

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 19, 2018

Findings Date: February 19, 2018

Team Leader: Gloria C. Hale

Assistant Chief: Lisa Pittman

Project ID #: F-11400-17

Facility: BMA of North Charlotte

FID #: 955788

County: Mecklenburg

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

Project: Add 10 dialysis stations for a total of 38 stations upon completion of this project and Project I.D. #F-11375-17 (relocate 12 stations to develop the new FKC Mallard Creek facility)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA of North Charlotte proposes to add ten dialysis stations to its existing facility for a total of 38 certified dialysis stations upon completion of this project and Project I.D. #F-11375-17 (relocate 12 stations to develop the new FKC Mallard Creek facility).

Need Determination

The 2017 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 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for 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 of North Charlotte in the July 2017 SDR is 4.11 patients per station per week. This utilization rate was calculated based on 148 in-center dialysis patients and 36 certified dialysis stations as of December 31, 2016 (148 patients /36 stations = 4.11 patients per station per week). Application of the facility need methodology indicates that 17 additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		102.78%
Certified Stations		36
Pending Stations		4
Total Existing and Pending Stations		40
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		148
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		133
Step	Description	Result
	Difference (SDR2 - SDR1)	15
(i)	Multiply the difference by 2 for the projected net in-center change	30
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.2256
(ii)	Divide the result of Step (i) by 12	0.0188
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.2256
(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	181.3888
(v)	Divide the result of Step (iv) by 3.2 patients per station	56.6840
	and subtract the number of certified and pending stations to determine the number of stations needed	16.6840

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 17 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2017 SDR. 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 10 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2017 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*. *Policy GEN-3*, on page 33, 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 58-60, and Exhibit O-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 9, Section L, pages 50-53, and Exhibit L-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 10-12, Section C, pages 13-16, and Section N, page 56. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how 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.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates how the proposed project would meet each component of *Policy GEN-3: Basic Principles*. Specifically, the applicant adequately demonstrates how the proposed project would promote safety and quality, promote equitable access, and maximize healthcare value.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (2) Repealed effective January 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. d/b/a BMA of North Charlotte proposes to add ten dialysis stations to its existing facility for a total of 38 certified dialysis stations upon completion of this project and Project I.D. #F-11375-17 (relocate 12 stations to develop the new FKC Mallard Creek facility).

Patient Origin

On page 373, the 2017 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.

In Section C.8, page 18, the applicant provides the historical in-center patient origin for BMA of North Charlotte as of June 30, 2017, which is summarized in the following table:

**BMA of North Charlotte
Historical Patient Origin
June 30, 2017**

County	In-Center Patients
Mecklenburg	140
Cabarrus	1
Cumberland	1
Gaston	3
Rowan	1
Union	1
South Carolina	1
Other States	8
TOTALS	156

In Section C.1, page 13, the applicant provides the projected patient origin for BMA of North Charlotte for operating year one (OY1), Calendar Year (CY) 2019, and OY2, CY2020, following completion of the project, as follows:

**BMA of North Charlotte
 Projected Patient Origin**

	OY1 CY2019	OY2 CY2020	County Patients as Percent of Total	
County	In-Center Patients	In-Center Patients	OY1	OY2
Mecklenburg	126.6	133.0	94.8%	95.0%
Cabarrus	1.0	1.0	0.7%	0.7%
Gaston	3.0	3.0	2.2%	2.1%
Rowan	1.0	1.0	0.7%	0.7%
Union	1.0	1.0	0.7%	0.7%
South Carolina	1.0	1.0	0.7%	0.7%
TOTAL	133.6	140.0	100.0%	100.0%

The applicant provides the assumptions used to project in-center patient origin in Section C.1, pages 13-14. The applicant provides the methodologies used to project in-center patient origin in Section C.1, page 15. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.4, page 8, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP, and utilizes data from the July 2017 SDR to apply the facility need methodology provided in Section B.2, page 6, to demonstrate how the facility qualifies for the 10 proposed additional stations. In Section C.1, pages 13-14, the applicant provides the following assumptions for projecting in-center patients:

