that it used an average number of in-center patients, rounded down to the nearest whole number, to calculate its revenues for the first and second operating years of the project. Therefore, the number of in-center patients used in operating year one was 99 and the number of in-center patients used in operating year two was 103. The Project Analyst calculates the number of in-center patients used to calculate revenues for operating years one and two, as follows:

- The applicant's methodology for calculating projected utilization for the beginning of operating year one, January 1, 2018, is 98.3 in-center patients, as stated in Section C.1, page 18. The applicant projects 100.8 in-center patients at the end of operating year one. Therefore, the average number of in-center patients for operating year one, rounded down to the nearest whole number, is 99 (98.3+100.8 / 2 = 99.5).
- Likewise, in Section C.1, page 18, the applicant begins operating year two with 100.8 in-center patients and ends with 105.8 in-center patients. The average number of in-center patients for operating year two, rounded down to the nearest whole number, is 111 (100.8+105.8 /2 = 103.3).

In Section R, pages 71 and 74, the applicant projects operating expenses and revenues, respectively, summarized as follows:

BMA West Charlotte

	Operating Year 1	Operating Year 2
Average # of In-Center Patients	99.5	103.3
Projected Treatments ((156 / Pt) - 5%))	14,746	15,309
Projected Average Charge (Gross Patient Revenue / Projected # Treatments)	$ 3,968	$ 3,976
Gross Patient Revenue	$ 58,507,948	$ 60,872,832
Deductions from Gross Patient Revenue	$ 53,564,139	$ 55,729,195
Net Patient Revenue	$ 4,943,809	$ 5,143,637
Total Expenses	$ 4,381,816	$ 4,567,800
Net Income	$ 561,992	$ 575,837

Totals may not sum due to rounding

The applicant projects that revenues 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 are reasonable, including projected utilization, cost and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the operating needs of the project. Furthermore, the applicant demonstrates the financial feasibility of the proposal is based on reasonable projections of cost 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

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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."* BMA West Charlotte is located in Mecklenburg County; thus, the service area for this project is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The applicant proposes to add two dialysis stations to its existing BMA West Charlotte facility for a total of 29 certified dialysis stations upon completion of this project, Project ID #F-11099-15 (relocate four stations to FMC Aldersgate) and Project ID #11144-16 (add two stations).

According to the July 2016 SDR, there are 21 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities
December 31, 2015

Dialysis Facilities	Owner*	# of Patients	# of Certified Stations	Percent Utilization	Patients per Station
BMA Beatties Ford	FMC	127	32	99.22%	3.97
BMA Nations Ford	FMC	115	28	102.68%	4.11
BMA of East Charlotte	FMC	85	25	85.00%	3.40
BMA of North Charlotte	FMC	116	28	103.57%	4.14
BMA West Charlotte	FMC	101	29	87.07%	3.48
Brookshire Dialysis	DVA	0	0	0.00%	0.00
Carolinas Medical Center	CMHA	10	9	27.78%	1.11
Charlotte Dialysis	DVA	128	36	88.89%	3.56
Charlotte East Dialysis	DVA	113	26	108.65%	4.35
DSI Charlotte Latrobe Dialysis	DSI	53	24	55.21%	2.21
DSI Glenwater Dialysis	DSI	134	41	81.71%	3.27
FMC Charlotte	FMC	142	43	82.56%	3.30
FMC Matthews	FMC	99	21	117.86%	4.71
FMC of Southwest Charlotte	FMC	0	0	0.00%	0.00
FMC Regal Oaks	FMC	0	0	0.00%	0.00
FMC Aldersgate	FMC	0	0	0.00%	0.00
Huntersville Dialysis	DVA	0	10	0.00%	0.00
Mint Hill Dialysis	DVA	45	12	93.75%	3.75
North Charlotte Dialysis Center	DVA	152	41	92.68%	3.71
South Charlotte Dialysis	DVA	71	22	80.68%	3.23
University City Dialysis	DVA	0	0	0.00%	0.00

*FMC is Fresenius Medical Care Holdings, Inc., CMHA is Charlotte Mecklenburg Hospital Authority, DVA is DaVita HealthCare Partners, Inc., and DSI is DSI Renal Inc.

As illustrated above, FMC owns 10 of the 21 dialysis facilities in Mecklenburg County. Three FMC dialysis facilities (FMC of Southwest Charlotte, FMC Regal Oaks, and FMC Aldersgate) and two DVA dialysis facilities (Brookshire Dialysis and University City Dialysis) show zero patients and zero certified stations because they have received agency approval, but have not yet been certified. One DVA facility, Huntersville Dialysis, has received certification for 10 new stations, but did not provide services in 2015. Notwithstanding the facilities with zero patients, only two have utilization rates less than 80%, neither of which are FMC facilities. Therefore, all of FMC's operational facilities and all but two of the other operational dialysis facilities in the county are reasonably well utilized.

