

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 17, 2023

Findings Date: February 17, 2023

Project Analyst: Donna Donihi

Cosigner: Mike Mckillip

Project ID #: L-12277-22

Facility: Fresenius Medical Clinic Tarboro

FID #: 150155

County: Edgecombe

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

Project: Cost overrun for Project ID# L-12103-21 (add 4 dialysis stations for a total of 18)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant”) proposes a cost overrun for Fresenius Medical Clinic Tarboro, (FMC Tarboro) Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

A certificate of need was issued on January 19, 2022, for Project L-12103-21, (add 4 dialysis stations for a total of 18) for a proposed capital cost of \$712,514. This application is a cost overrun of \$1,013,678, which results in a total combined capital cost of \$1,726,192. In Section F, page 43, the applicant states that the cost overrun is due to the construction costs related to BMA having to absorb the shell construction cost, and the increased cost of labor, supplies, engineering, and architect fees.

Need Determination

In Project ID# L-12103-21, the application was found to be conforming with the need determination in the 2021 SMFP. The applicant proposes no changes in the current application which would affect that 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 2022 SMFP. Therefore, there is no need determination applicable to this review.

Policies

Project ID# L-12103-21 was found to be consistent with Policy GEN-3: Basic Principles, as published in the 2022 SMFP. The applicant proposes no changes in the current application which would affect that determination. There are no policies in the 2022 SMFP that are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed

C

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

A certificate of need was issued on January 19, 2022, for Project ID # L-12103-21 (Add no more than four dialysis stations pursuant to Condition 2 of the facility need a methodology for a total of no more than 18 stations upon project completion) for the proposed capital cost of \$712,514. This application is a COR of \$1,013,678, which results in a total combined capital cost of \$1,726,192.

Patient Origin

On page 115, of the 2022 SMFP defines the service area for the county need methodology for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.” FMC Tarboro is in Edgecombe County. Thus, the service area for this application is Edgecombe County. Facilities may serve residents of counties not included in their service area.

In the previously approved application for Project ID # L-12103-21, the applicant identified the current and projected patient origin for FMC Tarboro. The applicant adequately identified the population to be served and no changes are proposed in this application that would affect that determination.

Analysis of Need

The following table compares the previously approved capital cost and the proposed capital cost, as reported in Section Q. Form F.1b, page 77.

FMC Tarboro			
Previously Approved and Proposed Capital Cost			
	Previously Approved Cost (L-12103-21)	Proposed Cost (L-12277-22)	Difference
Construction/Renovation Contract(s)	\$494,044	\$1,302,722	\$808,678
Architect/Engineering fees	\$44,464	\$117,245	\$72,781
Furniture	\$93,230	\$93,230	\$0
Contingency	\$80,776	\$212,995	\$132,678
Total Capital Costs	\$712,514	\$1,726,192	\$1,013,678

In Section C. page 31, the applicant states the following to explain the reason for the proposed cost overrun:

“The original construction estimates did not include shell construction for the new space to be developed.” ... The availability of skilled labor workers has been impacted by the COVID-19 pandemic. The cost for architect and engineering fees (A&E) has also increased... This increase in contingency costs is due to the increased construction and labor cost in an effort to avoid the need for any further cost overruns.”

The applicant’s representation regarding the need for additional capital expenditure to develop the proposed facility are reasonable and adequately supported for the following reasons:

- The applicant demonstrates the cost of supplies, material, and labor have increased since the original application was approved.
- The applicant demonstrates unexpected costs which are necessary due to the shell not being provided by the landlord.

- The applicant does not propose to change the scope of services offered to the patients projected to be served.

Projected Utilization

In Project ID#L-12103-21, the applicant adequately demonstrated that projected utilization was based on reasonable and adequately supported assumptions. The applicant proposes no changes in the current application that would affect that determination.

Access

In Project ID# L-12103-21, 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

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identified the population to be served in Project ID# L-12103-21, and the applicant does not project a change in that population.
- Projected utilization was deemed reasonable and adequately supported in Project ID# L-12103-21 and the applicant does not project any changes.
- The applicant adequately identified the extent to which all residents, including underserved groups, will have access to the proposed services and the applicant does not project any changes.

- (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

In Project ID#L-12103-21, this Criterion was determined to be non-applicable. In this application, the applicant does not propose any change that would affect that determination. Therefore, Criterion (3a) is not applicable to this review.

- (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 proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Section E, page 36, the applicant explains why there are no alternative methods of meeting the needs of the proposed project. The applicant states that a decision not to develop the project due to the higher cost would result in higher utilization rates and potentially interrupt patient admissions.

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

- The applicant does not propose to change the scope of services or patients to be served from the previously approved Project ID # L-12103-21.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc., (hereinafter the certificate holder) shall materially comply with the representations in this application and in Project ID# L-12103-20. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The total approved capital expenditure for the project is \$1,726,192, an increase of \$1,013,678 over the previously approved capital expenditure of \$712,514.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable**

and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.

- b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on July 1, 2023.
4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of any charges for providing health services by the person proposing the service.

