ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: January 27, 2017
Findings Date: January 27, 2017

Project Analyst: Julie Halatek
Team Leader: Lisa Pittman

Project ID #: E-11235-16
Facility: BMA of Burke County
FID #: 955785
County: Burke
Applicant(s): Bio-Medical Applications of North Carolina, Inc.
Project: Add 3 dialysis stations for a total of 36 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA of Burke County (BMA-BC) proposes to add three dialysis stations for a total of 36 certified dialysis stations upon project completion.

The application references two applications which were still in progress at the time the current application was submitted. Those projects, Project I.D. #E-11009-15 (relocate the existing facility and add 6 stations) and E-11094-15 (add 2 stations) were completed and certified in October 2016.

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of four dialysis stations in Burke County; thus, the applicant cannot apply to add any additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for BMA-BC in the July 2016 SDR is 3.96 patients per station per week, or 99.0 percent (3.96 / 4 patients per station = 0.99 or 99.0%). This utilization rate was calculated based on 99 in-center dialysis patients and 25 certified dialysis stations (99 patients / 25 stations = 3.96 patients per station per week).

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

October 1 Review – July 2016 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		86.5%
Certified Stations		25
Pending Stations		8
Total Existing and Pending Stations		**33**
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		99
In-Center Patients as of 6/30/15 (January 2016 SDR) (SDR1)		92
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.1522
(ii)	Divide the result of Step (i) by 12	0.0127
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.1522
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	114.0652
(v)	Divide the result of Step (iv) by 3.2 patients per station	35.6454
	and subtract the number of certified and pending stations to determine the number of stations needed*	**3**

*Note: According to Step Two of the facility need methodology in the July 2016 SDR, "*Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)*(v). *In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number."*

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three. Step (C) of the facility need methodology states, *"The facility may apply to expand to meet the need established …, up to a maximum of ten stations."* The applicant proposes to add three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles on page 39 of the 2016 SMFP. Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 12, 14-15, Section O, pages 60-65, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, pages 13-15, Section C, page 22, Section I, pages 43-45, Section L, pages 53-57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B, pages 13-15, Section N, page 59, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

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

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to add three dialysis stations for a total of 36 certified dialysis stations upon project completion.

BMA-BC currently has a home peritoneal dialysis training and support program, and projects continued growth in this program. BMA-BC was approved to add a home hemodialysis training and support program as part of Project I.D. #E-11009-15 and projects growth in this program as part of this project.

Patient Origin

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

In Section C.8, page 25, the applicant provides a table showing the historical patient origin for in-center (IC) and home peritoneal (PD) dialysis patients served by BMA-BC, as shown below:

BMA-BC Patients by County – 6/30/2016		
County	**# of IC Patients**	**# of PD Patients**
Burke	98	5
Caldwell	3	1
McDowell	2	0
Total	**103**	**6**

In Section C.1, page 18, the applicant provides the projected patient origin for BMA-BC for in-center (IC), home peritoneal dialysis (PD), and home hemodialysis (HH) patients for the first two operating years (OY) following completion of the project, as shown below.

BMA-BC Patients by County – Operating Years 1 & 2								
County	**Operating Year 1 CY 2018**			**Operating Year 2 CY 2019**			**County Patients as % of Total**	
	IC	**HH**	**PD**	**IC**	**HH**	**PD**	**OY 1**	**OY 2**
Burke	118.3	4.2	6.3	127.0	6.6	6.8	95.5%	95.9%
Caldwell	3.0	0.0	1.0	3.0	0.0	1.0	3.0%	2.7%
McDowell	2.0	0.0	0.0	2.0	0.0	0.0	1.5%	1.4%
Total	**123.3**	**4.2**	**7.3**	**132.0**	**6.6**	**7.8**	**100.0%**	**100.0%**

The applicant provides the assumptions and methodology for the projections above on pages 18-21. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C.2, pages 21-22, the applicant states the need for the proposed project is based on the continued growth of the patient population at BMA-BC. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section B.2, pages 9-10.

