

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 28, 2020

Findings Date: February 28, 2020

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: F-11827-19

Facility: BMA West Charlotte

FID #: 190635

County: Mecklenburg

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

Project: Relocate entire 29-station facility within Mecklenburg County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (“BMA” or “the applicant”) proposes to relocate an existing 29-station dialysis facility, BMA West Charlotte, from 3057 Freedom Drive, in Charlotte to a new location on Freedom Drive in Charlotte. BMA is a subsidiary of Fresenius Medical Care Holdings, Inc. (FMC).

Need Determination

The applicant is proposing to relocate existing dialysis stations within Mecklenburg County. Neither the county nor facility need methodologies in the 2019 State Medical Facilities Plan (SMFP) are applicable to this review.

Policies

There are two policies in the 2019 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy ESRD-2: Relocation of Dialysis Stations (page 25 of the 2019 SMFP) states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate existing dialysis stations within Mecklenburg County; thus, there will be no change to the dialysis station inventory of Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 31 of the 2019 SMFP) states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water

conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, pages 11-12, the applicant provides a written statement describing its plan to assure improved energy efficiency and water conservation. On page 11, the applicant states:

"Fresenius Medical Care (parent to BMA) is committed to ensuring the building will maximize improved energy efficiency. The facility plumbing systems have been designed to ensure conservation of water. FMC building specifications require the exterior building envelope (consisting of roofing, wall, and glass systems) to meet current requirements for energy conservation."

The applicant includes a listing of methods used by FMC to maintain efficient energy operations on pages 11-12 of the application.

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Mecklenburg County.
- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(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 relocate an existing 29-station dialysis facility, BMA West Charlotte, from 3057 Freedom Drive, in Charlotte to a new location less than one mile away.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The existing facility and the proposed relocated facility are located in Mecklenburg County; thus, the service area for this facility is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

BMA West Charlotte provides in-center (IC) dialysis only. In Section C.2, page 13, the applicant provides the patient origin for BMA West Charlotte as of December 31, 2018, as summarized in the table below.

BMA West Charlotte
1/1/2018/-12/31/2018

COUNTY	# IC PATIENTS	% IC Total
Mecklenburg	95.0	100.0%
Total	95.0	100.0%

The applicant provides the following projected patient origin for the second full operating year following project completion, in Section C, page 13.

BMA West Charlotte
1/1/2023/-12/31/2023

COUNTY	# IC PATIENTS	% IC Total
Mecklenburg	114.3	100.0%
Total	114.3	100.0%

In Section C, pages 13-14, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

The applicant proposes to relocate the entire 29-station facility. In Section C, page 15, the applicant explains why the facility needs to be relocated. The applicant states:

“The existing facility is reaching the end of its useful life, and will require significant upgrades to bring the facility to contemporary standards for dialysis facilities. These upgrades cannot be accomplished while the facility continues to operate. Thus, the patients would have to be displaced for a time during the upgrades. Unfortunately, BMA does not have capacity in existing nearby facilities to accommodate the current, or projected patient population of the facility.

Thus, in the interest of ensuring continued access to care, in a patient friendly facility, BMA has elected to relocate the entire facility to a new location less than one mile away. The new facility can be developed without interrupting patient care or displacing patients while renovations are completed.”

The information is reasonable and adequately supported based on the following:

- The applicant adequately demonstrates the need the existing and proposed patients have for the services provided.
- The applicant adequately demonstrates the need to replace the existing, obsolete facility and relocate it to a new location nearby.

Projected Utilization

In Section Q, Assumptions for Form C Utilization, pages 62-63, the applicant describes its need methodology and assumptions for projecting in-center utilization for the facility, summarized as follows:

- The applicant states that it projects patients forward from the June 30, 2019 census data, which the applicant states was submitted to the Agency on the ESRD Data Collection form in August 2019. The applicant provides a table on page 62 that shows the facility census as of December 31, 2018 and June 30, 2019, as summarized below.

