

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 20, 2015  
Findings Date: July 20, 2015

Project Analyst: Bernetta Thorne-Williams  
Team Leader: Fatimah Wilson

Project ID #: J-11025-15  
Facility: BMA of Fuquay-Varina Kidney Center  
FID #: 980755  
County: Wake  
Applicants: Bio-Medical Applications of North Carolina, Inc.

Project: Cost Overrun for Project I.D. # J-10339-14 to add four stations and offer home training and support services

### 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.

NA

The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Fuquay-Varina Kidney Center (BMA Fuquay-Varina), propose a cost overrun for Project I.D. # J-10339-14, to add four dialysis stations and establish home training and support services to the existing facility in Wake County for a total of 23 stations upon project completion. Effective February 14, 2015, the applicant was issued a certificate of need (CON) for Project I.D. # J-10339-14. The approved capital cost was \$11,800. The applicant proposes that the proposed cost overrun application will not affect the proposed completion date of the project which will remain December 31, 2015.

### **Need Determination**

The applicant does not propose to increase the number of licensed beds in any category, add any new health services or acquire equipment for which there is a need determination in the 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2015 SMFP that are applicable to this review.

### **Policies**

Policy GEN-3: BASIC PRINCIPLES, page 38, of the 2015 is not applicable to this review. In Project I.D. # J-10339-14, the application was consistent with Policy GEN-3. The applicant proposes no changes in the current application that would affect that determination.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES was not applicable in Project I.D. # J-10339-14 because the capital expenditure was not greater than \$2 million. The proposed cost overrun application also does not have a capital expenditure greater than \$2 million, therefore, this policy is not applicable to this review.

In addition, there are no other policies in the 2015 SMFP that are applicable to this review.

### **Conclusion**

In summary, the applicant was previously approved to add four dialysis stations for a total of 23 dialysis stations at BMA Fuquay-Varina and to establish home training and support services. In Project I.D. # J-10339-14, the applicant was conforming to this Criterion. The applicant proposes no changes in the current application that would affect that determination. Therefore, this criterion is not applicable to this review.

- (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

Effective February 14, 2015, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Fuquay-Varina Kidney Center (BMA Fuquay-Varina) was issued a Certificate of Need (CON) for Project I.D. # J-10339-14, to add four dialysis stations and establish home training and support services to the existing facility in Wake County for a total of 23 stations upon project completion. The original project was approved for a capital cost of \$11,800. The additional stations were expected to be certified by December 31, 2015. The current CON application is for a cost overrun. The total capital cost is now expected to be \$702,023, an

increase of \$690,223 [ $\$702,023 - \$11,800 = \$690,223$ ] or 58% [ $\$690,223 / \$11,800 = 58\%$ ] of the approved capital cost. See Section VI.2, page 13.

The following table compares the previously approved capital cost and the proposed capital cost in this application.

<b>BMA Fuquay-Varina PREVIOUSLY APPROVED AND PROPOSED CAPITAL COSTS</b>			
	Previously Approved Cost	Proposed Cost	Total Difference
<b>Construction Costs</b>	<b>\$0</b>	<b>\$520,443</b>	<b>\$520,443</b>
<b>Miscellaneous Costs</b>			
(RO) Water Treatment Equipment	\$1,000	\$2,936	\$1,936
Equipment/Furniture	\$10,800	\$75,076	\$64,276
Architect/Engineering Fees	\$0	\$46,840	\$46,840
<b>Subtotal Capital Costs</b>	<b>\$11,800</b>	<b>\$645,295</b>	<b>\$633,495</b>
Contingency	\$0	\$56,728	\$56,728
<b>Total Capital Costs</b>	<b>\$11,800</b>	<b>\$702,023</b>	<b>\$690,223</b>

The applicant seeks approval for an increased capital cost to convert examination/treatment rooms to home hemodialysis training rooms. The original project scope will not change nor will the population to be served; including access by underserved groups.

