

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 13, 2018

Findings Date: July 13, 2018

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: J-11470-18

Facility: Cary Kidney Center

FID #: 180166

County: Wake

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

Project: Relocate an existing dialysis facility, Cary Kidney Center, to a new location in Cary

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. d/b/a Cary Kidney Center [**BMA Cary**] proposes to relocate an existing dialysis facility from 5048 Old Raleigh Road in Cary to leased space in an existing building located at 400 Keisler Drive in Cary.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Wake County. Neither the county nor the facility need methodologies in the 2018 State Medical Facilities Plan (2018 SMFP) are applicable to this review. Additionally, Policy GEN-3: Basic Principles is not applicable because neither need methodology is applicable to the review.

Policies

There are two policies in the 2018 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27 and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 33.

“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 contiguous counties 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 Wake County, thus there will be no change to the dialysis inventory of Wake County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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 is greater than \$2 million, but less than \$5 million. In Section B.5, pages 10-11, Section K.1, page 40, and Exhibits B and K, the applicant describes how it will assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the projects plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

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 Cary proposes to relocate an existing dialysis facility from 5048 Old Raleigh Road in Cary to leased space in an existing building located at 400 Keisler Drive in Cary, which is 1.8 miles and six minutes driving time from the current site. According the January 2018 SDR, BMA was certified for 28 stations as of December 1, 2017. On May 24, 2016, the applicant was approved (Project I.D. J-11133-16) to relocate four dialysis stations from BMA Cary to a new facility in Morrisville, which would leave BMA Cary with 24 stations upon completion of that project. In Section C.1, page 12, the applicant states that it proposes to relocate BMA Cary as a 24-station dialysis facility.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 12, the applicant provides the projected patient origin for BMA Cary for in-center (IC), home hemodialysis (HHD) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2020			Operating Year 2 CY2021			Percent of Total	
	IC	HHD	PD	IC	HHD	PD	OY1	OY2
Wake	78.4	0	0	82.8	0	0	98.74%	98.81%
Durham	1.0	0	0	1.0	0	0	1.26%	1.19%
Total	79	0	0	83	0	0	100.0%	100.0%

The BMA Cary facility does not currently provide home hemodialysis (HHD) or peritoneal dialysis (PD) training or support, and the applicant is not proposing to add those services as part of the project. In Section C, pages 12-13, 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

In Section C, pages 12-14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On pages 12-14, the applicant describes the assumptions as follows:

- The applicant begins the projections for the future patient population of BMA Cary by using the ending in-center patient census of Wake County patients of 86 as of December 31, 2017.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Wake County which is 5.6% to project the Wake County patient population forward.
- The applicant does not project an increase in the facility’s patient population residing in Durham County.
- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)
Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

Projected Utilization

Cary Kidney Center
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In Section C, page 13, the applicant provides the methodology used to project in-center patient utilization, as shown in the following table.

Begin with Wake County patients dialyzing at BMA Cary as of December 31, 2017.	86
Project the Wake County patient population forward six months to June 30, 2018 using the Five-Year Average Annual Change Rate for Wake County of 5.6%	$86 \times 1.028 = 88.41$
Subtract 20 patients projected to transfer their care to FMC Morrisville upon completion of Project I.D. # J-11133-16.	$88.41 - 20 = 68.41$
Project the Wake County population forward six months to December 31, 2018 using the Five-Year Average Annual Change Rate for Wake County of 5.6%.	$68.41 \times 1.028 = 70.3$
Project the Wake County population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Wake County of 5.6%.	$70.3 \times 1.056 = 74.3$
Project the Wake County population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Wake County of 5.6%.	$74.3 \times 1.056 = 78.4$
OY1: Add one patient from Durham County. This is the projected ending census for OY 1.	$78.4 + 1 = 79.4$
Project the Wake County population forward one year to December 31, 2021 using the Five-Year Average Annual Change Rate for Wake County of 5.6%.	$78.4 \times 1.056 = 82.8$
OY2: Add one patient from Durham County. This is the projected ending census for OY 2.	$82.8 + 1 = 83.8$

Thus, the applicant projects that BMA Cary will serve a total of 79 in-center patients at the end of OY1 for a utilization rate of 82.3% or 3.3 patients per station per week (79 patients / 24 stations = 3.3 / 4 = 0.823 or 82.3%). The performance standard required by 10A NCAC 14C .2203(b) is not applicable to this review because the applicant is not proposing to establish a new facility or increase the number of dialysis stations in an existing facility.

