

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 27, 2018

Findings Date: June 27, 2018

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Lisa Pittman

Project ID #: F-11475-18

Facility: BMA of North Charlotte

FID #: 955788

County: Mecklenburg

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

Project: Add one dialysis station for a total of 39 stations upon completion of this project, Project ID# F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility and Project ID# F-11400-17 (add 10 stations)

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 one dialysis station for a total of 39 stations upon completion of this project, Project ID# F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility and Project ID# F-11400-17 (add 10 stations). The parent company of BMA is Fresenius Medical Care Holdings, Inc. (Fresenius).

Need Determination

The 2018 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 2018 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 January 2018 SDR is 4.333 patients per station per week. This utilization rate was calculated based on 156 in-center dialysis patients and 36 certified dialysis stations as of June 30, 2017 (156 patients /36 stations = 4.333 patients per station per week). Application of the facility need methodology indicates that 1 additional station is needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		108.33%
Certified Stations		36
Pending Stations		14
Total Existing and Pending Stations		50
In-Center Patients as of 6/30/17 (SDR2)		156
In-Center Patients as of 12/31/16 (SDR1)		148
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.1081
(ii)	Divide the result of step (i) by 12	0.0090
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0541
(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	164.4324
(v)	Divide the result of step (iv) by 3.2 patients per station	51.3851
	and subtract the number of certified and pending stations to determine the number of stations needed	1

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 1 station. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2018 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 1 new station and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 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 56-60, 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 48-52, 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 9-11, Section C, pages 13-17, and Section N, pages 54-55. 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 Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

BMA proposes to add one dialysis station to the BMA of North Charlotte facility for a total of 39 stations upon completion of this project, Project ID# F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility and Project ID# F-11400-17 (add 10 stations).

Patient Origin

On page 365 the 2018 SMFP defines the service area for dialysis stations as “a dialysis station’s service area is 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 19, the applicant provides the historical in-center (IC) patient origin for the BMA of North Charlotte facility as of December 31, 2017, summarized in the following table:

Historical Patient Origin as of 12/31/17: BMA of North Charlotte

COUNTY OF RESIDENCE	# IN-CENTER PTS
Mecklenburg	134
Cabarrus	2
Gaston	2
Rowan	2
Cumberland	1
Durham	1
Guilford	1
Sampson	1
South Carolina	2
Other States	12
Total	158

In Section C.1, page 13, the applicant projects patient origin for BMA of North Charlotte for operating year one (OY1), Calendar Year (CY) 2019, and OY 2, CY 2020, following completion of the project as follows:

Projected Patient Origin: BMA of North Charlotte

COUNTY	OY 1 (CY 2019)	OY 2 (CY 2020)	COUNTY PATIENTS AS % OF TOTAL	
			OY 1	OY 2
Mecklenburg	116.0	121.9	92.80%	93.12%
Cabarrus	2	2	1.60%	1.53%
Gaston	2	2	1.60%	1.50%
Rowan	2	2	1.60%	1.50%
South Carolina	2	2	1.60%	1.50%
Other States	1	1	0.80%	0.80%
Total	125.0	130.9	100.00%	100.00%

The applicant provides the assumptions and methodology used to project its patient origin on pages 13-16. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 14-15, describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The applicant projects the first two full operating years of the project will be January 1, 2019 – December 31, 2019 (CY2019) and January 1, 2020 – December 31, 2020 (CY2020).
2. As of December 31, 2017, the current patient census of Mecklenburg county residents at BMA of North Charlotte was 134 in-center patients.
3. As of December 31, 2017, the patient census of non-Mecklenburg county residents at BMA of North Charlotte was a total of 24 in-center patient from other states, other NC counties and South Carolina as follows:
 - a. 12 in-center patients from Other States: BMA will assume that 1 in-center patient from other states will receive dialysis from BMA of North Charlotte during the year.
 - b. 4 in-center patients from counties not in close proximity to Mecklenburg County (Cumberland, Durham, Guilford and Sampson counties). BMA assumes that these patients are transient patients and does not project them to continue dialyzing at BMA of North Charlotte during the interim and project years.
 - c. 8 in-center patients from South Carolina and three other North Carolina counties that are in close proximity to Mecklenburg County (Cabarrus, Gaston and Rowan counties). BMA assumes that these patients are dialyzing at BMA of North Charlotte as a matter of patient choice and projects that they will continue to dialyze at BMA of North Charlotte. However, BMA does not project any growth of this patient population.

