ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date:	May 3, 2016
Findings Date:	May 3, 2016
Project Analyst:	Gloria C. Hale
Team Leader:	Fatimah Wilson
Project ID #:	F-11144-16
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 27 dialysis stations upon completion of this project and Project ID #F-11099-15 (relocate four stations to FMC Aldersgate)

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. (BMA) d/b/a BMA West Charlotte proposes to add two dialysis stations for a total of 27 certified dialysis stations upon completion of this project and Project I.D. #F-11099-15 (relocate four stations to FMC Aldersgate).

Need Determination

The 2016 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Mecklenburg 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 BMA West Charlotte in the January 2016 SDR is 3.28 patients per station. This utilization rate was calculated based on 95 in-center dialysis patients and 29 certified dialysis stations as of June 30, 2015 (95 patients / 29 stations = 3.28 patients per station).

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

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		81.90%
Certified Stations		29
Pending Stations		0
Total Existing and Pending Stations		**29**
In-Center Patients as of 6/30/15 (SDR2)		95
In-Center Patients as of 12/31/14 (SDR1)		91
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.0879
(ii)	Divide the result of step (i) by 12	0.0073
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.0438
(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	99.16
(v)	Divide the result of step (iv) by 3.2 patients per station	30.99
	and subtract the number of certified and pending stations to determine the number of stations needed	**1.99**

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 two. 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 5-7, Section B.4, pages 12-13, and 16, and Section O.1, pages 61-64. 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, page 14, Section C.3, page 21, and Section L.1, pages 53-57. The applicant states in Section B.4, page 14, that the majority of its dialysis patients are covered by Medicare and/or Medicaid and projects that greater than 85% 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 B.4, pages 15-16, and Section N.1, page 59. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

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 January 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

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA West Charlotte, whose parent company is FMC, proposes to add two dialysis stations to its existing facility for a total of 27 certified dialysis stations upon completion of the proposed project and Project ID #F-11099-15 (relocate four stations to FMC Aldersgate).

Population to be Served

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

In Section C.8, page 23, the applicant provides a table showing the historical patient origin for BMA West Charlotte, as follows:

BMA West Charlotte
Historical Patient Origin
June 30, 2015 [December 31, 2015]*

County	Number of In-Center Dialysis Patients
Mecklenburg	99
Burke	1
Union	1
Totals	101

*Project Analyst's correction is in brackets. Data is for December 31, 2015, as reported on the December 2015 ESRD Data Collection Form.

In Section C.1, page 19, 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 July 1, 2017 – June 30, 2018	Operating Year 2 July 1, 2018 – June 30, 2019	County Patients as Percent of Total	
	In-Center	In-Center	Year 1	Year 2
Mecklenburg	108.7	115.0	100.0%	100.0%
Total	**108.7**	**115.0**	**100.0%**	**100.0%**

In Section C.1, pages 19-20, the applicant provides the assumptions and methodology used to project patient origin. The applicant states, in Section C.1, page 19, that the two patients who were dialyzing at BMA West Charlotte from Burke and Union counties, as of June 30, 2015 [December 31, 2015], were transient patients and therefore, would not continue to dialyze at BMA West Charlotte.

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 27 stations upon completion of this project and Project ID #F-11099-15 (relocate four stations to FMC Aldersgate) pursuant to the 2016 SMFP Facility Need Methodology.

Projected Utilization

As of June 30, 2015, as reported in the January 2016 SDR, the utilization rate at BMA West Charlotte was 81.90% or 3.28 patients per station per week based on 95 in-center patients utilizing 29 certified dialysis stations.

In Section C.1, pages 19-20, 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 5.8% as reported in the January 2016 SDR.
- Two patients, one from Burke County and one from Union County, are not expected to continue receiving dialysis at BMA West Charlotte. BMA assumes these two patients were transient patients.

- The applicant projects that five patients at BMA West Charlotte will transfer their care to FMC Aldersgate, a new dialysis facility, upon its certification on June 30, 2017 (Project I.D. #F-11099-15).
- Lastly, the applicant states that the project will be completed by June 30, 2017.

In Section C.1, page 20, the applicant provides the following methodology used to project utilization:

BMA West Charlotte	In-Center
Beginning facility census of Mecklenburg County patients only, December 31, 2015	99
Project Mecklenburg County patient population forward one year to December 31, 2016 using the Mecklenburg County Five Year AACR of 5.8%	(99 x 0.058) + 99 = 104.7
Project Mecklenburg County patient population forward six months to June 30, 2017	[(104.7 x 0.058/12 x 6)] + 104.7 = 107.7
Subtract the five Mecklenburg County patients projected to transfer to FMC Aldersgate	107.7 – 5 = 102.7
Project Mecklenburg County patient population forward one year to June 30, 2018, the end of Operating Year One	(102.7 x 0.058) + 102.7 = 108.7
Project the Mecklenburg County patient population forward one year to June 30, 2019, the end of Operating Year Two	(108.7 x 0.058) + 108.7 = 115.0

The applicant states, in Section C.2, page 20, that it has rounded down to 108 patients to be dialyzing at the BMA West Charlotte facility at the end Operating Year One. Therefore, the applicant projects that 108 patients will be dialyzing on 27 stations for a projected utilization rate of 4.00 patients per station per week (108 in-center patients/ 27 stations =4.00) which exceeds 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 two additional dialysis stations at BMA West Charlotte.