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

- The applicant begins its utilization projection with the existing patients of BMA Cary,
- The applicant grows the Wake County patient population by the January 2018 SDR Wake County AACR and holds the patient population from Durham County constant, and
- The facility proposes to serve the same population as historically served by BMA Cary at the existing facility.

Access

In Section C.3, page 14, the applicant states the facility's services are available to all residents of the service area without regard to income, race, gender, handicap, age or ability to pay. In Section L.7, page 50, the applicant provides the historical (CY2017) payor mix for BMA Cary, as shown below.

Payment Source	Percent of Total Patients
Self Pay/Indigent/Charity	0.65%
Medicare	63.09%
Medicaid	11.30%
Commercial Insurance	10.34%
Medicare / Commercial	14.03%
Misc. (VA)	0.58%
Total	100.0%

As shown in the table above, BMA Cary reports that 88.4% of its patients were Medicare or Medicaid recipients in CY2017. In Section L.1, page 47, the applicant projects the same percentage of Medicare and Medicaid recipients for BMA Cary in the second operating year of the project. The projected payor mix is reasonable and adequately supported.

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 Cary proposes to relocate an existing dialysis facility from 5048 Old Raleigh Road in Cary to leased space in an existing building located at 400 Keisler Drive in Cary, which is 1.8 miles and six minutes driving time from the current site. Thus the facility will still be accessible to the same population presently served, including underserved groups.

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 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

In Section E.1, page 20, the applicant states it had no alternative to proposed relocation because lease is expiring and “*the space has out lived its useful life.*”

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The applicant states the facility lease at the current location is expiring.
- The applicant states renovation of the existing space and remaining in the current location is not viable to due to the negative impact it would cause to patient access to care.

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. d/b/a Cary Kidney Center 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. d/b/a Cary Kidney Center shall relocate 24 stations from existing location of Cary Kidney Center to the proposed new site for a total of no more than 24 stations at Cary Kidney Center upon project completion.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Cary Kidney Center shall install plumbing and electrical wiring through the walls for no more than 24 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Cary Kidney Center 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 Cary proposes to relocate an existing dialysis facility from 5048 Old Raleigh Road in Cary to leased space in an existing building located at 400 Keisler Drive in Cary.

Capital and Working Capital Costs

In Section F.1, page 22, the applicant projects \$2,565,870 in capital costs to develop the proposed project as summarized below:

Projected Capital Costs

Construction Costs	\$1,772,085
Miscellaneous Costs	\$793,785
Total	\$2,565,870

In Sections F.10 - F.12, page 25, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 23, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	BMA	Total
Loans	\$	\$
Accumulated reserves or OE *	\$2,565,870	\$2,565,870
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$2,565,870	\$2,565,870

* OE = Owner's Equity

Exhibit F-1 contains a letter dated March 15, 2018 from the Senior Vice President and Treasurer, authorizing and committing accumulated reserves of Fresenius Medical Care Holdings (FMCH), the parent company for BMA, for the capital costs of the project. Exhibit F-2 contains a copy of the Consolidated Financial Statements for FMCH for the year ending December 31, 2016. The report indicates that as of December 31, 2016, FMCH had \$356 million in cash and cash equivalents, \$20.1 billion in total assets and \$8.7 billion in net assets (total assets less total liabilities).

Financial Feasibility

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

	1st Full Fiscal Year CY2020	2nd Full Fiscal Year CY2021
Total Treatments	11,411	12,004
Total Gross Revenues (Charges)	\$45,507,068	\$47,871,952
Total Net Revenue	\$3,726,376	\$3,920,026
Average Net Revenue per Treatment	\$326.56	\$326.56
Total Operating Expenses (Costs)	\$3,587,309	\$3,708,100
Average Operating Expense per Treatment	\$314.37	\$308.91
Net Income	\$139,067	\$211,927