COUNTY	12/31/2018	6/30/2019
Mecklenburg	99	95
Cabarrus	1	0
Cleveland	1	0
Guilford	1	0
Total	102	95

The applicant states that it is not uncommon for a dialysis facility’s census to “ebb and flow” as an explanation for the slight decline in patients from December 2018 to June 2019.

- The applicant states that it assumes the Mecklenburg County patients on June 30, 2019 will continue to dialyze there and will increase at a rate equal to the 4.2% Mecklenburg County Five-Year Average Annual Change Rate (AACR) published in the July 2019 SDR.

- Services will be offered as of December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

In Section Q, page 63, the applicant provides its projected utilization methodology, based on its stated assumptions, as summarized in the following table.

Begin with facility census of Mecklenburg County patients as of June 30, 2019.	95
Project this population forward six months to December 31, 2019, using the Mecklenburg County Five-Year AACR of 4.2% (4.2% / 12 x 6 = 2.1%)	95x 1.021 = 97.0
Project Mecklenburg County patients forward one year to December 31, 2020, using the Mecklenburg County Five-Year AACR of 4.2%.	97.0 x 1.042 = 101.1
Project Mecklenburg County patients forward one year to December 31, 2021, using the Mecklenburg County Five-Year AACR of 4.2%.	101.1 x 1.042 = 105.3
Project Mecklenburg County patients forward one year to December 31, 2022, using the Mecklenburg County Five-Year AACR of 4.2%.	105.3 x 1.042 = 109.7
Project Mecklenburg County patients forward one year to December 31, 2023, using the Mecklenburg County Five-Year AACR of 4.2%.	105.3 [109.7]* x 1.042 = 114.3

Source: Table in Section Q

*The above table has a typographical error in the final calculation, but arrives at the correct total

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

- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five-Year AACR for Mecklenburg County as published in the January 2019 SDR to project growth of Mecklenburg County residents.
- While the Criteria and Standards for End Stage Renal Disease Services are not applicable to this review, 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 promulgated in 10A NCAC 14C .2203(b).

Access

In Section C, page 17, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

In Section L, page 44, the applicant projects the following payor mix during the second full year of operation following completion of the project, as summarized in the following table.

**BMA West Charlotte
CY2023**

Payment Source	# In-Center Patients	% In-Center Patients
Self-Pay	3.6	3.13%
Insurance*	3.8	3.34%
Medicare*	81.3	71.09%
Medicaid*	5.5	4.79%
Medicare/Commercial	17.3	15.12%
Misc. (including VA)	2.9	2.54%
Total	114.3	100.00%

*Including any managed care plans

The projected payor mix is reasonable and adequately supported based on the following:

- The applicant bases future payor mix on the historical payor mix for the facility.
- The percentages of patient population served at the facility are comparable to the percentages of the population in the service area.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

C

BMA proposes to relocate an existing 29-station dialysis facility, BMA West Charlotte, from 3057 Freedom Drive, in Charlotte to a new location less than one mile away.

In Section D, pages 21-22, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. The applicant states that the facility relocation of less than one mile from the current location will not create any adverse impact to the patients of the facility and will ensure continued access to care in a location which meets the needs of the patients. BMA states that the relocated facility will continue to provide the same complement of dialysis stations and services. BMA further states:

“To the extent that patients may realize some impact, it will be positive impacts. Their nephrology physician will be on the same campus. The vascular access center will be on the same campus. And eventually a home training program will be on the same campus. This relocation is entirely focused on the needs of the dialysis patients of the area.”

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 relocate an existing 29-station dialysis facility, BMA West Charlotte, from 3057 Freedom Drive, in Charlotte to a new location less than one mile away.

In Section E, page 23, the applicant states that there is no other alternative that would meet the need for the proposed project. However, it is obvious by the applicant's discussion that it did consider the alternative of renovating the existing facility.

The applicant states that the existing facility is reaching the end of its useful life as a dialysis facility and the extent of renovations necessary would require a temporary cessation of operations at the facility, displacing the patients served by the facility. Further complicating the situation, BMA states that it does not have capacity for the current or projected patient population of BMA West Charlotte in other nearby facilities, thus the displacement could involve travel time and distance for the patients. Therefore, the applicant determined this was not an effective alternative.

