

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 13, 2015

Findings Date: August 13, 2015

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: F-11041-15

Facility: BMA of North Charlotte

FID #: 955788

County: Mecklenburg

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

Project: Cost overrun for Project ID #F-10333-14 (add four dialysis stations)

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

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte was issued a certificate of need (CON) for Project I.D. #F-10333-14 on January 10, 2015 to add four dialysis stations upon completion of the project and two other projects, Project I.D. #F-10249-14 (add two dialysis stations) and Project I.D. #F-10091-13 (add three dialysis stations) for a total of 36 stations. The current CON application is for a “cost overrun” of the initial approval of Project I.D. #F-10333-14 but also involves Project I.D. #F-10249-14 and Project I.D. #F-10091-13 since it involves the proposed renovation of the BMA of North Charlotte dialysis facility. There is no material change in scope from the originally approved project, or the other two associated projects, in this application.

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

Consequently, this Criterion is not applicable.

- (2) Repealed effective July 1, 1987.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

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte was issued a certificate of need (CON) for Project I.D. #F-10333-14 on January 10, 2015 to add four dialysis stations upon completion of the project and two other projects, Project I.D. #F-10249-14 (add two dialysis stations) and Project I.D. #F-10091-13 (add three dialysis stations) for a total of 36 stations. The original project was approved for a capital cost of \$235,400. Project I.D. #F-10249-14 (add two dialysis stations) was approved for \$112,250 and Project I.D. #F-10091-13 was approved for \$269,229. The applicant states, in Section VI, page 13, "*BMA has been approved to combine the capital costs approved for CON Project ID #s F-10091-13, F-10249-14 and F-10333-14 for a total capital cost of \$616,879.*" Therefore, the current CON application is for a "cost overrun" of \$198,311 of the initial approval of all three projects combined for a total capital cost of \$815,190 ($\$616,879 + \$198,311 = \$815,190$), an increase of 32.2%. The applicant states, in Section I, page 2, that construction estimates for the expansion/renovation of space at BMA of North Charlotte were higher than initially projected. There is no material change in scope from the originally approved project, or the two other associated projects in this application.

The following table is from Section VI.1, pages 14-15, and lists the originally approved capital costs for each of the associated projects, the proposed costs, and the differences that are associated with this cost overrun application.

**BMA of North Charlotte
 Project Capital Costs**

| CATEGORY | PREVIOUSLY APPROVED PROJECT ID #F-10333-14 | PREVIOUSLY APPROVED PROJECT ID #F-10249-14 | PREVIOUSLY APPROVED PROJECT ID #F-10091-13 | ALL THREE PROJECTS | PROPOSED IN CURRENT APPLICATION | DIFFERENCE |
|------------------------------|--|--|--|--------------------|---------------------------------|------------------|
| A. Construction Contract | \$25,000 | \$98,550 | \$195,360 | \$318,910 | \$465,391 | \$146,481 |
| B. Miscellaneous | | | | | | |
| Dialysis Machines | Leased | Leased | Leased | Leased | Leased | Leased |
| Water Treatment Equipment | \$192,000 | \$8,500 | \$0 | \$200,500 | \$215,000 | \$14,500 |
| Equipment/Furniture | \$18,400 | \$5,200 | \$36,750 | \$60,350 | \$67,550 | \$7,200 |
| Architect/Engineering Fees | \$0 | \$0 | \$17,583 | \$17,583 | \$41,885 | \$24,302 |
| Subtotal miscellaneous costs | \$210,400 | \$13,700 | \$54,333 | \$278,433 | \$324,435 | \$46,002 |
| Subtotal Capital Costs | \$235,400 | \$112,250 | \$249,693 | \$597,343 | \$789,826 | \$192,483 |
| Contingency | \$0 | \$0 | \$19,536 | \$19,536 | \$25,364 | \$5,828 |
| C. Total Capital Cost | \$235,400 | \$112,250 | \$269,229 | \$616,879 | \$815,190 | \$198,311 |

As shown in the table above, the cost overrun is largely due to increased construction costs, water treatment equipment and furniture costs, and architect/engineering fees. The applicant states, in supplemental information, that the increased construction costs are largely due to a failure on the part of the estimators to account for the fact that much of the renovation has to be done during hours when dialysis patients are not dialyzing, such as during evenings, overnight hours, or Sundays, in order to avoid disruption to patients' daytime dialysis schedules. This necessarily results in higher labor costs. In addition, the applicant states, in supplemental information, that a temporary water treatment system would need to be installed while a new water treatment system is being removed and replaced.

The applicant adequately demonstrates the need for the proposed cost overrun. Consequently, 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 II.5, page 6, the applicant states, *“There is no suitable alternative, but to proceed with this project.”* The applicant further states that the BMA of North Charlotte facility continues to be utilized at a high rate, citing a utilization rate of 110.71% as reported in the January 2015 Semiannual Dialysis Report (SDR). The applicant states that if the project is not approved, it would have to *“abandon plans for the expansion at the BMA North Charlotte facility.”*

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 the 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 North Charlotte shall comply with all conditions of approval on the certificates of need for Project I.D. #F-10333-14, Project I.D. #F-10249-14, and Project I.D. #F-10091-13 except as specifically modified by the conditions of approval for this application, Project I.D. #F-11041-15.**
 - 2. The total combined capital expenditure for Project I.D. #F-10333-14, Project I.D. #F-10249-14, Project I.D. #F-10091-13, and Project I.D. #F-11041-15 shall be \$815,190.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte 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 North Charlotte 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

This CON application is for a cost overrun of the initial approval of Project I.D. #F-10333-14, but also involves Project I.D. #F-10249-14 and Project I.D. #F-10091-13, for a total combined capital cost of \$815,190 for the project. In Section VI.6, page 17, the applicant states the additional capital cost of \$198,311 will be financed through accumulated reserves

of the applicant. In Section VII.1, page 19, the applicant projects no start-up expenses or initial operating expenses.