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 that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 Cary proposes to relocate an existing dialysis facility from 5048 Old Raleigh Road in Cary to leased space in an existing building located at 400 Keisler Drive in Cary. According the January 2018 SDR, BMA was certified for 28 stations as of December 1, 2017. On May 24, 2016, the applicant was approved (Project I.D. J-11133-16) to relocate four dialysis stations from BMA Cary to a new facility in Morrisville, which would leave BMA Cary with 24 stations upon completion of that project. In Section C.1, page 12, the applicant states that it proposes to relocate BMA Cary as a 24-station dialysis facility.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates twelve dialysis centers in Wake County. Also, BMA has been approved to develop three additional facilities in Wake County, FMC Morrisville, FMC Rock Quarry, and FMC White Oak, but the facilities were not yet operational on June 30, 2017. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on June 30, 2017. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	28	0	75.00%	3.0000
BMA of Raleigh Dialysis	50	0	88.00%	3.5200
Cary Kidney Center (BMA)	28	-4	83.93%	3.3571
FMC Apex (BMA)	20	0	76.25%	3.0500
FMC Central Raleigh (BMA)	19	0	78.95%	3.1579
FMC Eastern Wake (BMA)	17	0	69.12%	2.7647
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	16	0	60.94%	2.4375
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	0	12	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	30	0	93.33%	3.7333
Wake Dialysis Clinic (BMA)	50	4	98.00%	3.9200
Wake Forest Dialysis (DaVita)	22	-7	90.91%	3.6364
Zebulon Kidney Center (BMA)	28	0	88.39%	3.5357

Source: January 2018 SDR, Table B.

As shown in the table above, seven of the thirteen operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station), and eleven of the thirteen operational Wake County dialysis facilities were operating at or above 75% utilization (3.0 patients per station), as of June 30, 2017.

In Section G.1, page 30 of the application, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in Wake 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 proposal would not result in an increase in the number of dialysis stations in Wake County.

- The applicant adequately demonstrates that the proposed relocation of existing dialysis stations is needed in addition to the existing or approved dialysis stations in Durham County.

Conclusion

The Agency reviewed the:

- Applications
- Exhibits in 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.

- (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 31, the applicant provides current and projected staffing in full time equivalents (FTEs) for BMA Cary. The applicant does not project any changes in its FTE staff for BMA Cary associated with the proposed relocation. 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, Section R. In Section I, page 36, the applicant identifies the medical director for the facility. Exhibit I-6 of the application contains letter from the medical director expressing his intention to continue serving in that capacity for BMA Cary. In Section H.3, page 32, the applicant describes the methods used to recruit and fill vacant or new positions. 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.

CA

In Section I.1, page 35, the applicant provides a list of the necessary ancillary and support services, as shown below.

BMA Cary Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	BMA Cary
Self-care training (in-center)	BMA Raleigh
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	BMA Raleigh or FMC New Hope
Psychological counseling	Wake County Mental Health
Isolation – hepatitis	BMA Cary
Nutritional counseling	BMA Cary
Social Work services	BMA Cary
Acute dialysis in an acute care setting	WakeMed, UNC Rex Hospital
Emergency care	BMA Cary
Blood bank services	WakeMed, UNC Rex Hospital
Diagnostic and evaluation services	Wake Radiology
X-ray services	Wake Radiology
Laboratory services	Spectra Laboratory
Pediatric nephrology	UNC Hospitals
Vascular surgery	Raleigh Access Center, Rex Vascular
Transplantation services	Duke Hospital, UNC Hospital
Vocational rehabilitation & counseling	Wake County Vocational Rehabilitation
Transportation	Wake County Social Services

The applicant provides supporting documentation in Exhibit I. 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.

C

In Section K.2, page 42, the applicant states that the project involves upfitting 5,564 square feet of leased space. Line drawings are provided in Exhibit K-1. On page 40-41, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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.

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

C

In Section L.1, page 46, the applicant states the facility's services are available to all residents of the service area without regard to income, race, gender, handicap, age or ability to pay. In Section L.7, page 50, the applicant provides the historical (CY2017) payor mix for BMA Cary, as shown below.

Payment Source	Percent of Total Patients
Self Pay/Indigent/Charity	0.65%
Medicare	63.09%
Medicaid	11.30%
Commercial Insurance	10.34%
Medicare / Commercial	14.03%
Misc. (VA)	0.58%
Total	100.0%

As shown in the table above, BMA Cary reports that 88.4% of its patients were Medicare or Medicaid recipients in CY2017.