Access

In Section L.1, page 53, the applicant states that it is the policy of BMA to provide *"services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."* The applicant projects, in Section L.1, page 54, that 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, demonstrates the need the population has for two additional stations at BMA West Charlotte and 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 27, 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 have 100% 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 two additional stations are needed and that the facility is projected to continue to experience growth. Furthermore, if two stations are not added, the facility will exceed 100% utilization. Therefore, adding fewer stations was not the most effective alternative.

3. 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, this is not an effective 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 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 27 certified stations upon completion of Project I.D. #F-11099-15 (relocate four stations to FMC Aldersgate) 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 27 dialysis stations at BMA West Charlotte upon completion of this proposed project and Project I.D. #F-11099-15 (relocate four stations to FMC Aldersgate).

Capital and Working Capital Costs

In Section F.1, page 28, the applicant states that there will be no capital costs for the project. In Section F.9, page 32, the applicant states that the dialysis machines will be leased.

In Sections F.10 and F.11, page 23, 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 March 15, 2016 from the Assistant Treasurer of the parent company, Fresenius Medical Care (FMC) Holdings, Inc., authorizing the project and confirming that the project will not require any capital expenditure.

Financial Feasibility

In Section R, 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
Commercial Insurance	$1,164.86
Medicare	$247.53
Medicaid	$182.82
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 105 and the number of in-center patients used in operating year two was 111. 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, June 30, 2007, is 102.7 in-center patients, as stated in Section C.1, page 20. The applicant projects 108.7 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 105 (102.7+108.7/2 = 105.7).
- Likewise, in Section C.1, page 20, the applicant begins operating year two with 108.7 in-center patients and ends with 115.0 in-center patients. The average number of in-center patients for operating year two, rounded down to the nearest whole number, is 111 (108.7+115.0/2 = 111.85).

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
Total Net Revenue	$5,017,731	$5,304,395
Total Operating Costs	$4,458,023	$4,668,426
Net Profit	**$559,708**	**$635,969**

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 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."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

BMA, Inc. d/b/a BMA West Charlotte, whose parent company is FMC, proposes to add two dialysis stations to its existing facility for a total of 27 certified dialysis stations upon completion of Project I.D. #F-11099-15 (relocate four stations to FMC Aldersgate) and this project.

According to the January 2016 SDR, there are 19 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities
June 30, 2015

Dialysis Facilities	Owner*	# of Patients	# of Certified Stations	Percent Utilization	CON Issued/Not Certified
BMA Beatties Ford	FMC	122	32	95.31%	11
BMA Nations Ford	FMC	114	24	118.75%	0
BMA of East Charlotte	FMC	85	25	85.00%	-4
BMA of North Charlotte	FMC	109	28	97.32%	8
BMA West Charlotte	FMC	95	29	81.90%	0
Carolinas Medical Center	CMHA	14	9	38.89%	0
Charlotte Dialysis	DVA	126	36	87.50%	0
Charlotte East Dialysis	DVA	104	26	100.00%	0
DSI Charlotte Latrobe Dialysis	DSI	56	19	73.68%	0
DSI Glenwater Dialysis	DSI	132	41	80.49%	0
FMC Charlotte	FMC	133	40	83.13%	0
FMC Matthews	FMC	99	21	117.86%	0
FMC of Southwest Charlotte	FMC	0	0	0.00%	10
FMC Regal Oaks	FMC	0	0	0.00%	12
FMC Aldersgate	FMC	0	0	0.00%	0
Huntersville Dialysis	DVA	0	0	0.00%	10
Mint Hill Dialysis	DVA	44	11	100.00%	0
North Charlotte Dialysis Center	DVA	134	35	95.71%	-14
South Charlotte Dialysis	DVA	70	23	76.09%	0

*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 19 dialysis facilities in Mecklenburg County. Three FMC dialysis facilities and one DVA dialysis facility show zero patients and zero certified stations because they have received agency approval but have not been certified yet. Notwithstanding the facilities with zero patients, only three have utilization rates less than 80%. Therefore, most of the operational dialysis facilities in the county are reasonably well utilized.

According to Table B in the January 2016 SDR, there is a surplus of eight dialysis stations in Mecklenburg County. However, the applicant is applying for additional stations based on the facility need methodology. In Section C.1, page 20, the applicant demonstrates that BMA West Charlotte will serve a total of 108 in-center patients on 27 dialysis stations at the end of the first operating year, which is 4.00 patients per station per week, or a utilization rate of 100.00% (108/27 = 4.00; 4.00/4 = 100.00%). 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 40, the applicant states that BMA West Charlotte currently employs 25.80 full time equivalent (FTE) employees and that it proposes to add 3.00 additional FTEs upon completion of the project, as illustrated in the table below:

BMA West Charlotte
Current and Proposed FTEs

Position	Current	Additional	Total
Medical Director*			
Registered Nurse	6.00	1.00	7.00
Patient Care Technician	14.00	2.00	16.00
Clinical Manager	1.00	0.00	1.00
Administrator	0.15	0.00	0.15
Dietitian	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Other**	2.65	0.00	2.65
Total FTEs	**25.80**	**3.00**	**28.80**

*This is an independent contractor, not an employee.
**Other includes Chief Technician, Equipment Technician, In-Service, and Clerical.