In Section II.1, page 5, the applicant states:

*“Project ID # J-10339-14 was an application to add four dialysis stations and home therapies training and support at the BMA Fuquay-Varina dialysis facility in Wake County, NC. At the time of the application, BMA failed to include costs for the development of the home training area. This was an oversight.”*

In Section II.5, page 6, the applicant states:

*“There is no suitable alternative, but to proceed with this project. Failure to approve this Cost Overrun CON application ultimately would force Bio-Medical Applications of North Carolina, Inc. to abandon plans for the addition of home dialysis training and support at the BMA Fuquay-Varina facility.*

*BMA notes that Fuquay-Varina is on the southern end of Wake County. The dialysis facility is approximately 25 miles by road from the BMA Raleigh Dialysis facility where BMA offers home therapies training and support. ...”*

In the original application, the applicant adequately demonstrated need for the home training services; however, the applicant underestimated the capital cost necessary to complete the

project. The applicant adequately demonstrates the need for the proposed cost overrun. Consequently, the cost overrun 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

The applicant discusses the reasons for the cost overrun in Section II.1. In Section II.5, page 6, the applicant states, "*There is no suitable alternative, but to proceed with this project.*"

The applicant adequately demonstrates that the proposed alternative is the most effective and least costly alternative to meet the *previously* identified need for additional stations and to offer home hemodialysis training and support services.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the cost overrun 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 Fuquay-Varina Kidney Center shall comply with all conditions of approval on the certificate of need for Project I.D. # J-10339-14 except as specifically modified by the conditions of approval for this application, Project I.D. # J-11025-15.**
- 2. The total combined capital expenditure for Project I.D. # J-10339-14 and Project I.D. # J-11025-15 shall be \$702,023.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Fuquay-Varina shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VI of the application and that would otherwise require a certificate of need.**

**4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Fuquay-Varina Kidney Center 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

The proposed project is for a cost overrun for Project I.D. # J-10339-14. The total capital cost is now expected to be \$702,023, an increase of \$690,223 [ $\$702,023 - \$11,800 = \$690,223$ ] or 58% [ $\$690,223 / \$11,800 = 58\%$ ] of the approved capital cost. See Section VI.12, page 13.

In Section VI.5, page 15, the applicant states the total capital cost of the project will be funded with accumulated reserves. In Exhibit 8, the applicant provides an April 15, 2015 letter signed by the Senior Vice President & Treasurer, Fresenius Medical Care Holdings, Inc. [FMC], which states in part:

*“BMA is submitting a Cost Overrun Certificate of Need Application for CON Project ID # J-10339-14, the addition of [sic] add four dialysis stations at BMA of Fuquay-Varina dialysis facility in Wake County. As a part of the project, BMA proposed to develop existing space within the facility for the provision of home dialysis training and support. Unfortunately, the cost for development of the home training program was overlooked in the prior application. The project calls for an additional capital expenditure of \$690,223 for the home program. The total capital costs for the program will be \$702,023.*

*As Senior Vice President & Treasurer, I am authorized and do hereby authorize the addition of four dialysis stations, and the home dialysis program for capital costs of \$702,023. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$702,023 as may be needed for this project.”*

In Exhibit 6, the applicant provides the audited financial statement for [FMC] and Subsidiaries for the years ending December 31, 2012 and December 31, 2013. As of December 31, 2013, FMC and Subsidiaries had cash and cash equivalents totaling \$276 million with \$16.6 billion in total assets and \$8.5 billion in net assets (total assets less total liabilities).

In Section VIII.4, page 19, the applicant reproduces a copy of Table X.2, from the original application (Project I.D. # J-10339-14). In Project I.D. # J-10339-14, the applicant projected that revenues would exceed expenses in the first two years of operation after completion of the project. That application was determined to be conforming to this criterion with regard to the

financial feasibility of the proposed addition of four dialysis stations and home training and support services. The applicant does not propose any changes that would affect that determination.

In summary, the applicant adequately demonstrates the availability of funds for the increased capital needs of the project. Therefore, the cost overrun 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

In Project I.D. # J-10339-14, the applicant was approved to add four dialysis stations to the existing BMA of Fuquay-Varina facility and to establish home training and support services.

In Project I.D. # J-10339-14, the application was conforming to this criterion and no changes are proposed in this application that affect that determination. Consequently, the cost overrun 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 Project I.D. # J-10339-14, the applicant proposed an increase of 2.00 full-time equivalent (FTE) positions for a total of 17.2 upon project completion. The applicant does not propose any additional staff in this application. In Project I.D. # J-10339-14, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project I.D. # J-10339-14, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project I.D. # J-10339-14, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project I.D. # J-10339-14, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project I.D. # J-10339-14, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project I.D. # J-10339-14, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project I.D. # J-10339-14, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to this criterion.

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

C

Project I.D. # J-10339-14, was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The 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

Project I.D. # J-10339-14 was conforming to the Criteria and Standards for End-Stage Renal Disease Services promulgated in 10A NCAC 14C .2200, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to this criterion.