C

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

Capital and Working Capital Costs

The applicant states, in Section Q. Form F.1a, page 77, the total capital cost of the project is now expected to be \$1,726,192, an increase of \$1,013,678 over the previously approved capital cost of \$712,514. The applicant states the increase in capital costs is due to an increase in construction costs. The following table compares the previously approved capital cost and the proposed capital cost, as reported in Section Q.

FMC Tarboro			
Previously Approved and Proposed Capital Cost			
	Previously Approved Cost (L-12103-21)	Proposed Cost (L-12277-22)	Difference
Construction/Renovation Contract(s)	\$494,044	\$1,302,722	\$808,678
Architect/Engineering Fees	\$44,464	\$117,245	\$72,781
Furniture	\$93,230	93,230	\$0
Contingency	\$80,776	\$212,995	\$132,678
Total Capital Costs	\$712,514	\$1,726,192	\$1,013,678

In the previously approved application the applicant stated there will be no start-up expenses or initial operating expenses since FMC Tarboro is an existing facility. The applicant does not propose any start-up expenses or initial operating expenses in this application.

In Section Q, the applicant provides the assumptions used to project capital costs. The applicant adequately demonstrates the projected capital needs of the project are based on reasonable and adequately supported assumptions.

Availability of Funds

In Section F.5, page 44, the applicant states it will fund the project with accumulated reserves. Exhibit F.2 contains a letter from the Senior Vice President and Treasurer for the applicant documenting the availability of accumulated reserves to fund the project. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

Project ID# L-12103-21, the applicant projected revenues would exceed expenses in the first two years of operation. In that review, the Agency determined that the applicant had demonstrated the financial feasibility of the proposed project was based on reasonable and adequately supported assumptions. The applicant is not proposing any changes in this application that would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

Page 115, of the 2022 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* FMC Tarboro is in Edgecombe County. Thus, the service area for this application is Edgecombe County. Facilities may serve residents of counties not included in their service area.

In Project ID# L-12103-21, the Agency determined that the applicant adequately demonstrated that the project would not result in unnecessary duplication of existing or approved services in the service area. No changes are proposed in this application that affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason stated above.

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

C

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Project ID#L-12103-21, the Agency determined the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason stated above.

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

C

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Project ID# L-12103-21 the Agency determined the application was found conforming to this criterion and no changes are proposed in this application that affect that determination. Consequently, the application is conforming to this criterion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason stated above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

NA

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina County, in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy-saving features have been incorporated into the construction plans.

C

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Section K, page 57, the applicant states that the COR application follows as a direct result of the landlord not building the shell which is necessary and were unknown at the time the originally approved application was filed. The applicant provides line drawings in Exhibit K.2.

In Section K, page 58, the applicant explains why the proposal will not unduly increase the costs and charges of the services to the public. The applicant states:

“The project is a necessary part of doing business... The cost of the development is not passed on to the patient... This project will not increase costs or charges to the public for the proposed services.”

In Project ID# L-12103-21 the Agency determined the applicant was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason described above.

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

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

C

In Project ID #L-12277-22, the Agency determined the applicant adequately demonstrated 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. The applicant proposes no changes in the current application which would affect the Agency's determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above

- (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

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Project ID#L-12103-21, the Agency determined the application was conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

The applicant proposes a cost overrun for FMC Tarboro, Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Project ID# L-12103-21, the Agency determined the applicant adequately demonstrated the elderly and the medically underserved groups identified in this subdivision, would be served by the applicant's proposed services and the extent to which each of these groups would be expected to utilize the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

- (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 ID#L-12103-21, the Agency determined the applicant adequately demonstrated it would offer a range of means by which a person would have access to its services. The applicant proposes no changes in the current application which would affect the Agency's determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

The applicant proposes a cost overrun for Fresenius Medical Care Tarboro, (FMC Tarboro) Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Project ID# L-12103-21, the Agency determined the applicant adequately demonstrated the proposed health services would accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect the Agency's determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason described above.

- (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 proposes a cost overrun for Fresenius Medical Care Tarboro, (FMC Tarboro) Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

On page 115, of the 2022 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* FMC Tarboro is in Edgecombe County. Thus, the service area for this application is Edgecombe County. Facilities may serve residents of counties not included in their service area.

In Project ID# L-12103-21, the Agency determined the applicant adequately demonstrated the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition would have a positive impact on the cost effectiveness, quality, and access to the services proposed. The applicant proposes no changes in the current application which would affect the Agency’s determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes a cost overrun for FMC Tarboro Project ID# L-12103-21 (add 4 dialysis stations for a total of 18).

In Section Q. Form O. pages 87-91, the applicant, identifies the dialysis facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 128 dialysis facilities located in North Carolina.

In Section O.4, page 70, the applicant states that during the 18 months immediately preceding the submission of the application, there were no incidents resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing the information provided by the applicant and considering the quality of care at all the facilities, the applicant provides sufficient evidence that quality of care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

In Project ID# L-12103-21, the Agency determined that the application is conforming with all applicable 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.