

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 20, 2023

Findings Date: January 20, 2023

Project Analyst: Gregory F. Yakaboski

Co-Signer: Mike McKillip

Project ID #: F-12278-22

Facility: Fresenius Kidney Care Regal Oaks

FID #: 150024

County: Mecklenburg

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

Project: Cost overrun for Project ID# F-12162-21 (add 2 dialysis stations for a total of 21 stations upon completion of this project and Project ID #F-12136-21)

REVIEW CRITERIA

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter "BMA" or "the applicant") proposes a cost overrun (COR) for Project ID# F-12162-21 (add 2 dialysis stations for a total of 21 stations upon completion of this project and Project ID #F-12136-21)

Need Determination

Project ID# F-12162-21 was found to be consistent with the 2021 SMFP calculated facility need determination for up to two dialysis stations consistent with Condition 2 of the facility need determination. 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 are no need determinations applicable to this review.

Policies

Project ID# F-12162-21 was found to be consistent with *Policy GEN-3: Basic Principles* as published in the 2021 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

In Project ID# F-12162-21, the applicant was previously approved to add up to two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 dialysis stations upon completion of this project and Project ID# F-12136-21. In the original review, the application was found to conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes a COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

A certificate of need was issued on May 27, 2022, for Project ID# F-12162-21 which authorized a capital cost of \$1,132,526. The current application proposes a capital cost increase of \$1,148,730 over the previously approved capital cost for a total combined capital cost of \$2,281,258. The cost overrun application is necessary due to the expense of constructing the shell for the new space, increased costs for labor, construction, materials, architect and engineering fees due to current market conditions, including the impact of the COVID pandemic. The application proposes no material changes in scope from the originally approved project.

Patient Origin

On page 113, the 2021 SMFP defines the service area for dialysis stations as “...*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.” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In Project ID# F-12162-21, the Agency determined the applicant had adequately identified the projected patient origin for the facility. The applicant proposes no changes in the current application which would affect that determination.

Analysis of Need

On Form F.1b, in Section Q, page 76, the applicant provides a summary of the capital cost approved in Project ID# F-12162-21, the changes proposed in this application, and the new projected capital costs, as show in the table below.

	Previously Approved Capital Costs (F-12162-21)	Projected New Capital Costs (F-12278-22)	Projected New Total Capital Costs
Construction/Renovation Contracts	\$718,408	\$916,419	\$1,634,827
Architect/Engineering Fees	\$64,657	\$82,477	\$147,134
Non-Medical Equipment	\$189,713	\$0	\$189,713
Furniture	\$42,290	\$0	\$42,290
Other (Construction Contingency)	\$117,460	\$149,834	\$267,294
Total	\$1,132,526	\$1,148,730	\$2,281,258

In Section C, page 31, the application explains why it believes the proposed increase in capital cost is necessary to develop the proposed project:

- **Increased Construction Contract and Skilled Labor Costs:** The original project included the construction of 2,667 square feet of new space. Typically, the landlord covers the costs of construction of the shell of the new space, however, the applicant states that *“in this case, the landlord chose not to build the shell space because of the volatility in the construction market as a result of the COVID 19 pandemic, thus increases in construction cost are due to the cost that BMA will now be incurring to develop the space for the additional stations.”*
- **Increased Architect and Engineering Fees:** the applicant states that these fees have increased due to the increase in construction costs upon which the fees are based as a percentage of the construction costs.
- **Increased Construction Contingency:** The applicant states that the contingency costs have increased due to the increased construction and labor costs.

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

- The applicant adequately explains the necessity of the increased capital expenditure to develop the project as approved in Project ID# F-12162-21.

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

Projected Utilization

In Project ID# F-12162-21, the Agency determined the applicant had demonstrated its projected utilization was based on reasonable and adequately supported assumptions. The applicant proposes no changes in the current application which would change the projected utilization from the previous project, or which would otherwise affect the Agency's determination in that project.