1. The current patient population at BMA of North Charlotte who reside in Mecklenburg County are a part of the Mecklenburg County ESRD patient population as a whole and as such will increase at the Five Year Average Annual Change Rate (AACR) for Mecklenburg County of 5.1% as published in the July 2017 SDR.
2. Eight patients reside in other states and are assumed to be transient patients. These patients will not be carried forward in the projections.
3. One patient resides in Cumberland County and is also assumed to be a transient patient. This patient will not be carried forward in the projections.
4. Seven patients reside in Cabarrus, Gaston, Rowan, and Union counties and one patient resides in South Carolina. These patients are expected to continue dialyzing at BMA of North Charlotte out of patient choice. No growth in the number of patients residing in these counties is expected.
5. Fourteen patients will transfer from BMA of North Charlotte to Fresenius Medical Care (FMC) Aldersgate (Project I.D. #F-11099-15) upon completion of that project

which is expected by March 31, 2018. Therefore, 14 patients will be subtracted from BMA of North Charlotte by March 31, 2018.

6. Sixteen patients are projected to transfer from BMA of North Charlotte to Fresenius Kidney Care (FKC) Mallard Creek (Project I.D. #F-11375-17) upon completion of that project which is expected on December 31, 2018. Therefore, 16 patients will be subtracted from BMA of North Charlotte by December 31, 2018.
7. The first two operating years for the proposed project will be CY2019 and CY2020.

Projected Utilization of In-Center Patients

The applicant provides its methodology for projecting utilization for in-center patients for OY1 and OY2, in Section C.1, page 15, as follows:	In-Center Patients
The applicant begins with the Mecklenburg County in-center patient census at the facility on June 30, 2017.	140
The Mecklenburg County in-center patient census is projected forward six months to December 31, 2017, increased by one-half the Five Year AACR for Mecklenburg County of 5.1%.	$140 \times 1.0255 = 143.6$
The Mecklenburg County in-center patient census is projected forward three months to March 31, 2018, increased by one-fourth the Five Year AACR for Mecklenburg County of 5.1%.	$143.6 \times 1.01275 = 145.4$
The applicant subtracts 14 in-center patients projected to transfer to FMC Aldersgate.	$145.4 - 14 = 131.4$
The census of Mecklenburg County in-center census is projected forward nine months to December 31, 2018, increased by three-fourths the Five Year AACR for Mecklenburg County of 5.1%.	$131.4 \times 1.03825 = 136.4$
The applicant subtracts 16 in-center patients projected to transfer to FKC Mallard Creek.	$136.4 - 16 = 120.4$
The applicant adds seven patients from other counties and South Carolina. This is the beginning census for the project.	$120.4 + 7 = 127.4$
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5.1% to December 31, 2019.	$120.7 [120.4] \times 1.051 = 126.6$
The applicant adds seven patients from other counties and South Carolina. This is the ending census for OY1.	$126.6 + 7 = 133.6$
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5.1% to December 31, 2020.	$126.6 \times 1.051 = 133.0$
The applicant adds the seven patients from other counties and South Carolina. This is the ending census for OY2.	$133.0 + 7 = 140.0$

The applicant states, in Section C.1, page 15, that it projects to serve 133 in-center patients by the end of OY1, rounded down, which is 3.50 patients per station per week (133 patients/ 38 dialysis stations = 3.50). Therefore, the applicant’s projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identifies the patient origin and adequately demonstrates the need for 10 additional dialysis stations at BMA of North Charlotte.

Access

In Section C.3, page 16, the applicant states that BMA has a long history of serving the underserved population in the state and that each facility serves “*low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*” The applicant further states that BMA will continue to provide access to low income and medically underinsured persons. In Section L.7, page 54, the applicant states that 86.2% of BMA of North Charlotte’s patients were Medicare or Medicaid recipients in CY2016. In Section L.1, page 51, the applicant projects that 84.7% of all of BMA of North Charlotte’s patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The population to be served by the proposed project will be from the same counties as they have been historically, with the exception of those likely to be transient patients from other states.
- The applicant uses reasonable assumptions and methodology to project the number of in-center patients to be served at the facility.
- The applicant projects that the facility will serve a similar percentage of Medicaid and Medicare recipients as it has historically.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

The applicant proposes to add 10 dialysis stations to an existing facility, therefore there will be no reduction or elimination of a service, including the relocation of a facility.