4. The applicant projects growth of the Mecklenburg county residents at 5.1% which is the Mecklenburg County Five Year Average Annual Change Rate (AACR) per the January 2018 SDR.
5. BMA will subtract 14 patients from the patient census of BMA of North Charlotte as of March 31, 2018 because BMA has previously projected that 14 patients will transfer their care to FMC Aldersgate upon completion of that project. The FMC Aldersgate project was expected to be completed as of March 31, 2018.
6. BMA will subtract 16 patients from the patient census of BMA of North Charlotte as of December 31, 2018 because BMA has previously projected that 16 patients will transfer their care to FKC Mallard Creek upon completion of that project. The FKC Mallard Creek project is expected to be completed as of December 31, 2018.

Projected Utilization

The applicant’s methodology for in-center patients is shown in the following table.

Begin with Mecklenburg County patients dialyzing at the facility as of December 31, 2017.	134
Project Mecklenburg County patient census forward 3 months to March 31, 2018, using the 25% of the 5 year AACR of 5.1% for Mecklenburg County.	$134 \times 1.028 = 135.7$
Subtract the 14 patients projected to transfer to FMC Aldersgate.	$135.7 - 14 = 121.7$
Project Mecklenburg County patient census forward 9 months to December 31, 2018, using the 75% of the 5 year AACR of 5.1% for Mecklenburg County.	$121.7 \times 1.0383 = 126.4$
Subtract the 16 patients projected to transfer to FKC Mallard Creek.	$126.4 - 16 = 110.4$
Add in the 9 patient from South Carolina, other counties and other states. This is the beginning census for the proposed project as of January 1, 2019.	$110.4 + 9 = 119.4$
Project the Mecklenburg County patient census forward one year to December 31, 2019.	$119.4 \times 1.051 = 125.5$
Add in the 9 patient from South Carolina, other counties and other states. This is the ending census for OY1 (CY2019).	$125.5 + 9 = 134.5$
Project the Mecklenburg County patient census forward one year to December 31, 2020.	$134.5 \times 1.051 = 141.4$
Add in the 9 patient from South Carolina, other counties and other states. This is the ending census for OY2 (CY2020).	$141.4 + 9 = 150.4$

Source: Table in Section C, page 16.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2019) the facility is projected to serve 125 in-center patients and at the end of OY2 (CY2020) the facility is projected to serve 130 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.2051 patients per station per week or 80.13% (125 patients / 39 stations = 3.2051/ 4 = 0.801275 or 80.13%).
- OY2: 3.333 patients per station per week or 83.32% (130 patients / 39 stations = 3.333/4 = 0.83325 or 83.32%).

The projected utilization of 3.2051 patients per station per week at the end of OY1 is equal to or exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant adequately identifies the patient origin.
- The applicant assumes a projected annual rate of growth of 5.1 percent for the in-center Mecklenburg County patient census at BMA of North Charlotte, which is equal to the Mecklenburg County Five Year Average Annual Change Rate as published in the January 2018 SDR.
- The applicant adequately demonstrates the need for one additional dialysis station at BMA of North Charlotte pursuant to the facility need methodology in the 2018 SMFP. Projected utilization at the end of OY1 exceeds the minimum standard for in-center patients per week required by 10A NCAC 14C .2203(b).

Access

In Section C.3, page 15, the applicant states each of BMA's 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.1, page 49, the applicant projects the following payor mix during the second full fiscal year of operation (CY2020) following completion of the project, as illustrated in the following table.

PAYOR CATEGORY	% OF TOTAL PATIENTS
Self Pay/Indigent/Charity	1.50%
Medicare	61.63%
Medicaid	15.37%
Commercial Insurance	8.11%
Medicare/Commercial	11.48%
Miscellaneous (Incl. VA)	1.91%
Total	100.00%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose to reduce or eliminate a service, nor does the applicant propose to relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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

BMA proposes to add one dialysis station to the BMA of North Charlotte facility for a total of 39 stations upon completion of this project, Project ID# F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility and Project ID# F-11400-17 (add 10 stations).