According to Table B in the July 2016 SDR, there is a surplus of 13 dialysis stations in Mecklenburg County. However, the applicant is eligible to apply for additional stations based on the facility need methodology. In Section C.1, page 18, the applicant demonstrates that BMA West Charlotte will serve a total of 100.8 (rounded down to 100) in-center patients on 29 dialysis stations at the end of the first operating year, which is 3.45 patients per station per week (100/29 = 3.448). Therefore, the facility is expected to serve more than 3.2 patients per

station per week at the end of the first operating year as required by 10A NCAC 14C.2203(b).

The applicant adequately demonstrates the proposed project will not result in the unnecessary duplication of existing or approved dialysis services or facilities in Mecklenburg 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 38, the applicant states that BMA West Charlotte currently employs 28.60 full time equivalent (FTE) positions and that it does not propose to add any additional FTE positions upon completion of the project, as shown in the table below:

BMA West Charlotte Current and Proposed FTE Positions			
Position	Current	Additional	Total
Registered Nurse	7.00	0.00	7.00
Patient Care Technician	16.00	0.00	16.00
Clinical Manager	1.00	0.00	1.00
Administrator	0.20	0.00	0.20
Dietitian	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Chief Tech	0.15	0.00	0.15
Equipment Tech	1.00	0.00	1.00
In-Service	0.25	0.00	0.25
Clerical	1.00	0.00	1.00
Total FTEs	**28.60**	**0.00**	**28.60**

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

In Exhibit I.5, the applicant provides a letter from Dr. George Hart, Medical Director of BMA West Charlotte, dated September 13, 2016, indicating his support for the project and his willingness to continue to serve as Medical Director of the facility. In Section H.3, page 39, the applicant states it does not anticipate any difficulties in filling staff positions as it provides a range of benefits and competitive salaries to attract qualified 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.1, page 41, the applicant lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting, blood bank services, diagnostic/evaluation services will be referred to Carolinas Medical Center. Exhibit I-3 includes an affiliation agreement between BMA West Charlotte and Gaston Memorial Hospital. Exhibit I-4 contains a transplant agreement with Carolinas Medical Center. Exhibit I-1 contains an agreement for home training services. Exhibit I-2 contains an agreement for lab services with Spectra. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 42-44, stating that BMA facilities in Charlotte and Mecklenburg County have relationships with the medical community in the area, including area physicians and hospitals. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare system. 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;

C

In Section L.1, pages 51, the applicant states that it has historically served underserved populations and that it is its policy to *"provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."*

In Section L.7, page 55, the applicant provides the historical in-center payor mix for BMA West Charlotte, as follows:

BMA West Charlotte
Historical Payor Source
CY 2015

Payor Source	Percentage of In-Center Patients
Private Pay/Indigent/ Charity	1.00%
Medicare	71.72%
Medicaid	5.54%
Commercial Insurance	5.52%
Medicare/Commercial	8.69%
VA	7.53%
Total	**100.00%**

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

Percent of Population						
County	**% 65+**	**% Female**	**% Racial and Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
2014 Estimate	**2014 Estimate**	**2014 Estimate**	**2014 Estimate**	**2010-2014**	**2010-2014**	**2014 Estimate**
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

http://www.census.gov/quickfacts/table Latest Data as of 12/22/15
*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."

However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

[1] http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf

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%

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(e), page 53, the applicant states,

> *"BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. ... In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act."*

In Section L.6, page 54, the applicant states that no civil rights complaints have been lodged against any BMA facilities in North Carolina in the past five years.

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, page 52, the applicant provides the projected payor mix for the proposed services at BMA West Charlotte as shown in the table below:

BMA West Charlotte
Projected Payor Mix, OY2
1/1/19-12/31/19

Payor Source	Percentage
Private Pay/Indigent/Charity	1.29%
Medicare	69.27%
Medicaid	6.08%
Commercial Insurance	5.80%
Medicare/Commercial	10.85%
Miscellaneous, including VA	6.72%
Total	**100.00%**

Totals may not sum due to rounding

As shown in the table above, the applicant projects that over 86% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1, page 52, the applicant provides the assumptions used to project payor mix. The applicant states that its payor mix is calculated based upon treatment volumes. This is due to the fact that a patient's health care coverage may change throughout the year, in particular due to conversions to Medicare. Therefore, the applicant states that its payor source by treatment volumes are more accurate. The applicant's projected percentages by payor source are comparable with the applicant's historical (CY 2015) stated in Section L.7, page 55. 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 L.4, page 54, the applicant states,

"Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA West Charlotte has 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 BMA West Charlotte will provide a range of means by which a person can access its 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.1, page 56, the applicant states that health related education programs are welcome at the facility. Exhibit M-1 includes a letter from the applicant to the Nursing Program at Central Piedmont Community College, dated September 14, 2016, inviting the school to include BMA West Charlotte in its clinical rotations for its nursing students. The information provided in Section M.1 and Exhibit M-1 is reasonable 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

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the 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."* BMA West Charlotte is located in Mecklenburg County; thus, the service area for this project is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The applicant, whose parent company is FMC, proposes to add two dialysis stations to its existing facility for a total of 29 certified dialysis stations upon completion of this proposed project, Project ID #F-11099-15 (relocate four stations to FMC Aldersgate) and Project ID #F-11144-16 (add two stations).