- (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 22, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that the facility’s projected utilization will be greater than 80% at the end of OY1, therefore maintaining the status quo would result in higher utilization rates and potentially cause admissions to be restricted. Therefore, this is not the most effective alternative.
- Apply for Fewer Stations – The applicant states that the facility need methodology indicated that the facility needed 17 dialysis stations, however the facility need methodology limits the applicant to adding no more than 10 stations. The applicant states that the facility is projected to grow and will exceed 100% utilization if the 10 stations are not added. Therefore, proposing to add less than 10 stations is not the most effective alternative.
- Include Home Therapies – The applicant states that it could have proposed to include home therapies at the facility, however there is not enough space to do so. Therefore, this is not the most effective alternative.
- Relocate stations to BMA of North Charlotte – The applicant states it considered relocating dialysis stations from other BMA facilities in Mecklenburg County to BMA of North Charlotte, however all of the other facilities are operating at over 80% of capacity with the exception of the new FMC Southwest Charlotte and new FMC Regal Oaks facilities. Therefore, this is not the most effective alternative.

In Section C.2, page 16, the applicant states that the projected population at BMA of North Charlotte will result in a utilization rate of 87.5% and that “*failure to add these 10 stations will lead to higher utilization rates at the facility.*” Therefore, the proposed alternative represented in the application is the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that the proposal is its most effective alternative to meet the identified need.

This determination is based on a review of the:

- Information in the application, and
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall materially comply with the last made representation.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall develop and operate no more than 10 additional dialysis stations for a total of no more than 38 certified stations upon completion of the project and Project I.D. #F-11375-17 (relocate 12 stations to develop the new FKC Mallard Creek facility).**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall install plumbing and electrical wiring through the walls for 10 additional dialysis stations for a total of no more than 38 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte proposes to add ten dialysis stations to its existing facility for a total of 38 certified dialysis stations upon completion of this project and Project I.D. #F-11375-17 (relocate 12 stations to develop the new FKC Mallard Creek facility).

Capital and Working Capital Costs

In Section F.1, page 25, the applicant states that there will be no capital cost for the project. In Sections F.10-F.12, page 28, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since BMA of North Charlotte is an existing facility.

Financial Feasibility

In the pro forma financial statements, page 75, the applicant states in its assumptions for in-center patients that the calculated average annual number of patients, rounded down, is used to calculate the revenues. Thus, for OY1 the applicant projects to begin with 127.4 patients and end with 133.6 patients for an average of 130 in-center patients, rounded down. Similarly, for OY2 the applicant projects to begin with 133.6 patients and end with 140.0 patients for an average of 136 in-center patients, rounded down.

The applicant provides pro forma financial statements for the first two operating years of the project following completion. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

BMA of North Charlotte		
	OY1 (CY2019)	OY2 (CY2020)
Total In-Center Treatments	19,266	20,115
Total Gross Revenues (Charges)	\$ 76,832,808	\$ 80,378,140
Deductions from Gross Revenues	\$ 70,704,762	\$ 73,967,325
Total Net Revenue	\$ 6,128,046	\$ 6,410,815
Average Net Revenue per Treatment	\$ 318	\$ 319
Total Operating Expenses (Costs)	\$ 5,943,880	\$ 6,146,357
Average Operating Expense per Treatment	\$ 309	\$ 306
Net Income	\$ 184,166	\$ 264,458

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

This determination is based on a review of the information in the application, including any exhibits.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte proposes to add ten dialysis stations to its existing facility for a total of 38 certified dialysis stations upon completion of this project and Project I.D. #F-11375-17 (relocate 12 stations to develop the new FKC Mallard Creek facility).

On page 373, the 2017 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.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 18 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2016**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	93.75%
BMA of East Charlotte	BMA	Charlotte	25	92.00%
BMA of North Charlotte	BMA	Charlotte	36	102.78%
BMA West Charlotte	BMA	Charlotte	29	86.21%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	84.72%
Charlotte East Dialysis	DaVita	Charlotte	34	88.24%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
BMA of North Charlotte	BMA	Charlotte	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Fresenius Medical Care Southwest Charlotte***	BMA	Charlotte	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	74.39%
South Charlotte Dialysis	DaVita	Charlotte	22	86.36%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2017 SDR, Table B.

* Facility under development.

** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Charlotte in the July 2017 SDR, Table B. In addition, the FID# should be 160337.

