ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:	April 29, 2021
Findings Date:	April 29, 2021
Project Analyst:	Mike McKillip
Team Leader:	Fatimah Wilson
Project ID #:	F-12019-21
Facility:	Metrolina Vascular Access Care, LLC
FID #:	180517
County:	Mecklenburg
Applicants:	Metrolina Vascular Access Care, LLC Fresenius Vascular Care Charlotte MSO, LLC
Project:	Cost overrun and change of scope for Project ID # F-11612-18 (develop a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease)

REVIEW CRITERIA

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

Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC (hereinafter referred to collectively as "the applicant") proposes a cost overrun and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

A certificate of need was issued on April 30, 2019 for Project I.D. # F-11612-18 and authorized a capital cost of $2,900,000. The current application proposes a capital cost increase of $1,200,00 over the previously approved capital cost for a total combined capital cost of

$4,100,000. The COR/COS application is necessary due to increased construction costs for approximately 2,000 square feet of additional space and an increase in non-medical equipment costs associated with the additional space.

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 2021 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

The combined projected capital cost to develop the project is greater than $2 million; thus, Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities* in the 2021 SMFP applies to this review.

Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities*, on page 29 of the 2021 SMFP, states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The combined proposed capital expenditure for both projects is greater than $2 million but less than $5 million. In Section B, page 29, the applicant states:

> *"The new facility in which the approved project will be located was designed in compliance with all applicable federal, state, and local building codes. The facility will meet the standards for energy efficiency and consumption. Further, the new facility will*

be designed to be energy efficient and to conserve water and complies with the latest edition of the North Carolina Energy Conservation Codes. Water conservation design standards include the use of low-flow toilets within the facility. Water-reducing flow restrictors are used in the lavatories. MVAC is working with experienced, North Carolina certified architects to ensure that the additional renovations necessary for this project will be completed with energy efficiency and water conservation in mind."

The applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

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 based on the following:

- The application does not propose any changes to the original proposal that would make any need determinations applicable to this review.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(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 and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

A certificate of need was issued on April 30, 2019 for Project I.D. # F-11612-18 and authorized a capital cost of $2,900,000. The current application proposes a capital cost increase of $1,200,00 over the previously approved capital cost for a total combined capital cost of

$4,100,000. The COR/COS application is necessary due to increased construction costs for approximately 2,000 square feet of additional space and an increase in non-medical equipment costs associated with the additional space. In Section C.1, page 42, the applicant describes the project as follows:

> *"Since the original approval, the North Carolina has changed the version of FGI* [Facility Guidelines Institute] *Standards to 2018, which required several modifications to the design of the project. In addition, the design team has met with the physicians, staff, and partners to discuss needs for the designed space. As a result, it was determined that some minor schematic changes were required regarding staff changing and restrooms to meet the updated North Carolina regulations and COVID-19 precautions. Physicians also requested that the number of patient recovery bays and waiting room size be increased beyond minimum FGI standards to provide for increased patient safety and satisfaction, improved comfort, and minimized impact to patient flow should some recovery times be extended for patient safety. Accordingly, the architect schematics were revised to include three additional patient recovery bays and a larger waiting room. Further review by the physicians also resulted in a request to add a physician dictation and related work area closer to the semi-restricted and restricted spaces. Adding this physician space enhances patient flow and safety by eliminating the need for the physicians to leave the direct patient care area for administrative tasks related to charting and case preparation. None of these changes impacted reviewable services.*
>
> *Additional non-patient related design changes include:*
> - *Storage space was increased to allow for improved organization and potential equipment needs.*
> - *The building owner and architect made a significant change to the location of the mechanical units requiring that those units be installed inside the ground floor rather than on the roof as previously planned.*
> - *The size of the autoclave was increased as the applicant has faced challenges with physician approval of disposable surgical instruments and outsourcing of sterilization. That change required an increase to the square footage of the clean and soiled utility rooms in order to meet manufacturer specification for the larger autoclave unit.*
>
> *Each of the design changes required small additional square footage for a total increase of 2,000 sq. feet from approximately 7,000 sq. feet to approximately 9,000 sq. feet. The applicants have also identified additional non-medical equipment costs of $75,000 for the larger autoclave and $65,681 for additional IT hardware equipment associated with the increased space. With the larger area, an addition $10,000 of furniture has been planned."*