Projected Utilization

In Section C.1, page 18, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

BMA-BC Patients by County – Operating Years 1 & 2								
County	**Operating Year 1 CY 2018**			**Operating Year 2 CY 2019**			**County Patients as % of Total**	
	IC	**HH**	**PD**	**IC**	**HH**	**PD**	**OY 1**	**OY 2**
Burke	118.3	4.2	6.3	127.0	6.6	6.8	95.5%	95.9%
Caldwell	3.0	0.0	1.0	3.0	0.0	1.0	3.0%	2.7%
McDowell	2.0	0.0	0.0	2.0	0.0	0.0	1.5%	1.4%
Total	**123.3**	**4.2**	**7.3**	**132.0**	**6.6**	**7.8**	**100.0%**	**100.0%**

In Section C.1, pages 18-21, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below:

- The Burke County patient population will grow at a rate of 9.3 percent (the Five Year AACR for Burke County as published in the July 2016 SDR) through the end of the second year of operation.

- The applicant assumes no increase for the patients who utilize the facility and live outside of Burke County, but assumes that those patients will continue to dialyze at BMA-BC and are added to the calculations when appropriate.

- The applicant assumed, as part of Project I.D. #E-11009-15, that two in-center patients will change modality to home hemodialysis in each of the first two operating years following that project's completion (CY 2017 and CY 2018). The applicant assumes that same projection will continue through the first two operating years following completion of this project.

- The project is scheduled for completion on January 1, 2018. OY1 is CY 2018. OY2 is CY 2019.

In Section C.1, page 20, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

BMA-BC	In-Center Dialysis
Starting point of calculations is Burke County patients dialyzing at BMA-BC on June 30, 2016.	98
Burke County patient population is projected forward by six months to December 31, 2016. Projection is based on one-half of the AACR for Burke County (9.3%).	[98 X (0.093 / 12 X 6)] + 98 = 102.6
Burke County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (9.3%).	(102.6 X 0.093) + 102.6 = 112.1
As part of Project I.D. #E-11009-15, two Burke County patients were projected to switch from in-center to home hemodialysis after completion of the project. The two in-center patients are subtracted.	112.1 – 2 = 110.1
The five patients from other counties are added. This is the projected census on December 31, 2017 and the starting census for this project.	110.1 + 5 = 115.1
Burke County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (9.3%).	(110.1 X 0.093) + 110.1 = 120.3
Two in-center Burke County patients are projected to switch to home hemodialysis and are subtracted from the Burke County projections.	120.3 – 2 = 118.3
The five patients from other counties are added. This is the projected census on December 31, 2018 (OY1).	118.3 + 5 = 123.3
Burke County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (9.3%).	(118.3 X 0.093) + 118.3 = 129.3
Two in-center Burke County patients are projected to switch to home hemodialysis and are subtracted from the Burke County projections.	129.3 – 2 = 127.3
The five patients from other counties are added. This is the projected census on December 31, 2019 (OY2).	127.3 + 5 = 132.3

The applicant projects to serve 123 in-center patients on 36 stations, which is 3.42 patients per station per week (123 patients / 36 stations = 3.42), by the end of OY1 and 132 in-center patients on 36 stations, which is 3.67 patients per station per week (132 patients / 36 stations = 3.67), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C.2203(b). The July 2016 SDR indicates that BMA-BC's utilization rate was 99 percent (3.96 patients per station per week) as of December 31, 2015. In this application, the applicant projects the Burke County in-center patient census will increase annually by 9.3 percent, which is the Burke County AACR published in the July 2016 SDR.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need to add three dialysis stations to its existing facility for a total of 36 dialysis stations upon project completion and the completion of associated projects.

Home Hemodialysis and Peritoneal Dialysis

In Section C.1, page 18, the applicant states that it expects its Burke County home peritoneal dialysis patient census will continue to increase annually at a rate of 9.3 percent,

which is the Burke County AACR published in the July 2016 SDR, and that patients from other counties will continue to be added to the utilization calculations, though no growth will be projected for patients residing outside of Burke County. On page 21, the applicant provides the calculations used to arrive at the projected home peritoneal dialysis patient census for OY1 and OY2 as summarized in the table below.

