

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 16, 2017

Findings Date: November 16, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: F-11383-17

Facility: Metrolina Kidney Center (BMA Monroe)

FID #: 955949

County: Union

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

Project: Cost overrun on Project I.D. #F-11242-16 (Add 5 stations for a total of 16 stations upon completion of this project) and Project ID # F-11208-16 (relocate 10 stations to FKC Indian Trail) and develop a peritoneal dialysis and home hemodialysis training program

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Agency 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. (BMA) proposes a cost overrun for Project I.D. #F-11242-16 (Add 5 stations for a total of 16 stations upon completion of this project) and Project ID # F-11208-16 (Relocate 10 stations to FKC Indian Trail) and develop a peritoneal dialysis (PD) and home hemodialysis (HHD) training program. The facility, Metrolina Kidney Center, is also referred to as BMA Monroe in this application.

The certificate of need was issued on January 6, 2017 for Project I.D. #F-11242-16 and authorized a capital cost of \$1,579,685. The current application is for a cost overrun of \$677,832, due to the following changes listed by the applicant in Section C.14(b), page 13:

- A change in capital cost for the project results in the cost overrun.

- The low bid to renovate the second floor of BMA Monroe is \$677,832 higher than BMA estimated. The second floor renovation is proposed for the home therapies program.
- The \$677,832 overrun includes \$616,211 for construction costs and \$61,621 for design fees.

In Project I.D. #F-11242-16, the applicant projected occupancy and offering of services by December 31, 2018. In this cost overrun application, the applicant projects occupancy and offering of services by the same date, December 31, 2018. There is no material change in scope from the originally approved project in this application.

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 2017 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2017 SMFP that are applicable to this review.

Policies

Policy GEN-3: BASIC PRINCIPLES on page 33 of the 2017 SMFP is not applicable to this review. Project I.D. #F-11242-16 was found to be consistent with Policy GEN-3 in the original review. The applicant proposes no changes in the current application that would affect that determination in the previous application. There are no other policies in the 2017 SMFP that are applicable to this review.

Conclusion

In summary, the applicant was previously approved to add 5 dialysis stations in Project ID #F-11242-16 and develop a PD and home hemodialysis training program, and to relocate 10 dialysis stations to FKC Indian Trail in Project ID #F-11208-16. In both of those reviews, the application 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

The applicant, BMA proposes a cost overrun for Project I.D. #F-11242-16 (Add 5 dialysis stations for a total of 16 dialysis stations and develop a PD and home hemodialysis training program upon completion of this project) and Project I.D. F-11208-16 (Relocate 10 stations to develop FKC Indian Trail - a new facility).

A certificate of need was issued on January 6, 2017 for Project I.D. #F-11242-16 as described above. The original approved capital expenditure was \$1,579,685. The current application is for a cost overrun of \$677,832, and the applicant now projects a total capital cost of \$2,257,517.

Patient Origin

The 2017 SMFP, page 373, defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #F-11242-16, the applicant defined its primary service area as Union and Anson counties, and South Carolina. The current application is a cost overrun for that project. In Project I.D. #F-11242-16, the applicant adequately identified the population to be served and no changes are proposed in this application that affect that determination.

Analysis of Need

In Section C.14(b), page 13, the applicant describes the reasons for the cost overrun application, as summarized below:

- A change in capital cost for the project results in the cost overrun.
- The low bid to renovate the second floor of BMA Monroe is \$677,832 higher than BMA estimated. The second floor renovation is proposed for the home therapies program.
- The \$677,832 overrun includes \$616,211 for construction costs and \$61,621 for design fees.

The following table compares the previously approved capital cost for Project I.D. #F-11242-16 and the proposed capital cost in this application, as reported in Section F.1, page 17.

BMA MONROE			
Previously Approved vs. Proposed Capital Expenditures			
Item/Category	Previously Approved Cost F-11242-16	Total Additional Cost F-11383-17	Total Overrun Cost
Construction Contract	\$1,452,215	\$616,211	\$2,068,426
Architect/Engineering Fees	\$0	\$61,621	\$61,621
Equipment/Furniture	\$127,470	\$0	\$127,470
Total	\$1,579,685	\$677,832	\$2,257,517

The project scope, the population to be served, and access by underserved groups as demonstrated in the original application will not change as a result of this application. The applicant’s representations regarding the need for an additional capital expenditure to offer in-center dialysis and peritoneal and home hemodialysis training and support services are reasonable and adequately supported.