In Section E.1, page 23, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo- The applicant states that maintaining the status quo is not an effective alternative due to the fact that BMA of North Charlotte is projected to exceed 80% utilization by the end of OY1. If additional stations are not developed higher utilization rates will develop and potentially restrict patient access.
- Relocate stations from another BMA facility in Mecklenburg County- The applicant states that all BMA facilities in Mecklenburg County are operating at above 80% utilization except for 2: FMC Southwest Charlotte and FMC Regal Oaks. The applicant states that FMC Southwest Charlotte is growing rapidly with

BMA already having to move 3 additional stations into the facility. FMC Regal Oaks is a newer facility and BMA expects patient transfers to FMC Real Oaks will increase utilization at that facility.

On page 23, the applicant states that its proposal is the most effective alternative because BMA will be simply replacing one of the stations which are being relocated to FKC Mallard Creek (Project ID# F-11375-17) with no capital expenditure since the space for the stations already exists at the facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 1 additional dialysis station for a total of no more than 39 certified stations at BMA of North Charlotte upon completion of this project, Project ID #F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility) and Project ID #F-11400-17 (add 10 stations) which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. 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

BMA proposes to add one dialysis station to the BMA of North Charlotte facility for a total of 39 stations upon completion of this project, Project ID# F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility and Project ID# F-11400-17 (add 10 stations).

Capital and Working Capital Costs

In Section F, pages 24 and 27, the applicant states that the proposed project will not involve any capital expenditures or initial operating expenses.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section R, Form B, page 76, the applicant projects that revenues will exceed operating expenses in the second operating year of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	18,080	18,969
Total Gross Revenues (Charges)	\$72,103,040	\$75,648,372
Total Net Revenue	\$5,920,616	\$6,211,735
Average Net Revenue per treatment	\$327.47	\$327.47
Total Operating Expenses (Costs)	\$5,998,043	\$6,211,243
Average Operating Expense per treatment	\$331.75	\$327.44
Net Income	(\$77,427)	\$492

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- 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.

- (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

BMA proposes to add one dialysis station to the BMA of North Charlotte facility for a total of 39 stations upon completion of this project, Project ID# F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility and Project ID# F-11400-17 (add 10 stations).

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is 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.

According to the January 2018 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2017**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	98.21%
BMA of East Charlotte	BMA	Charlotte	25	87.00%
BMA of North Charlotte	BMA	Charlotte	36	108.33%
BMA West Charlotte	BMA	Charlotte	29	81.03%
FMC Charlotte	BMA	Charlotte	43	89.53%
FMC Matthews	BMA	Matthews	21	119.05%
Fresenius Medical Care Southwest Charlotte	BMA	Charlotte	10	75.00%
FMC Regal Oaks***	BMA	Charlotte	12	16.67%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	19.44%
Charlotte Dialysis	DaVita	Charlotte	36	83.33%
Charlotte East Dialysis	DaVita	Charlotte	34	83.82%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.19%
Huntersville Dialysis	DaVita	Huntersville	10	95.00%
Mint Hill Dialysis	DaVita	Mint Hill	16	82.81%
North Charlotte Dialysis Center	DaVita	Charlotte	41	70.12%
South Charlotte Dialysis**	DaVita	Charlotte	22	82.95%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: January 2018 SDR, Table B.

* Facility under development.

**Under Project ID #F-11323-17 this facility is being relocated to a new location.

***Newly certified per applicant. See Section G, page 32.

In Section G, pages 32-34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. On page 32 the applicant states:

“Of the 18 operational dialysis facilities in the county with in-center stations, nine are operated by BMA. Eight of the BMA facilities were operating at or above the 80% utilization level as of December 31, 2017. Only the newly certified FMC Regal Oaks facility was operating at less than 80%.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates the need for one additional dialysis station at BMA of North Charlotte pursuant to the facility need methodology in the 2018 SMFP.
- The applicant adequately demonstrates that the proposed 1 new dialysis station at BMA of North Charlotte is needed in addition to the existing or approved dialysis stations.
- Projected utilization at the end of OY1 exceeds the minimum standard for in-center patients per week required by 10A NCAC 14C .2203(b).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 35, the applicant provides the current staffing for the facility, and states that BMA of North Charlotte is not projected to add any full time equivalent (FTE) positions as a result of this proposal. The applicant states the facility currently staffs 36.45 FTE positions. In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 37.

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 35-36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 39, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 38, the applicant includes a list of providers of the necessary ancillary and support services as shown in the table below.