On page 23, the applicant states:

“After considering the effects of such a major renovation, coupled with the costs, BMA determined that it was more economical and more patient focused to relocate the facility to the new campus.”

The applicant adequately demonstrates that the alternative proposed in this application is the more effective alternative to meet the patients' needs for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the more effective alternative.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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. 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 Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate the 29-station facility from the existing location of BMA West Charlotte to the proposed new site for a total of no more than 29 stations at BMA West Charlotte upon completion of this project.
 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls of BMA West Charlotte for no more than 29 dialysis stations, which shall include any isolation or home hemodialysis stations.
 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 29 dialysis stations at the existing BMA West Charlotte 3057 Freedom Drive location.
 5. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to relocate an existing 29-station dialysis facility, BMA West Charlotte, from 3057 Freedom Drive, in Charlotte to a new location less than one mile away.

Capital and Working Capital Costs

In Section Q Form F.1a, page 65, the applicant projects \$2,410,552 in capital cost to develop the proposed project as summarized below:

Construction Contract	\$1,678,893
Architect/Engineering Fees	\$151,100
Non-medical Equipment	\$229,000
Furniture	\$176,971
Other (Generator)	\$83,088
Other (Contingency)	\$91,500
Total	\$2,410,522

The applicant provides assumptions for the projected capital cost in Section Q, page 66.

In Section F, pages 25-26, the applicant states there will be no start-up or initial operating expense associated with the proposed project because it is an existing facility which is already operational.

Availability of Funds

In Section F, page 24, the applicant states funding for the capital expense of the proposed project will be through corporate accumulated reserves.

Exhibit F-2 contains a letter dated November 15, 2019 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for BMA, authorizing the project and committing accumulated reserves of FMCH for the capital costs of the project. The letter further states:

“This project is to be funded through Fresenius Medical Care Holdings, Inc., accumulated reserves. Our 2018 Consolidated Balance Sheet reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.”

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q Form F.2, page 68, 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 West Charlotte
Projected Revenues and Operating Expenses**

	Operating Year 1 CY2022	Operating Year 2 CY2023
Total Treatments	15,913.7	16,582.1
Total Gross Revenues (Charges)	\$100,113,335	\$104,318,095
Total Net Revenue	\$4,128,543	\$4,301,941
Average Net Revenue per Treatment	\$259	\$259
Total Operating Expenses (Costs)	\$4,101,722	\$4,209,376
Average Operating Expense per Treatment	\$258	\$254
Net Income/Profit	\$26,821	\$92,565

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q 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, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - 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 relocate an existing 29-station dialysis facility, BMA West Charlotte, from 3057 Freedom Drive, in Charlotte to a new location less than one mile away. On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The existing and proposed locations are in Mecklenburg County; thus, the service area for this facility is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table B of the July 2019 SDR, there are 21 facilities which currently provide in-center dialysis in Mecklenburg County. South Charlotte Dialysis has been approved to be relocated to a new location and three other approved facilities are not yet operational, as summarized below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	FMC	Charlotte	32	95.31%
BMA Nations Ford	FMC	Charlotte	28	79.46%
BMA of East Charlotte	FMC	Charlotte	26	89.42%
BMA West Charlotte	FMC	Charlotte	29	87.93%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
FMC Charlotte	FMC	Charlotte	44	89.20%
FMC Matthews	FMC	Matthews	21	114.29%
FMC of North Charlotte	FMC	Charlotte	40	96.88%
FKC Mallard Creek*	FMC	Charlotte	0	0.00%
FKC Regal Oaks	FMC	Charlotte	12	93.75%
FKC Southeast Charlotte*	FMC	Pineville	0	0.00%
FMC Aldersgate	FMC	Charlotte	10	27.50%
FMC Southwest Charlotte	FMC	Charlotte	13	92.31%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
South Charlotte Dialysis**	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: January 2019 SDR, Table B.

* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

The table above shows that twelve of the operational and/or approved dialysis facilities in Mecklenburg County are FMC related facilities.

In Section G, page 31, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in Mecklenburg County. The applicant states that the stations to be relocated already exist, will be relocated less than one mile away, and there will be no increase or decrease in the number of dialysis stations or facilities in Mecklenburg County.

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

- The applicant adequately demonstrates that the proposed relocation of existing dialysis stations is needed to serve its existing and projected patients and therefore needed in addition to the existing or approved dialysis stations in Mecklenburg County.
- The proposal would not result in an increase in the number of dialysis stations in Mecklenburg County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

- (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 Q Form H, page 76, the applicant provides its current and projected staffing in full-time equivalent (FTE) positions, as shown in the table below.

**BMA West Charlotte
 Current and Projected FTE Positions**

Position	Current As of 9/30/19	OY 1 CY2022	OY 2 CY2023
Administrator	1.00	1.00	1.00
Registered Nurses	4.00	4.00	4.00
Patient Care Technicians	13.00	13.00	13.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Business Office	2.00	2.00	2.00
FMC Director Operations	0.15	0.15	0.15
In-Service	0.25	0.25	0.25
Chief Technician	0.15	0.15	0.15
Total FTE Positions	23.55	23.55	23.55

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, page 32, the applicant describes the methods

used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 33, the applicant identifies the current medical director as Dr. George Hart. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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, page 35, the applicant states that the following ancillary and support services are necessary for the proposed services and adequately explains how each ancillary and support service is or will be made available, as summarized below.

**BMA West Charlotte
 Ancillary and Support Services**

Services	Provider
Self-care training Home hemodialysis Peritoneal dialysis Accessible follow-up program	FMC Charlotte, FMC Southwest Charlotte, INS Charlotte, or INS Huntersville (patient choice)
Psychological counseling	CMC Mental Health or Randolph Behavioral Health
Isolation – hepatitis	Provided on site by applicant
Nutritional counseling	Provided on site by applicant
Social Work services	Provided on site by applicant
Acute dialysis in an acute care setting	Atrium Health-CMC
Emergency care	Provided on site by applicant until ambulance arrival
Blood bank services	Atrium Health-CMC
Diagnostic and evaluation services	Atrium Health-CMC
X-ray services	Atrium Health-CMC
Laboratory services	Provided on site by applicant
Pediatric nephrology	Atrium Health-CMC
Vascular surgery	Metrolina Vascular Access Center, Atrium Health-CMC, or Presbyterian Novant Hospital
Transplantation services	Atrium Health-CMC
Vocational rehabilitation & counseling	CMC Rehabilitation
Transportation	Charlotte Area Transportation, Medicaid Transport Services, or Local Cab Vendors

In Section I, page 35, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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.

C

In Section K, page 38, the applicant states that the project involves 7,891 square feet of new construction. Line drawings are provided in Exhibit K-1.

On page 38, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

On page 39, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 39-40, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 40-41, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. The applicant provides supporting documentation in Exhibit K-4.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (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, page 43, the applicant provides the historical payor mix for CY 2018 at BMA West Charlotte, as shown in the table below.

**BMA West Charlotte
 CY2018**

Payment Source	# In-Center Patients	% In-Center Patients
Self-Pay	3.19	3.13%
Insurance*	3.40	3.34%
Medicare*	72.51	71.09%
Medicaid*	4.88	4.79%
Medicare/Commercial	15.42	15.12%
Misc. (including VA)	2.59	2.54%
Total	102.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L, page 42, the applicant provides the following comparison.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area*
Female	40.0%	51.9%
Male	60.0%	48.1%
Unknown		
64 and Younger	72.6%	88.8%
65 and Older	27.4%	11.2%
American Indian	0.0%	0.8%
Asian	1.1%	6.4%
Black or African-American	92.6%	32.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	2.1%	46.4%
Other Race	4.2%	13.4%
Declined / Unavailable	0.0%	

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information 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.