Patient Origin

On page 49, the 2021 SMFP states, *"An OR's service area is the single or multicounty grouping shown in Figure 6.1."* In Figure 6.1, page 55 of the 2021 SMFP, Mecklenburg

County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # F-11618-18, the Agency determined the applicant had adequately identified the population to be served by the proposed project at that time. The applicant proposes no changes in the current application which would change the projected patient origin from the previous project, or which would otherwise affect the Agency's determination in that project.

Analysis of Need

The following table compares the previously approved capital cost and the proposed capital cost for Metrolina Vascular Access Care (MVAC), as reported on Form F.1b in Section Q.

MVAC – Previously Approved & Proposed Capital Cost			
	Previously Approved (F-11618-18)	**Projected Changes to Capital Cost (F-12019-21)**	**New Total Projected Capital Cost**
Site Preparation	$350,000	$177,477	$527,477
Construction/Renovation Contracts	$1,575,000	$584,040	$2,159,040
Architect/Engineering Fees	$100,000	66,000	$166,000
Medical Equipment	$74,000	$0	$74,000
Non-medical Equipment	$106,000	$112,622	$218,622
Furniture	$20,000	$8,000	$28,000
Consultant Fees	$45,00	$0	$45,000
Interest During Construction	$42,677	$74,711	$117,388
Contingency and Development Fees	$350,000	$117,091	$467,091
Pre-opening Expenses	$237,323	$60,059	$297,382
Total Capital Cost	**$2,900,000**	**$1,200,00**	**$4,100,000**

In Section C,8, pages 41-43, the applicant explains why it believes the proposed increase in capital cost is necessary to develop the proposed project:

- Increased Construction Contract Costs: The applicant states the increased costs for construction are due to the additional space and changes in design, as well as delays in construction due to COVID quarantine requirements.

- Increased Architect & Engineering Fees: The applicant states that due to the design changes necessary to develop the proposed project, the applicant incurred additional costs involving redesigning architectural drawings and schematics.

- Increased Non-medical and Furniture: The applicant states that the design changes and additional space resulted in increased costs for office equipment, information technology and furniture.

- Interest Expenses: The applicant states interest during construction costs were increased due to the delays in construction.

- Contingency Expenses: The applicant states contingency expenses are based on a percentage of total costs, and therefore have increased.

The information is reasonable and adequately supported based on the following:

- The applicant adequately explains the reasons the additional costs are necessary to develop the proposed project.

- The applicant provides supporting documentation for its statements in Exhibits K-5.1 and K-5.2.

- 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 I.D. # F-11612-18, 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

In Project I.D. # F-11612-18, the Agency determined the applicant had 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

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

- The application for Project I.D. # F-11612-18 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 increase in projected capital cost 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 I.D. # F-11612-18 and there are no changes proposed in this application which would affect that determination.

- The application for Project I.D. # F-11612-18 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 I.D. # F-11612-18, 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 cost overrun and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

A certificate of need was issued on April 30, 2019 for Project I.D. # F-11612-18 and authorized a capital cost of $2,900,000. The current application proposes a capital cost increase of $1,200,00 over the previously approved capital cost for a total combined capital cost of $4,100,000. The COR/COS application is necessary due to increased construction costs for approximately 2,000 square feet of additional space and an increase in non-medical equipment costs associated with the additional space.