In Exhibit I.6, the applicant provides a letter from Dr. George Hart, Medical Director of BMA West Charlotte, dated March 4, 2016, indicating his support of the project and his willingness to continue to serve as Medical Director of the facility. In Section H.3, page 41, 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 43, the applicant lists the providers of the necessary ancillary and support services for the proposed project. See Exhibits I-1, I-3, I-4, and I-5 for documentation of service agreements. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 45-46, stating that BMA facilities in Charlotte and Mecklenburg County have relationships with the medical community in the area, including area 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 53-54, 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 57, 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**	**% Caucasian**	**% Persons in Poverty***	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance***
Mecklenburg	10%	52%	49%	15%	6%	19%
Statewide	15%	51%	64%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*These statistics are not comparable to other geographic levels of these estimates.

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

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

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

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

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L.3, page 55, the applicant states,

"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 56, the applicant states that none of its facilities in North Carolina have had any civil rights complaints lodged against them 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 54, 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

Payor Source	Percentage
Self Pay/Indigent/Charity	1.00%
Medicare	71.72%
Medicaid	5.54%
Commercial Insurance	5.52%
Medicare/Commercial	8.69%
Miscellaneous, including VA	7.53%
Total	**100.00%**

As shown in the table above, the applicant projects that 86% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1, page 54, the applicant provides the assumptions used to project payor mix. The applicant states that its payor mix is calculated based upon the number of treatments provided by type of health care coverage rather than the number of patients it has by health care coverage. 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 consistent with the applicant's historical (CY 2015) stated in Section L.7, page 57. 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 56, 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 58, 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 March 15, 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."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

BMA, Inc. d/b/a BMA West Charlotte, whose parent company is FMC, proposes to add two dialysis stations to its existing facility for a total of 27 certified dialysis stations upon completion of this proposed project and Project I.D. #F-11099-15 (relocate four stations to FMC Aldersgate).

According to the January 2016 SDR, there are 19 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities
June 30, 2015

Dialysis Facilities	Owner*	# of Patients	# of Certified Stations	Percent Utilization	CON Issued/Not Certified
BMA Beatties Ford	FMC	122	32	95.31%	11
BMA Nations Ford	FMC	114	24	118.75%	0
BMA of East Charlotte	FMC	85	25	85.00%	-4
BMA of North Charlotte	FMC	109	28	97.32%	8
BMA West Charlotte	FMC	95	29	81.90%	0
Carolinas Medical Center	CMHA	14	9	38.89%	0
Charlotte Dialysis	DVA	126	36	87.50%	0
Charlotte East Dialysis	DVA	104	26	100.00%	0
DSI Charlotte Latrobe Dialysis	DSI	56	19	73.68%	0
DSI Glenwater Dialysis	DSI	132	41	80.49%	0
FMC Charlotte	FMC	133	40	83.13%	0
FMC Matthews	FMC	99	21	117.86%	0
FMC of Southwest Charlotte	FMC	0	0	0.00%	10
FMC Regal Oaks	FMC	0	0	0.00%	12
FMC Aldersgate	FMC	0	0	0.00%	0
Huntersville Dialysis	DVA	0	0	0.00%	10
Mint Hill Dialysis	DVA	44	11	100.00%	0
North Charlotte Dialysis Center	DVA	134	35	95.71%	-14
South Charlotte Dialysis	DVA	70	23	76.09%	0

*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 in the table above, four dialysis facilities show 0% utilization because they have received agency approval but have not been certified yet. Twelve facilities are operating above 80% capacity and with the exception of the facilities that are not yet operational, only three have utilization rates less than 80%. Therefore, the operational dialysis facilities in the county are reasonably well utilized.

In Section N.1, page 59, 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 5.8% as published within the January 2016 SDR."*

In addition, the applicant states, on page 59, that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that over 86% of its patients at BMA West Charlotte will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 59, 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 Criterion (3) and (4), respectively, are incorporated herein by reference.

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

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

In Exhibit A.4, the applicant provides a listing of all FMC and FMC-affiliated ESRD facilities owned and operated in the state. In Section O.3, pages 65-66, the applicant provides information on quality of care provided at its facilities, including citations received during the 18 months immediately preceding the submittal of the application through the date of the decision, and their resolution. Two FMC facilities had one immediate jeopardy citation each. As stated on page 66, both facilities are now in full compliance with all CMS Guidelines. 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.2, pages 19-21, and Section P, page 68, the applicant projects 108 in-center patients dialyzing on 27 stations at the end of the first operating year for a utilization rate of 4.00 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 19-20, and Section C.6, page 22. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.