Projected Utilization

In Section C.15, page 13, the applicant provides the projected utilization for BMA Monroe and states that there are no changes to its projected utilization from those projections provided as part of Project I.D. #F-11242-16.

In Project I.D. #F-11242-16, the applicant adequately demonstrated that projected utilization was based on reasonable and adequately supported assumptions regarding continued growth in the patient population that requires dialysis services. The applicant proposes no changes in the current application that would affect that determination.

Access

In Project I.D. #F-11242-16, the applicant adequately demonstrated the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. The applicant proposes no changes in the current application that would affect that determination.

Conclusion

In the original application, the applicant adequately identified the population to be served, demonstrated the need to add five dialysis stations and develop a PD and HHD training program, and demonstrated the extent to which all residents of the service area, including underserved groups, are likely to have access to its services. The applicant proposes no change in this that would affect that determination. In this application, 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 E.1, page 15, the applicant describes the alternative it considered prior to submitting this application for the cost overrun, which are:

- Submit the Cost Overrun Application – the applicant states that this alternative is the more effective and only alternative because it does not have home therapies in Union County, thus patients have to travel to Charlotte to receive training for home dialysis.

The average length of time to reach one facility in Charlotte is more than 25 miles and approximately one hour (due to traffic). To reach the recently opened FMC Regal Oaks is nearly 23 miles and approximately 45 minutes. Either way, the patients are inconvenienced for several weeks to obtain their training for home dialysis treatments.

- Forego the Cost Overrun Application – the applicant states that this alternative would mean that the patients it serves would have no option for home therapies other than traveling to Charlotte.

After considering the above alternatives, the applicant states that it determined the project as presented in the application is the only 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 the proposal is the less costly or more 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 Metrolina Kidney Center (BMA Monroe) shall materially comply with all the conditions of approval on the certificate of need for Project I.D. #F-11242-16.**
 - 2. The total approved capital expenditure for Project I.D. #F-11242-16 and Project I.D. #F-11383-17 combined is \$2,257,517, an increase of \$677,832 over the previously approved capital expenditure of \$1,579,685.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Metrolina Kidney Center (BMA Monroe) shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application and that would otherwise require a certificate of need.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Metrolina Kidney Center (BMA Monroe) 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 a cost overrun for Project I.D. #F-11242-16.

Capital and Working Capital Costs

The total capital cost is now expected to be \$2,257,517, an increase of \$677,832 over the previously approved Project I.D. #F-11242-16 capital cost of \$1,579,685, which is above the allowed 115 percent overage for capital expenditures. The following table compares the previously approved capital cost and the proposed capital cost in this application, as reported on Section F.1, page 17.

BMA MONROE			
Previously Approved vs. Proposed Capital Expenditures			
Item/Category	Previously Approved Cost F-11242-16	Total Additional Cost F-11383-17	Total Overrun Cost
Construction Contract	\$1,452,215	\$616,211	\$2,068,426
Architect/Engineering Fees	\$0	\$61,621	\$61,621
Equipment/Furniture	\$127,470	\$0	\$127,470
Total	\$1,579,685	\$677,832	\$2,257,517

Availability of Funds

In Section F.2, page 18, the applicant states the total capital cost of the project (original and additional capital) will be funded with accumulated reserves. In Exhibit F-1, the applicant provides an August 15, 2017 letter signed by the Senior Vice President and Treasurer, Fresenius Medical Care Holdings, Inc., the parent company for BMA, which states:

“As Senior Vice President, I am authorized and do hereby authorize the additional capital expenditure of \$677,832 for CON Project ID# F-11242-16. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$2,257,517 as may be needed for this project.”

In Exhibit F-2, the applicant provides the Fresenius Consolidated Financial Statement for the years ending December 31, 2016 and December 31, 2015. As of December 31, 2016, Fresenius had \$20,135,661 in total assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project.

Financial Feasibility

The applicant provides 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 second operating year of the project, as shown below in the table.

Project I.D. #F-11383-17		
Projected Revenues/Operating Expenses		
	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments*	8,002	8,447
Total Gross Revenues (Charges)	\$34,272,872	\$38,707,528
Total Net Revenue	\$2,832,366	\$3,344,884
Total Operating Expenses (Costs)	\$3,002,523	\$3,196,397
Net Income/(Loss)	(170,157)	\$148,487

*Adjusted for missed treatments.