In Section E, page 52, the applicant states there are no alternatives other than the alternative proposed in this application to meet the need. The applicant states, *"The architectural design changes proposed require additional square footage, so there is no other option."*

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 services or patients to be served from the previously approved Project I.D. # F-11612-18.

- The applicant provides credible 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

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. **Metrolina Vascular Access Care, LLC and Fresenius Vascular Care Charlotte MSO, LLC (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. # F-11612-18. Where representations conflict, the certificate holder shall materially comply with the last made representation.**

2. **The total combined capital expenditure for both projects is $4,100,000, an increase of $1,200,000 over the capital expenditure of $2,900,000 previously approved in Project I.D. # F-11612-18.**

3. **Upon completion of the project and Project I.D. # F-11612-18, Metrolina Vascular Access Care shall be licensed for no more than one operating room and one procedure room.**

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. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on September 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.**

5. **The certificate holder shall not acquire as part of this project any equipment that is not included in this project's and Project I.D. # F-11612-18's combined proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

6. **The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**

7. **For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in this application, in Project I.D. # F-11612-18, without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**

8. **The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**

9. **Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**

10. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

11. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

    a. **Payor mix for the services authorized in this certificate of need.**
    b. **Utilization of the services authorized in this certificate of need.**
    c. **Revenues and operating costs for the services authorized in this certificate of need.**
    d. **Average gross revenue per unit of service.**
    e. **Average net revenue per unit of service.**
    f. **Average operating cost per unit of service.**

12. 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 cost overrun and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

Capital and Working Capital Costs

A certificate of need was issued on April 30, 2019 for Project I.D. # F-11612-18 and authorized a capital cost of $2,900,000. The current application proposes a capital cost increase of $1,200,00 over the previously approved capital cost for a total combined capital cost of $4,100,000. The COR/COS application is necessary due to increased construction costs for approximately 2,000 square feet of additional space and an increase in non-medical equipment costs associated with the additional space. The following table compares the previously approved capital cost and the proposed capital cost for Metrolina Vascular Access Care (MVAC), as reported on Form F.1b in Section Q.

MVAC – Previously Approved & Proposed Capital Cost			
	Previously Approved (F-11618-18)	**Projected Changes to Capital Cost (F-12019-21)**	**New Total Projected Capital Cost**
Site Preparation	$350,000	$177,477	$527,477
Construction/Renovation Contracts	$1,575,000	$584,040	$2,159,040
Architect/Engineering Fees	$100,000	66,000	$166,000
Medical Equipment	$74,000	$0	$74,000
Non-medical Equipment	$106,000	$112,622	$218,622
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Consultant Fees	$45,00	$0	$45,000
Interest During Construction	$42,677	$74,711	$117,388
Contingency and Development Fees	$350,000	$117,091	$467,091
Pre-opening Expenses	$237,323	$60,059	$297,382
Total Capital Cost	**$2,900,000**	**$1,200,00**	**$4,100,000**

In Project I.D. # F-11612-18, the Agency determined the applicant had demonstrated the projected capital cost was based on reasonable and adequately supported assumptions. There are no changes proposed in this application which would affect that determination.

In Section C, pages 41-43, the applicant explains the need for the proposed increase in projected capital costs. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

On Form F.1b in Section Q, the applicant provides the assumptions used to project the proposed increase in capital cost. The applicant adequately demonstrates that the proposed increase in the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant had previously demonstrated to the Agency in Project I.D. # F-11612-18 that the projected capital costs in that application were based on reasonable and adequately supported assumptions, and there are no changes proposed in this application which would affect that determination.

- The applicant explains the need for the different costs that make up the combined total increase in capital cost for this COR/COS application and the explanations are reasonable and adequately supported.

- The applicant provides supporting documentation for the need for the proposed capital cost increase and the assumptions regarding the proposed capital cost increase in Exhibit K.