BMA-BC	Home PD Dialysis
Starting point of calculations is Burke County home PD patients dialyzing at BMA-BC on June 30, 2016.	5
Burke County patient population is projected forward by six months to December 31, 2016. Projection is based on one-half of the AACR for Burke County (9.3%).	[5 X (0.093 / 12 X 6)] + 5 = 5.2
Burke County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (9.3%).	(5.2 X 0.093) + 5.2 = 5.7
The one patient from Caldwell County is added. This is the projected census on December 31, 2017 and the starting census for this project.	5.7 + 1 = 6.7
Burke County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (9.3%).	(5.7 X 0.093) + 5.7 = 6.3
The one patient from Caldwell County is added. This is the projected census on December 31, 2018 (OY1).	6.3 + 1 = 7.3
Burke County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (9.3%).	(6.3 X 0.093) + 6.3 = 6.8
The one patient from Caldwell County is added. This is the projected census on December 31, 2019 (OY2).	6.8 + 1 = 7.8

In Section C.1, page 18, the applicant states that as part of Project I.D. #E-11009-15, it was approved to add a home hemodialysis training and support program. As part of that project, BMA projected that two in-center Burke County patients would change modality to home hemodialysis in each of the first two operating years of that project (CY 2017 and CY 2018). BMA states it will continue to project that two in-center Burke County patients will change modality to home hemodialysis every year, and projects its Burke County home hemodialysis patient census will continue to increase annually at a rate of 9.3 percent, which is the Burke County AACR published in the July 2016 SDR. On page 21, the applicant provides the calculations used to arrive at the projected home hemodialysis patient census for OY1 and OY2 as summarized in the table below.

BMA-BC	Home Hemodialysis
As part of Project I.D. #E-11009-15, two patients are projected to change from in-center to home hemodialysis in CY 2017.	2
Burke County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (9.3%).	(2 X 0.093) + 2 = 2.2
The two patients projected to change modality are added. This is the projected census on December 31, 2018 (OY1).	2.2 + 2 = 4.2
Burke County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (9.3%).	(4.2 X 0.093) + 4.2 = 4.6
The two patients projected to change modality are added. This is the projected census on December 31, 2019 (OY2).	4.6 + 2 = 6.6

Access

In Section L.1, pages 53-54, the applicant states that each of BMA's 105 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The table below, found in Section L.7, page 57, shows the CY 2015 payment sources of the facility, and shows that 84.08 percent of the patients had some or all of their services paid for by Medicare or Medicaid.

BMA-BC Historical Payor Mix – CY 2015	
Payment Source	**% Total Patients**
Self-Pay/Indigent/Charity	3.43%
Medicare	72.81%
Medicaid	2.71%
Commercial Insurance	5.66%
Medicare/Commercial	8.56%
Misc. (including VA)	6.83%
Total	**100.00%**

In Section L.1, page 54, the applicant projects 83.4 percent of its patients will have some or all of their services paid for by Medicare or Medicaid in CY 2019. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed, and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently

served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.1, page 29, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicant states that because it has projected utilization of greater than 80 percent at the facility at the end of the first operating year following expansion, the option of maintaining the status quo would result in higher utilization rates and potentially restrict patient admissions at BMA-BC.

- Apply for Fewer Stations – the applicant states, as it did in response to the previous alternative considered, that projected utilization of greater than 80 percent at the end of the first operating year following the expansion means that developing fewer stations would result in higher utilization rates at BMA-BC.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Burke County shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Burke County shall develop and operate no more than 3 additional dialysis stations for a total of**

no more than 36 certified dialysis stations upon project completion which shall include any home hemodialysis training or isolation stations.