Access to Medically Underserved Groups

The application for Project ID# F-12162-21 adequately demonstrated the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed services. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- The application for Project ID# F-12162-21 adequately identified the population to be served and there are no changes proposed in this application which would affect that determination.
- The applicant adequately explains why the proposed increased capital expenditure is necessary to provide the population to be served with the services proposed in this application.
- Projected utilization was deemed reasonable and adequately supported in Project ID# F-12162-21 and there are no changes proposed in this application which would affect that determination.
- The application for Project ID# F-12162-21 adequately identified the extent to which all residents, including underserved groups, were likely to have access to the proposed services, and there are no changes proposed in this application which would affect that determination.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

In Project ID# F-12162-21, Criterion (3a) was not applicable to that review. There are no changes proposed in this application which 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 COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

In Section E, page 36, the applicant states that there were no alternatives for meeting the need of the proposal as Project ID #F-12162-21 was already approved and the only way to be approved for the additional capital costs is to apply for the cost overrun. Without the cost overrun the project could not be developed as approved and failure to develop the approved project would lead to higher utilization rates and potentially interrupt patient admission to the facility.

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

- The applicant does not propose to change the scope of the previously approved Project ID #F-12162-21.
- 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. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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 certificate holder) shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than 2 additional in-center dialysis stations for a total of no more than 21 in-center (and home hemodialysis) stations at Fresenius Kidney Care Regal Oaks upon completion of this project and Project ID #F-12136-21 (relocate home therapies program and 2 stations).**
 3. **The approved combined capital expenditure for both Project ID# F-12162-21 and this project is 2,281,258, an increase of \$1,148,730 over the capital expenditure of \$1,132,526 previously approved in Project ID #F-12162-21.**
 4. **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.**
 5. **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 and charges for providing health services by the person proposing the service.

C

The applicant proposes a COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

Capital and Working Capital Costs

On Form F.1b, in Section Q, page 76, the applicant provides a summary of the capital cost approved in Project ID# F-12162-21, the changes proposed in this application, and the new projected capital costs, as show in the table below.

	Previously Approved Capital Costs (F-12162-21)	Projected New Capital Costs (F-12278-22)	Projected New Total Capital Costs
Construction/Renovation Contracts	\$718,408	\$916,419	\$1,634,827
Architect/Engineering Fees	\$64,657	\$82,477	\$147,134
Non-Medical Equipment	\$189,713	\$0	\$189,713
Furniture	\$42,290	\$0	\$42,290
Other (Construction Contingency)	\$117,460	\$149,834	\$267,294
Total	\$1,132,526	\$1,148,730	\$2,281,258

In Section C, page 31, Form F.1a Capital Cost Assumptions and Form F.1b, both in Section Q, pages 76-77, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected increased capital cost is necessary, reasonable and adequately supported based on the following:

- The applicant explains in detail the items in each category projecting an increase from the originally approved capital expenditure.
- The applicant has knowledge and experience in calculating costs related to the construction of ESRD facilities.

In Project ID # F-12162-21, the applicant stated that there were no working capital costs as Fresenius Kidney Care Regal Oaks is an existing facility that is already operational.

Availability of Funds

In Project ID# F-12162-21, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount of \$1,132,526. The current applicant proposes a capital cost increase of \$1,148,730 over the previously approved capital cost.

In Section F.5, page 42, the applicant states that the capital cost will be funded as shown in the table below,

Sources of Capital Cost Financing

Type	Bio-Medical Applications of North Carolina, Inc.
Loans	\$
Accumulated reserves or OE *	\$1,148,730
Bonds	\$
Other (Specify)	\$
Total Financing	\$1,148,730

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F-2 contains a letter dated October 17, 2022 from Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project.
- The applicant documents that it has adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

In Project ID# F-12162-21, the applicant projected revenues would exceed operating expense during the first two years of the project following project completion. The Agency determined Project ID#F-12162-21 had demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges. The applicant is not proposing any changes that would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits of the application
- Information publicly available during the review and used by the Agency

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 for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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 COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “...*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.*” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

Project ID# F-12162-21 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described 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 COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

The application for Project ID# F-12162-21 adequately demonstrated the availability of resources, including health manpower and management personnel to provide the proposed services and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described 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 health care system.