In supplemental information, the applicant provides a letter dated August 4, 2015, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc., which states:

“BMA has submitted a Cost Overrun Certificate of Need Application, Project ID #F-11041-15.

...

The cost overrun project calls for an additional capital expenditure of \$198,311.

As Senior Vice President & Treasurer, I am authorized and do hereby authorize the additional capital expenditure of 198,311 [sic] for total capital expenditures at BMA North Charlotte of \$815,190. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$815,190 as may be needed for this facility expansion.”

Exhibit 6 contains the Consolidated Financial Statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2013 and December 31, 2012. As of December 31, 2013, Fresenius Medical Care Holdings, Inc. and Subsidiaries show the company had \$275,719,000 in cash and cash equivalents. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The applicant provides a summary of its projected revenues and operating expenses in Section VIII, pages 21-22, for the first two full operating years of the project, illustrated as follows:

| BMA of North Charlotte | | |
|-------------------------------|-------------------------|-------------------------|
| | Operating Year 1 | Operating Year 2 |
| Total Net Revenue | \$7,946,760 | \$8,124,031 |
| Total Operating Costs | \$6,142,373 | \$6,298,042 |
| Profit (Loss) | \$1,804,387 | \$1,825,990 |

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the projected revenues and operating expenses, including the number of projected treatments, are reasonable.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues (charges) and operating costs. 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

In Project I.D. #F-10333-14, the application was found conforming to this criterion, and the applicant was approved to renovate the existing dialysis facility, BMA of North Charlotte, and add four dialysis stations for a total 36 stations upon completion of the project, Project I.D. #F-10249-14 (add two stations), and Project I.D. #F-10091-13 (add three stations). The applicant proposes no changes in the current application that would affect that determination. 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 Project I.D. #F-10333-14, the application was found conforming to this criterion, and the applicant was approved to renovate the existing dialysis facility, BMA of North Charlotte, and add four dialysis stations for a total 36 stations upon completion of the project, Project I.D. #F-10249-14 (add two stations), and Project I.D. #F-10091-13 (add three stations). The applicant proposes no changes in the current application that would affect that determination. Consequently, 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 Project I.D. #F-10333-14, the application was found conforming to this criterion, and the applicant was approved to renovate the existing dialysis facility, BMA of North Charlotte, and add four dialysis stations for a total 36 stations upon completion of the project, Project I.D. #F-10249-14 (add two stations), and Project I.D. #F-10091-13 (add three stations). The applicant proposes no changes in the current application that would affect that determination. Consequently, 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.

C

The applicant states, in Section II, page 5, that cost estimates for the renovation of the BMA of North Charlotte facility were higher than expected, therefore the development of the four additional stations proposed in Project I.D. #F-10333-14, the two additional stations proposed in Project I.D. #F-10249-14, and three additional stations proposed in Project I.D. #F-10091-13, for a total of 36 stations upon completion, will cost an additional \$198,311. There are no changes proposed to the scope or design of the project, and, as stated in Section VIII, page 20, there are no changes in the proposed charges for services from the previously approved application, Project I.D. #F-10333-14.

The total capital cost proposed for renovation of BMA of North Charlotte, for the combined projects, Project I.D. #F-10333-14, Project I.D. #F-10249-14, and Project I.D. #F-10091-13, is \$815,190. The estimated square footage of the facility is 11,263 and has not changed. The following table, from Section IX, page 27, illustrates the proposed costs of the project per square foot and per dialysis station:

| | Estimated Square Feet | Total Cost per Square Foot | Total Cost per Station |
|------------------------|------------------------------|-----------------------------------|-------------------------------|
| BMA of North Charlotte | 11,263 | \$72.37 | \$22,644.17 |
| Total | 11,263 | \$72.37 | \$22,644.17 |

In addition, the application was found to be conforming to all applicable energy saving features proposed in Project I.D. #F-10333-14. Therefore, the application is conforming to this criterion.

- (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. #F-10333-14, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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 Project I.D. #F-10333-14, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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 IV.6, page 10, the applicant provides the projected payor mix for the proposed services at BMA of North Charlotte, which is shown below:

| BMA of North Charlotte | |
|-------------------------------|-------------------|
| Payor | Percentage |
| Private Pay | 0.0% |
| Commercial Insurance | 12.3% |
| Medicare | 70.4% |
| Medicaid | 6.3% |
| Veterans Administration | 3.4% |
| Medicare/Medicaid | 0.0% |
| Medicare/Commercial | 7.0% |
| Other: Self/Indigent | 0.6% |
| Total | 100.0% |

The applicant projects no change for the proposed payor mix for in-center dialysis services, which indicates that 83.7% of patients have some or all of their services covered by Medicare and/or Medicaid. The applicant demonstrates that medically underserved populations would 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 Project I.D. #F-10333-14, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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 Project I.D. #F-10333-14, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

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

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

C

In Project I.D. #F-10333-14, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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 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

In Project I.D. #F-10333-14, the application was found conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C

.2200. The applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.