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Burke County shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Burke County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add three dialysis stations for a total of 36 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, pages 30-31, the applicant projects the capital cost for the proposed project will be $9,000, used for equipment and furniture. The dialysis machines will be leased. In Section F.13, pages 34-35, the applicant states that there are no working capital needs for the proposed project since BMA-BC is an existing facility.

Availability of Funds

Exhibit F-2 contains a copy of Fresenius Medical Care Holdings, Inc. and Subsidiaries (FMC) Consolidated Financial Statements for December 31, 2015. As of December 31, 2015, FMC had $249,300,000 in cash and cash equivalents, $19,332,539,000 in total assets and $10,144,288,000 in net assets (total assets less total liabilities). (See Exhibit F-2, page 3.) The applicant adequately demonstrates that sufficient funds will be available, should the need arise, for the capital needs of the project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
BMA-BC	**Operating Year 1 CY 2018**	**Operating Year 2 CY 2019**
Total Treatments	17,636	18,821
Total Gross Revenues (Charges)	$75,930,331	$77,114,767
Total Net Revenue	$6,991,719	$7,117,207
Total Operating Expenses (Costs)	$5,479,434	$5,651,592
Net Income/Profit	**$1,512,285**	**$1,465,615**

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See the financial section 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. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the project is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

BMA proposes to add three dialysis stations for a total of 36 certified dialysis stations upon project completion.

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

BMA-BC is the only dialysis center in Burke County. There are no other providers of dialysis services in Burke County. According to the July 2016 SDR, the applicant was serving 99 patients on 25 existing certified stations. Based on that data, the applicant demonstrates that as of December 31, 2015, the facility was operating at 99 percent of capacity or 3.96 patients per station per week (99 patients / 25 stations = 3.96 / 4 = .99 or 99%). Over a three year period, the applicant projects an increase of 24 in-center patients

from 99 in-center patients as of December 31, 2015 to 123 in-center patients as of December 31, 2018, the end of Operating Year One.

In Section C.1, pages 18-20, the applicant demonstrates that BMA-BC will serve a total of 123 in-center patients at the end of Operating Year One (CY 2018) for a utilization rate of 85.5 percent or 3.42 patients per station per week (123 patients / 36 stations = 3.42 / 4 = .855 or 85.5%). The projected utilization of 3.42 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C.2203(b).

The applicant adequately demonstrates the need to add three additional stations to BMA-BC based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Burke County. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H.1, page 40, the applicant provides the following table to illustrate the projected staffing for BMA-BC at the end of OY2.

BMA-BC – Proposed Facility Staffing	
Position	**Projected # of FTEs**
Medical Director*	
RN	5.75
Patient Care Technician	12.75
Clinical Manager	1.00
Director of Operations	0.20
Dietitian	1.00
Social Worker	1.00
Home Training Nurse	1.00
Chief Technician	0.20
Equipment Technician	1.35
In-Service	0.25
Clerical**	1.50
Total	**26.00**

*The Medical Director is a contract position and is not an employee of the facility.
**Includes Medical Records position.

The applicant states that the Medical Director is not directly employed by the facility but provides services on a contractual basis. In Section I.3, page 44, the applicant identifies Dr. Michele Higerd as the current Medical Director for the facility. Exhibit I-5 contains a copy of a letter from Dr. Higerd supporting the proposed project.

In Section H.3, pages 40-41, the applicant describes its experience and process for recruiting and retaining staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel, including the Medical Director, to provide the proposed dialysis services. Therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 43, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing support for the proposed project. The applicant discusses coordination with the existing health care system on pages 44-45. Exhibits I-2 through I-4, respectively, contain copies of agreements for lab services, acute services, and transplantation. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

(a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from

these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, pages 56-57, the applicant reports that 84.08 percent of the patients who received treatments at BMA-BC had some or all of their services paid for by Medicare or Medicaid in CY 2015. The historical payor mix for patients dialyzing at BMA-BC is shown in the table below.