BMA of North Charlotte Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	BMA of North Charlotte
Self-care training (in-center)	Refer to FMC Charlotte Home Training Program
Home training HH PD Accessible follow-up program	Refer to FMC Charlotte Home Training Program
Psychological counseling	Refer to CMC Randolph Road
Isolation – hepatitis	Refer to FMC Charlotte
Nutritional counseling	BMA of North Charlotte
Social Work services	BMA of North Charlotte
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	BMA of North Charlotte/911/Hospital
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	Spectra Labs
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Carolinas Medical Center; Sanger Heart and Vascular; MNA Vascular Access Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	Division of Vocational Rehabilitation Services
Transportation	Charlotte Area Transportation; A-1 Wheelchair Transport or Area Taxi Services

In Section I.1-2, pages 38-39, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1, I-2, I-3 and I-4.

In Section I, pages 38-41, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and I-4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes 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. Therefore, Criterion (9) is not applicable to this review.

- (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. Therefore, Criterion (10) is not applicable to this review.

- (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

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 52, the applicant provides the historical payor mix during CY 2017 at BMA of North Charlotte, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL PATIENTS
Self Pay/Indigent/Charity	1.50%
Medicare	61.63%
Medicaid	15.37%
Commercial Insurance	8.11%
Medicare/Commercial	11.48%
Miscellaneous (Incl. VA)	1.91%
Total	100.00%

Numbers may not sum due to rounding

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Mecklenburg	11%	52%	52%	14%	6%	13%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

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

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

- (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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 50, 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. The applicant will treat all patients the same regardless of race or handicap status.”

In Section L, page 51, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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, page 49, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL PATIENTS
Self Pay/Indigent/Charity	1.50%
Medicare	61.63%
Medicaid	15.37%
Commercial Insurance	8.11%
Medicare/Commercial	11.48%
Miscellaneous (Incl. VA)	1.91%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.50% of total services will be provided to self-pay/indigent/charity patients, 73.11% to Medicare patients and 15.37% to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for BMA of North Charlotte.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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, page 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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, page 53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA proposes to add one dialysis station to the BMA of North Charlotte facility for a total of 39 stations upon completion of this project, Project ID# F-11375-17 (relocate 12 stations to develop new FKC Mallard Creek facility and Project ID# F-11400-17 (add 10 stations).

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is 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.

According to the January 2018 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 January 2018 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2017**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	98.21%
BMA of East Charlotte	BMA	Charlotte	25	87.00%
BMA of North Charlotte	BMA	Charlotte	36	108.33%
BMA West Charlotte	BMA	Charlotte	29	81.03%
FMC Charlotte	BMA	Charlotte	43	89.53%
FMC Matthews	BMA	Matthews	21	119.05%
Fresenius Medical Care Southwest Charlotte	BMA	Charlotte	10	75.00%
FMC Regal Oaks***	BMA	Charlotte	12	16.67%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	19.44%
Charlotte Dialysis	DaVita	Charlotte	36	83.33%
Charlotte East Dialysis	DaVita	Charlotte	34	83.82%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.19%
Huntersville Dialysis	DaVita	Huntersville	10	95.00%
Mint Hill Dialysis	DaVita	Mint Hill	16	82.81%
North Charlotte Dialysis Center	DaVita	Charlotte	41	70.12%
South Charlotte Dialysis**	DaVita	Charlotte	22	82.95%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%

Source: January 2018 SDR, Table B.

* Facility under development.

**Under Project ID #F-11323-17 this facility is being relocated to a new location.

***Newly certified per applicant. See Section G, page 32.

In Section N.1, pages 54-55, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 54, the applicant states:

“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 applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O.3, page 59, the applicant identifies there are more than 100 Fresenius related dialysis facilities located in North Carolina. Exhibit A-4 contains a list of the Fresenius dialysis facilities located in North Carolina.

In Section O.3, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, BMA East Rocky Mount. The applicant states that BMA East Rocky Mount is currently back in full compliance with all CMS requirements. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS conditions for Coverage for the BMA East Rocky Mount facility in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past. 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

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- The applicant is not proposing to establish a new End Stage Renal Disease facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C, pages 13-17, the applicant demonstrates that BMA of North Charlotte will service a total of 125 in-center patients at the end of OY1 (CY2019) for a utilization rate of 80.13% or 3.2051 patients per station per week ($125 \text{ patients} / 39 \text{ stations} = 3.2051 / 4 = 0.801275$ or 80.13%). 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- In Section C, pages 13-17, 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.