The applicant’s total operating expenses are higher in this COR application than in the application for Project ID #F-11242-16. Clarifying information provided by the applicant on November 13, 2017 is excerpted as follows:

1. Expenses reported in Project ID #F-11242-16, “*were based upon run rates or cost per treatment rates from the 2015 fiscal year.*” The expenses reported in the COR application, “*were based on run rates from 2016.*”
2. Corporate office made changes in depreciation for Lease Hold Improvements that are, “*directly related to the cost overrun.*”
3. Corporate office made changes in how bad debt is expensed, “*that rate is facility specific, and not used across the board in our facilities.*”
4. Medical Director fees were calculated on a per treatment rate in Project ID #F11242-16. Now the fees, “*reflect a 2% increase, year over year, despite the number of treatments/patients at the facility.*”

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and 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

The applicant, BMA proposes a cost overrun for Project I.D. #F-11242-16 (Add 5 dialysis stations for a total of 16 dialysis stations and develop a PD and home hemodialysis training

program upon completion of this project) and Project I.D. F-11208-16 (Relocate 10 stations to develop FKC Indian Trail).

The 2017 SMFP, page 373, defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #F-11242-16, the applicant was approved to add dialysis stations to an existing dialysis facility per the facility need methodology and develop a PD and home hemodialysis training program (Union County did not have any home dialysis therapies). The current application is a cost overrun for that project. In Project I.D. #F-11242-16, the application was found to adequately demonstrate that the project would not result in unnecessary duplication of existing or approved dialysis services and no changes are proposed in this application that 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.

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In Section H, page 26, the applicant states that there are no changes in the staffing levels or positions from the original project.

In Project I.D. #F-11242-16, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. The applicant projects that revenues will exceed expenses in the second year of the proposed project and adequately demonstrates the availability of funds for the increased operational needs of the project. 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. #F-11242-16, the application was found 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.

C

The proposed project is for a cost overrun for Project I.D. #F-11242-16. In the original application, the applicant proposed to renovate 552 square feet of space for the home therapies programs. This cost overrun application does not propose any changes to the size of the area being renovated. In Section K.4, pages 30-33, the applicant states that there are no changes to the square footage as proposed in Project I.D. #F-11242-16. The first table below shows the previously approved and the proposed capital expenditures. The second table below shows the difference in the cost per square feet of the approved project and the proposed cost overrun project.

BMA MONROE			
Previously Approved vs. Proposed Capital Expenditures			
Item/Category	Previously Approved Cost F-11242-16	Total Additional Cost F-11383-17	Total Overrun Cost
Construction Contract	\$1,452,215	\$616,211	\$2,068,426
Architect/Engineering Fees	\$0	\$61,621	\$61,621
Equipment/Furniture	\$127,470	\$0	\$127,470
Total	\$1,579,685	\$677,832	\$2,257,517

In Section C.14(b), page 13, the applicant describes the reasons for the cost overrun application, as summarized below:

- A change in capital cost for the project results in the cost overrun.
- The low bid to renovate the second floor of BMA Monroe is \$677,832 higher than BMA estimated. The second floor renovation is proposed for the home therapies program.
- The \$677,832 overrun includes \$616,211 for construction costs and \$61,621 for design fees.

The discussion regarding the need for the cost overrun found in Criterion (3) is incorporated herein by reference. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. 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-11242-16, the application was found 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. #F-11242-16, the application was found 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. #F-11242-16, the application was found 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. #F-11242-16, the application was found 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. #F-11242-16, the application was found 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

The applicant, BMA proposes a cost overrun for Project I.D. #F-11242-16 (Add 5 dialysis stations for a total of 16 dialysis stations and develop a PD and home hemodialysis training

program upon completion of this project) and Project I.D. F-11208-16 (Relocate 10 stations to develop FKC Indian Trail).

The 2017 SMFP, page 373, defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

Project I.D. #F-11242-16 was approved to add five dialysis stations per the facility need methodology and to provide home PD and home hemodialysis training. The current application is for a cost overrun on construction costs to renovate the area proposed for home PD and home hemodialysis training. In Project I.D. #F-11242-16, the application was found 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

- (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

The applicant, BMA of North Carolina, Inc. owns and operates more than 100 dialysis facilities in North Carolina. In Project I.D. #F-11242-16, the application was found to be conforming to this criterion. In Section O.3, pages 46-47, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. The applicant states that the two facilities – RAI West College in Warsaw and BMA East Rocky Mount are back in compliance, effective April 11, 2016 and January 25, 2017, respectively. 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-11242-16, the Criteria and Standards for End-Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 were found conforming to that review, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to the performance standards in this rule.