BMA-BC Historical Payor Mix – CY 2015	
Payment Source	**% Total Patients**
Self-Pay/Indigent/Charity	3.43%
Medicare	72.81%
Medicaid	2.71%
Commercial Insurance	5.66%
Medicare/Commercial	8.56%
Misc. (including VA)	6.83%
Total	**100.00%**

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

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Burke	18%	50%	18%	21%	15%	20%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."*

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

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

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

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

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

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

C

In Section L.3(d), page 55, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section L.6, page 56, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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(a), page 53, the applicant states: *"It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."*

In Section L.1(b), page 54, the applicant projects that 83.4 percent of all patients in CY 2019 who will receive dialysis treatments at BMA-BC will have all or part of their services paid for by Medicare and/or Medicaid, as indicated in the table below:

BMA-BC Projected Payor Mix – CY 2019

Payment Source	% Total Patients
Self-Pay/Indigent/Charity	3.4%
Medicare	71.0%
Medicaid	4.1%
Commercial Insurance	6.2%
Medicare/Commercial	8.3%
Misc. (including VA)	6.9%
Total	**100.0%**

The projected payor mix is similar to the historical payor mix. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.4, page 56, the applicant states:

> *"Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA of Burke County has an open policy, which means that any Nephrologist may apply to admit patients to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.*
>
> *…. Transient patients are accepted upon proper coordination of care with the patient's regular nephrologist and a physician with staff privileges at the facility."*

The applicant adequately demonstrates that BMA-BC will provide a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

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

C

In Section M.2, page 58, the applicant states that BMA-BC welcomes all health-related education and training programs to visit, receive instruction at, and observe operation of the facility. Exhibit M-1 contains a letter from BMA to Western Piedmont Community College offering the BMA-BC facility to be included in the school's list of facilities for clinical rotation of its nursing students. The information provided in Section M is reasonable and credible and supports a finding of conformity to this criterion.

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

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

C

BMA proposes to add three dialysis stations for a total of 36 certified dialysis stations upon project completion.

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

BMA-BC is the only dialysis center in Burke County. There are no other providers of dialysis services in Burke County. According to the July 2016 SDR, the applicant was serving 99 patients on 25 existing certified stations. Based on that data, the applicant

demonstrates that as of December 31, 2015, the facility was operating at 99 percent of capacity or 3.96 patients per station per week (99 patients / 25 stations = 3.96 / 4 = .99 or 99%). Over a three year period, the applicant projects an increase of 24 in-center patients from 99 in-center patients as of December 31, 2015 to 123 in-center patients as of December 31, 2018, the end of Operating Year One.

In Section N, page 59, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

> *"BMA does not expect this proposal to have effect on the competitive climate in Burke County. At the present time, BMA is the only provider of dialysis services in Burke County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA of Burke County facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Burke County five year average annual change rate of 7.8%* [sic] *as published within the July 2016 SDR."*

See also Sections B, C, E, F, G, H, and L where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality, and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates that BMA-BC will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- The applicant demonstrates that BMA-BC will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3), and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

In Section B, pages 12, 14-15, Section O, pages 60-65, and Exhibits O-1 and O-2, the applicant discusses the methods it uses to ensure and maintain quality. In Section O.3, pages 62-65, the applicant lists three facilities that were cited for deficiencies that resulted in a finding of Immediate Jeopardy during the 18-month look-back period: BMA Lumberton, BMA East Charlotte, and RAI West College-Warsaw. See the table below and Exhibits O-2 through O-5.

BMA Quality Care		
Facility	**Survey Date**	**Back in Compliance**
BMA Lumberton	5/6/2015	Yes
BMA East Charlotte	8/11/2015	Yes
RAI West College-Warsaw	3/15/2016	Yes

Based on a review of the certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C.2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- BMA-BC is an existing facility.

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

-C- In Section C.1, pages 18-20, the applicant documents the need for the project and demonstrates that it will serve a total of 123 in-center patients on 36 stations at the end of the first operating year, which is 3.42 patients per station per week or a utilization rate of 85.5 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C.1, pages 18-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.