C

The applicant proposes a COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

The application for Project ID# F-12162-21 adequately demonstrated the availability of the ancillary ad support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- (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 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 COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

A certificate of need was issued on May 27, 2022, for Project ID# F-12162-21 which authorized a capital cost of \$1,132,526. The current application proposes a capital cost increase of \$1,148,730 over the previously approved capital cost for a total combined capital cost of \$2,281,258. The cost overrun application is necessary due to BMA now incurring the expense of constructing the shell for the new space when normally the landlord builds the shell space and BMA pays the lease, increased costs for labor, construction, materials, architect and engineering fees due to current market conditions including the impact of the COVID pandemic compared to the estimated costs in 2021 when the original application was submitted. The application proposes no material changes in scope from the originally approved project.

On Form F.1b, in Section Q, page 76, the applicant provides a summary of the capital cost approved in Project ID# F-12162-21, the changes proposed in this application, and the new projected capital costs, as show in the table below.

	Previously Approved Capital Costs (F-12162-21)	Projected New Capital Costs (F-12278-22)	Projected New Total Capital Costs
Construction/Renovation Contracts	\$718,408	\$916,419	\$1,634,827
Architect/Engineering Fees	\$64,657	\$82,477	\$147,134
Non-Medical Equipment	\$189,713	\$0	\$189,713
Furniture	\$42,290	\$0	\$42,290
Other (Construction Contingency)	\$117,460	\$149,834	\$267,294
Total	\$1,132,526	\$1,148,730	\$2,281,258

In Section K, pages 55-56, the applicant states that the original project included 2,667 square feet of new construction and 1,055 square feet of renovation. The square footage of new construction and renovation is remaining the same, however, the applicant will now cover the capital costs of the shell for the new construction as opposed to the landlord covering those capital costs.

In Section C, page 31, Form F.1a Capital Cost Assumptions and Form F.1b, both in Section Q, pages 76-77, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected increased capital cost is necessary, reasonable and adequately supported based on the following:

- The applicant explains in detail the items in each category projecting an increase from the originally approved capital expenditure.
- The applicant has knowledge and experience in calculating costs related to the construction of ESRD facilities.

The discussion regarding the need for the increased capital expenditure in Criterion (3) is incorporated herein by reference. The discussion regarding costs and charges found in Criterion (5) is incorporated by reference. In Project ID# F-12162-21, the applicant adequately demonstrated 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 and no changes are proposed in this application which would affect that determination.

On page 57, the applicant identifies and describes any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons 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 ... persons [with disabilities], 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 #F-12162-21, 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 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 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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Project ID #F12162-21, 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

In Project ID# F-12162-21, 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 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.

- (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# F-12162-21, 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 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.

- (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 ID# F-12162-21, the Agency determined the applicant adequately demonstrated that the proposed health services would accommodate the clinical needs of health professionals training programs in the area. 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 for all the reasons 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 COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

On page 113, the 2021 SMFP defines the service area for dialysis stations as “...*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.” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

A certificate of need was issued on May 27, 2022, for Project ID# F-12162-21 which authorized a capital cost of \$1,132,526. The current application proposes a capital cost increase of \$1,148,730 over the previously approved capital cost for a total combined capital cost of \$2,281,258. The cost overrun application is necessary due to BMA now incurring the expense of constructing the shell for the new space when normally the landlord builds the shell space and BMA pays the lease, increased costs for labor, construction, materials, architect and engineering fees due to current market conditions including the impact of the COVID pandemic compared to the estimated costs in 2021 when the original application was submitted and approved. The application proposes no material changes in scope from the originally approved project.

In Project I.D. #F-12162-21, 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 competitions would have a positive impact upon the cost effectiveness, quality, and access to the services proposed. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons 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 COR for Project ID# F-12162-21 (add two stations) for a total of 21 stations upon completion of this project and Project ID #F-12136-21.

In Section Q, Form O, pages 86-89, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 69, the applicant states that, during the 18 months immediately preceding submission of this application, incidents of immediate jeopardy have not occurred in any of

these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all related facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (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# F-12162-21, the Agency determined the application was conforming to 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 which would affect that determination. Consequently, the application is conforming to the performance standards in this Rule.