According to the July 2016 SDR, there are 21 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities
December 31, 2015

Dialysis Facilities	Owner*	# of Patients	# of Certified Stations	Percent Utilization	Patients per Station
BMA Beatties Ford	FMC	127	32	99.22%	3.97
BMA Nations Ford	FMC	115	28	102.68%	4.11
BMA of East Charlotte	FMC	85	25	85.00%	3.40
BMA of North Charlotte	FMC	116	28	103.57%	4.14
BMA West Charlotte	FMC	101	29	87.07%	3.48
Brookshire Dialysis	DVA	0	0	0.00%	0.00
Carolinas Medical Center	CMHA	10	9	27.78%	1.11
Charlotte Dialysis	DVA	128	36	88.89%	3.56
Charlotte East Dialysis	DVA	113	26	108.65%	4.35
DSI Charlotte Latrobe Dialysis	DSI	53	24	55.21%	2.21
DSI Glenwater Dialysis	DSI	134	41	81.71%	3.27
FMC Charlotte	FMC	142	43	82.56%	3.30
FMC Matthews	FMC	99	21	117.86%	4.71
FMC of Southwest Charlotte	FMC	0	0	0.00%	0.00
FMC Regal Oaks	FMC	0	0	0.00%	0.00
FMC Aldersgate	FMC	0	0	0.00%	0.00
Huntersville Dialysis	DVA	0	10	0.00%	0.00
Mint Hill Dialysis	DVA	45	12	93.75%	3.75
North Charlotte Dialysis Center	DVA	152	41	92.68%	3.71
South Charlotte Dialysis	DVA	71	22	80.68%	3.23
University City Dialysis	DVA	0	0	0.00%	0.00

*FMC is Fresenius Medical Care Holdings, Inc., CMHA is Charlotte Mecklenburg Hospital Authority, DVA is DaVita HealthCare Partners, Inc., and DSI is DSI Renal Inc.

As illustrated above, FMC owns 10 of the 21 dialysis facilities in Mecklenburg County. Three FMC dialysis facilities (FMC of Southwest Charlotte, FMC Regal Oaks, and FMC Aldersgate) and two DVA dialysis facilities (Brookshire Dialysis and University City Dialysis) show zero patients and zero certified stations because they have received agency approval, but have not yet been certified. One DVA facility, Huntersville Dialysis, has received certification for 10 new stations, but did not provide services in 2015. Notwithstanding the facilities with zero patients, only two have utilization rates less than 80%, neither of which are FMC facilities. Therefore, all of FMC's operational facilities and all but two of the other operational dialysis facilities in the county are reasonably well utilized.

According to Table B in the July 2016 SDR, there is a surplus of 13 dialysis stations in Mecklenburg County. However, the applicant is applying for additional stations based on the facility need methodology. In Section C.1, page 18, the applicant demonstrates that BMA West Charlotte will serve a total of 100.8 (rounded down to 100) in-center patients on 29 dialysis stations at the end of the first operating year, which is 3.45 patients per station per week (100/29 = 3.448). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C.2203(b).

In Section N.1, page 57, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

> *"BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA West Charlotte facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Mecklenburg County five year average annual change rate of 5.0% as published within the July 2016 SDR."*

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 86% of the patients at BMA West Charlotte will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 57, that its proposal will *"enhance the quality of the ESRD patients' lives…"*

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

The information provided by the applicant in those sections is reasonable 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 dialysis services. This determination is based on the information in the application and the following analysis:

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

- The applicant adequately demonstrates it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20), are incorporated herein by reference.

- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are 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 A.11, page 4, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc., which owns and operates 105 existing kidney disease treatment centers in North Carolina. In Exhibit A-4, the applicant provides a listing of all FMC and FMC-affiliated ESRD facilities owned and operated in North Carolina. In Section O.2, page 61, the applicant states that BMA West Charlotte meets the Conditions for Coverage for ESRD facilities. Exhibit O-2 contains BMA West Charlotte's 2013 Medicare Recertification Survey letter, including the Statement of Deficiencies. In Section O.3, pages 62-64, the applicant provides information on quality of care provided at its sister facilities, including citations received during the 18 months immediately preceding the submittal of the application, and their resolution. Three FMC facilities had immediate jeopardy citations: BMA Lumberton, BMA East Charlotte and RAI West College-Warsaw. The applicant summarizes the deficiencies cited, including the resolutions, and provides documentation in Exhibit O-3. On page 64, the applicant states that all three facilities were back in full compliance with all CMS Guidelines upon the submittal of the application. The applicant also refers to FMC White Oak's Survey, BMA's response and documentation from CMS; however, the Project Analyst does not find this information in the referenced Exhibit. 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. 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 proposal is conforming to all applicable Criteria

and Standards for End Stage Renal Disease Services in 10A NCAC 14C.2200. The specific findings are discussed below.

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- BMA West Charlotte 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, pages 18-19, and Section P, page 65, the applicant projects 100 in-center patients dialyzing on 29 stations at the end of the first operating year for a utilization rate of 3.45 patients per station per week, thereby documenting the need for the additional stations. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 17-18, and Section C.6, pages 20-21. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.