- (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 handicapped persons, in Section L, page 43, the applicant states:

“BMA does not have any obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.”

In Section L, page 44, 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, and
- exhibits to the application.

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 44, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**BMA West Charlotte
CY2023**

Payment Source	# In-Center Patients	% In-Center Patients
Self-Pay	3.6	3.13%
Insurance*	3.8	3.34%
Medicare*	81.3	71.09%
Medicaid*	5.5	4.79%
Medicare/Commercial	17.3	15.12%
Misc. (including VA)	2.9	2.54%
Total	114.3	100.00%

*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 03.13% of total services will be provided to self-pay patients, 86.21% to patients having some or all their services paid for by Medicare, and 4.79% to Medicaid patients.

On page 44, 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 the existing BMA West Charlotte patients.

The Agency reviewed the:

- application, and
- exhibits to the application.

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 45, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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 46, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- application, and
- exhibits to the application.

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 relocate an existing 29-station dialysis facility, BMA West Charlotte, from 3057 Freedom Drive, in Charlotte to a new location less than one mile away.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The existing and proposed locations are in Mecklenburg County; thus, the service area for this facility is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table B of the July 2019 SDR, there are 21 facilities which currently provide in-center dialysis in Mecklenburg County. South Charlotte Dialysis has been approved to be relocated to a new location and three other approved facilities are not yet operational, as summarized below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
BMA Beatties Ford	FMC	Charlotte	32	95.31%
BMA Nations Ford	FMC	Charlotte	28	79.46%
BMA of East Charlotte	FMC	Charlotte	26	89.42%
BMA West Charlotte	FMC	Charlotte	29	87.93%
Brookshire Dialysis	DaVita	Charlotte	10	40.00%
Carolinas Medical Center	CMC	Charlotte	9	33.33%
Charlotte Dialysis	DaVita	Charlotte	34	81.62%
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%
FMC Charlotte	FMC	Charlotte	44	89.20%
FMC Matthews	FMC	Matthews	21	114.29%
FMC of North Charlotte	FMC	Charlotte	40	96.88%
FKC Mallard Creek*	FMC	Charlotte	0	0.00%
FKC Regal Oaks	FMC	Charlotte	12	93.75%
FKC Southeast Charlotte*	FMC	Pineville	0	0.00%
FMC Aldersgate	FMC	Charlotte	10	27.50%
FMC Southwest Charlotte	FMC	Charlotte	13	92.31%
Huntersville Dialysis	DaVita	Huntersville	14	92.86%
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%
Mountain Island Lake Dialysis*	DaVita	Charlotte	0	0.00%
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%
South Charlotte Dialysis**	DaVita	Charlotte	23	85.87%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis	DaVita	Charlotte	10	50.00%

Source: January 2019 SDR, Table B.

* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

The table above shows that twelve of the operational and/or approved dialysis facilities in Mecklenburg County are FMC related facilities.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 47, the applicant states that it does not expect the facility relocation to have any effect on the competitive climate in Mecklenburg County. The applicant does not project to serve dialysis patients currently being served by another provider. The applicant further states:

“There are currently 24 dialysis facilities within Mecklenburg County. With this application, BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at BMA West Charlotte.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 47, the applicant states:

“Fresenius related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.”

Regarding the impact of the proposal on quality, in Section N, page 48, the applicant states:

“Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 48, the applicant states:

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

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would be a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits).
- Quality (see Sections C, N and O of the application and any exhibits).
- Access to medically underserved groups (see Sections C, D, L and N of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 Q Form A, pages 56-60, the applicant provides a list of more than 120 facilities owned, operated or managed by a Fresenius-related entity located in North Carolina.

In Section O, page 53, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents at any Fresenius-related facility related to quality of care resulting in an immediate jeopardy violation. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius-related 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.

NA

The applicant proposes to relocate its existing facility to a new location within Mecklenburg County. The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are not applicable to this review because the applicant does not propose to establish a new end stage renal disease facility or to add stations to an existing facility.