*** FMC Southwest Charlotte is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility.

According to Table D in the July 2017 SDR, there is a surplus of fourteen dialysis stations in Mecklenburg County. The applicant proposes to add 10 dialysis stations for a total of 38

dialysis stations upon completion of the project. However, the applicant is applying for additional stations based on the facility need methodology. As of December 31, 2016, BMA of North Charlotte was serving 148 patients on 36 dialysis stations per week, which is 4.11 patients per station per week or 102.78% of capacity. The applicant does not propose to establish a new facility. In Section C.1, pages 13-15, the applicant adequately demonstrates that BMA of North Charlotte will serve a total of 133 in-center patients on 38 dialysis stations at the end of OY1 (CY2019), for a utilization rate of 3.50 patients per station per week, or 87.5% of capacity ($133/38 = 3.50$; $3.50/4 = 87.5\%$). 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 need to add 10 additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in Mecklenburg County based on the following analysis:

- The applicant is not proposing to develop a new dialysis facility, rather it is proposing to add dialysis stations based on the facility need methodology.
- All other operational BMA dialysis facilities in Mecklenburg County, with the exception of Fresenius Medical Care (FMC) Southwest Charlotte and FMC Regal Oaks which are new facilities, are operating at over 80% of capacity.
- The applicant expects 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).

This determination is based on a review of the:

- Information in the application, including any exhibits, and
- Information which was publicly available during the review and used by the Agency.

Consequently, the applicant adequately demonstrates that 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 37, the applicant provides the current and projected staffing for the facility, which will increase by four full-time equivalents (FTEs), from 35.75 FTEs to 39.75 FTEs, upon completion of the proposed project. Projected direct care staff in OY2, is shown in Section H.7, page 39.

In Section H.6, page 39, the applicant states that dialysis services will be available from 6:00 a.m. to 10:00 p.m., Monday, Wednesday and Friday, and 6:00 a.m. to 5:00 p.m. Tuesday, Thursday and Saturday.

In Section H.3, page 37, the applicant states that it does not anticipate any difficulties filling staff positions and that it employs aggressive recruiting and advertising efforts to hire staff, along with providing a range of benefits and competitive salaries to attract and maintain staff. Exhibit I-5 contains a copy of a letter from Daniel Tierney, M.D., stating his support for the project and his willingness to continue serving as the Medical Director for the facility.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of BMA of North Charlotte.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 40, the applicant includes a list of providers of the necessary ancillary and support services. Exhibits I-2, I-3 and I-4 contain copies of agreements with providers for laboratory services, hospital services, and transplants, respectively.

In Section I.3, page 42, the applicant provides a listing of nephrologists at Metrolina Nephrology Associates who have agreed to provide medical coverage at the facility and who have expressed support for the project. In addition, the applicant states, on page 43, that BMA has informal relationships with other physicians in the area. Moreover, Exhibit I-5 contains a letter from the medical director of the facility that expresses his support for the proposed project.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- A list of current and projected necessary ancillary and support services, and by whom they will be made available, is documented.
- The applicant identifies nephrologists in the area who have agreed to provide medical coverage at the facility, and
- The facility's Medical Director has provided a letter of support.

This determination is based on a review of the information in the application, including any exhibits.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO.

- (11) Repealed effective January 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

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L.7, page 54, the applicant reports that 86.2% of the in-center patients who received treatments at BMA of North Charlotte in CY2016 had some or all of their services paid for by Medicare or Medicaid. The table below, from page 54 of the application, provides the historical (CY2016) payment sources for all of BMA of North Charlotte's patients:

Payment Source	Total Facility*
Self-Pay/Indigent/Charity	1.3%
Commercial Insurance	10.6%
Medicare	61.4%
Medicaid	13.3%
Misc., including VA	1.9%
Medicare/Commercial Insurance	11.6%
Total**	100.0%

*The percentages are rounded to the nearest tenth.

**Total may not foot due to rounding.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28¹. In 2015, over 85% of dialysis

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant's current payor mix would be of little value because 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 information in the application, including any exhibits, is reasonable and adequately supported because the applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any applicable exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 52, 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 applicant will treat all patients the same regardless of race or handicap status.”

In Section L.6, page 53, the applicant states there have been no civil rights complaints filed against any BMA North Carolina facilities in the past five years. Therefore, the application is conforming to this criterion.