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
Wake	11%	51%	40%	11%	6%	10%
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) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

¹<http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-report-FINAL.pdf>

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.

- (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.3, page 49, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”

In Section L.6, page 49, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.1(b), page 47, the applicant provides the following table showing the projected payor mix during the second operating year of the project (CY2021).

Payment Source	Percent of Total Patients
Self Pay/Indigent/Charity	0.65%
Medicare	63.09%
Medicaid	11.30%
Commercial Insurance	10.34%
Medicare / Commercial	14.03%
Misc. (VA)	0.58%
Total	100.0%

As shown in the table above, during the second year of operation, the applicant projects that 0.65% of total services will be provided to self-pay, indigent and charity care patients, 77.12% to Medicare patients (includes Medicare and Medicare/Commercial) and 11.3% to Medicaid patients.

On page 47, 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 Cary.

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.

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In Section L.4, page 49, 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.

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In Section M.1, page 51, 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-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.

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BMA Cary proposes to relocate an existing dialysis facility from 5048 Old Raleigh Road in Cary to leased space in an existing building located at 400 Keisler Drive in Cary. According the

January 2018 SDR, BMA was certified for 28 stations as of December 1, 2017. On May 24, 2016, the applicant was approved (Project I.D. J-11133-16) to relocate four dialysis stations from BMA Cary to a new facility in Morrisville, which would leave BMA Cary with 24 stations upon completion of that project. In Section C.1, page 12, the applicant states that it proposes to relocate BMA Cary as a 24-station dialysis facility.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wake County. Facilities may serve residents of counties not included in their service area.

The applicant operates twelve dialysis centers in Wake County. Also, BMA has been approved to develop three additional facilities in Wake County, FMC Morrisville, FMC Rock Quarry, and FMC White Oak, but the facilities were not yet operational on June 30, 2017. Wake Forest Dialysis Center (DaVita) is the only other provider of dialysis services in Wake County, and currently operates just one dialysis center. DaVita has been approved to develop one additional facility in Wake County, Oak City Dialysis, but the facility was not yet operational on June 30, 2017. The existing and approved Wake County dialysis facilities are shown below:

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/17	CON Issued Not Certified	% Utilization	Patients Per Station
BMA of Fuquay-Varina	28	0	75.00%	3.0000
BMA of Raleigh Dialysis	50	0	88.00%	3.5200
Cary Kidney Center (BMA)	28	-4	83.93%	3.3571
FMC Apex (BMA)	20	0	76.25%	3.0500
FMC Central Raleigh (BMA)	19	0	78.95%	3.1579
FMC Eastern Wake (BMA)	17	0	69.12%	2.7647
FMC Millbrook (BMA)	17	0	76.47%	3.0588
FMC Morrisville (BMA)	0	10	NA	NA
FMC New Hope (BMA)	36	0	86.11%	3.4444
FMC Northern Wake (BMA)	16	0	60.94%	2.4375
FMC Rock Quarry (BMA)	0	10	NA	NA
FMC White Oak (BMA)	0	12	NA	NA
Oak City Dialysis (DaVita)	0	10	NA	NA
Southwest Wake (BMA)	30	0	93.33%	3.7333
Wake Dialysis Clinic (BMA)	50	4	98.00%	3.9200
Wake Forest Dialysis (DaVita)	22	-7	90.91%	3.6364
Zebulon Kidney Center (BMA)	28	0	88.39%	3.5357

Source: January 2018 SDR, Table B.

As shown in the table above, seven of the thirteen operational Wake County dialysis facilities were operating above 80% utilization (3.2 patients per station), and eleven of the thirteen operational Wake County dialysis facilities were operating at or above 75% utilization (3.0 patients per station), as of June 30, 2017.

In Section N.1, page 52, 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 52, the applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Wake County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA Cary facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Wake County five year average annual change rate of 5.60 % as published within the January 2018 SDR.”

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.

In Section O.3, page 57, the applicant states Fresenius owns more than 100 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 57, 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.

NA

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 nor does that applicant propose to add stations to an existing facility.