The application is conforming to this criterion based on a review of:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1(b), page 51, the applicant projects that 84.7% of all patients who will receive treatments at BMA of North Charlotte in OY2, CY2020, will have some or all of their services paid for by Medicare or Medicaid. The table below, from page 51 of the application, shows the projected OY2 payor mix for the facility for all patients:

**BMA of North Charlotte
Projected Payor Mix, OY2 (CY2020)**

Payment Source	Percent of All Patients*
Self-Pay/Indigent/Charity	3.7%
Commercial Insurance	10.0%
Medicare	59.6%
Medicaid	13.5%
VA	1.6%
Medicare/Commercial Insurance	11.6%
Total	100.0%

*Percentages are rounded to the nearest tenth.

In supplemental information, the applicant provides the assumption used to project payor mix, stating that it is based on the facility's recent performance.

This application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 53, the applicant describes the range of means by which a person will have access to the dialysis services at BMA of North Charlotte, stating that any nephrologist may apply for privileges to admit patients and receive referrals from other nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services.

Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 55, the applicant states that BMA has communicated with local nursing programs, inviting them to utilize BMA of North Charlotte as an educational opportunity for their nursing students. Exhibit M-1 contains a copy of correspondence from the applicant to Central Piedmont Community College offering BMA of North Charlotte as a clinical training site for the college's nursing students.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant has demonstrated its intent to offer the facility as a clinical training site.

Therefore, the application is conforming to this criterion.

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte proposes to add ten dialysis stations to its existing facility for a total of 38 certified dialysis stations upon completion of this project and Project I.D. #F-11375-17 (relocate 12 stations to develop the new FKC Mallard Creek facility).

On page 373, the 2017 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.

According to the July 2017 SDR, there are 23 dialysis facilities in Mecklenburg County, 18 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2017 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2016**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	93.75%
BMA of East Charlotte	BMA	Charlotte	25	92.00%
BMA of North Charlotte	BMA	Charlotte	36	102.78%
BMA West Charlotte	BMA	Charlotte	29	86.21%
Brookshire Dialysis	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	84.72%
Charlotte East Dialysis	DaVita	Charlotte	34	88.24%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
BMA of North Charlotte	BMA	Charlotte	43	90.70%
FMC Matthews	BMA	Matthews	21	111.90%
FKC Southeast Mecklenburg County**	BMA	Charlotte	0	0.00%
FMC Regal Oaks*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
Fresenius Medical Care Southwest Charlotte***	BMA	Charlotte	10	40.00%
Huntersville Dialysis	DaVita	Huntersville	10	92.50%
Mint Hill Dialysis	DaVita	Mint Hill	16	96.88%
North Charlotte Dialysis Center	DaVita	Charlotte	41	74.39%
South Charlotte Dialysis	DaVita	Charlotte	22	86.36%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: July 2017 SDR, Table B.

* Facility under development.

** FKC Southeast Mecklenburg County is a new facility under development, however it is erroneously named FMC of Southwest Charlotte in the July 2017 SDR, Table B. In addition, the FID# should be 160337.

*** FMC Southwest Charlotte is an existing facility, however the FID# is erroneous as listed in the July 2017 SDR, Table B. The FID# should be 120485.

As illustrated above, BMA owns eight of the 17 operational dialysis facilities in Mecklenburg County. As shown in the table above, seven of BMA's eight operational dialysis facilities are operating above 80% utilization (3.2 patients per station per week) and six of those are operating above 90% utilization. Five dialysis facilities are operating below 80% utilization, including one BMA facility, two DSI facilities, a CMC facility, and one DaVita facility.

In Section N.1, page 56, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ...In this application, BMA projects that greater than 84% of the In-center patients will be relying upon government payors (Medicare /Medicaid). The facility must capitalize upon every opportunity for efficiency.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

The application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the proposed project will be cost-effective,
- The applicant adequately demonstrates it will provide quality services, and
- The applicant adequately demonstrates that it will provide access to medically underserved populations.

This determination is based on a review of:

- The information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

(19) Repealed effective January 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 Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina that it or an affiliated company owns and operates. In Section O.2, pages 61-62, the applicant identifies two of its facilities, BMA East Rocky Mount, and RAI West College Warsaw, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibits O-3 and O-4. The applicant states, on page 62, that both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

The applicant provides sufficient evidence that quality of care has been provided in the past.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant is proposing to add dialysis stations to an existing facility, BMA of North Charlotte. Therefore, this performance standard is not applicable to this review.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.1, page 15, the applicant projects to serve 133 in-center patients by the end of OY1, which is 3.50 patients per station per week ($133/38 = 3.50$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding

projected utilization found in Criterion (3) is incorporated herein by reference.