In Section F.5, the applicant projects that start-up costs will be $153,647 and initial operating expenses will be $261,123 for a total working capital of $414,770, which is an increase of 134,770 over the previously approved amount of $280,000 in Project I.D. # F-11612-18. On page 61-62, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant had previously demonstrated to the Agency in Project I.D. # F-11612-18 that the projected working capital costs in that application were based on reasonable and adequately supported assumptions, and there are no changes proposed in this application which would affect that determination.

- The applicant explains the need for the different costs that make up the combined total increase in working capital costs for this COR/COS application and the explanations are reasonable and adequately supported.

- The applicant provides supporting documentation for the need for the proposed working capital cost increase and the assumptions regarding the proposed capital cost increase in Exhibit F-5.

Availability of Funds

In Project I.D. # F-11612-18, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount

of $2,900,000. The current application proposes a capital cost increase of $1,200,000 over the previously approved capital cost for a combined total capital cost of $4,100,000.

In Section F, page 60, the applicant states the increase in projected capital and working capital costs will be funded through a loan from National Medical Care, Inc., a wholly owned affiliate of Fresenius Medical Care AG and Company.

Exhibit F-5.1 contains a letter dated February 4, 2021 from the Senior Vice President and Treasurer for National Medical Care, Inc. stating their intention to provide the funding for the projected increase in capital and working capital costs.

Exhibit F-5.3 contains the Consolidated Financial Statements for Fresenius Medical Care for the years ending December 31, 2019 and 2018. As of December 31, 2019, Fresenius Medical Care had $1 billion in cash and cash equivalent.

The applicant adequately demonstrates the availability of sufficient funds for the proposed increase in the projected capital cost based on the following:

- The applicant provides a letter from an appropriate company officer confirming the availability of the funding proposed for the capital and working capital needs of the project and a commitment to use that funding accordingly.

- The applicant provides adequate documentation of the funds it proposes to use to fund the capital needs of the project.

Financial Feasibility

In Project I.D. # F-11612-18, the applicant projected revenues would exceed operating expenses during each of the first three full fiscal years of operation following project completion. The Agency determined Project I.D. # F-11612-18 had demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges. The applicant projects no changes in this application to those projections and no changes which would otherwise affect the Agency's previous 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 increased capital and working 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 increased capital and working capital costs of the proposal for all the reasons described above.

- The applicant projects no changes to the assumptions and methodology in Project I.D. # F-11612-18 which demonstrated sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal was 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 and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

A certificate of need was issued on April 30, 2019 for Project I.D. # F-11612-18 and authorized a capital cost of $2,900,000. The current application proposes a capital cost increase of $1,200,00 over the previously approved capital cost for a total combined capital cost of $4,100,000. The COR/COS application is necessary due to increased construction costs for approximately 2,000 square feet of additional space and an increase in non-medical equipment costs associated with the additional space.

On page 49, the 2021 SMFP states, *"An OR's service area is the single or multicounty grouping shown in Figure 6.1."* In Figure 6.1, page 55 of the 2021 SMFP, Mecklenburg County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # F-11612-18, the Agency determined the applicant had adequately demonstrate that the project would not result in unnecessary duplication of existing or approved services in the service area. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

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 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 and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

In Project I.D. # F-11612-18, the Agency determined the applicant had adequately demonstrated the availability of sufficient health manpower and management personnel to provide the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

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 all the reasons 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 health care system.

C

The applicant proposes a cost overrun and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

In Project I.D. #F-11612-18, the Agency determined the applicant had adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

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 stated 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 cost overrun and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

A certificate of need was issued on April 30, 2019 for Project I.D. # F-11612-18 and authorized a capital cost of $2,900,000. The current application proposes a capital cost increase of $1,200,00 over the previously approved capital cost for a total combined capital cost of $4,100,000. The COR/COS application is necessary due to increased construction costs for approximately 2,000 square feet of additional space and an increase in non-medical equipment costs associated with the additional space. The following table compares the previously approved capital cost and the proposed capital cost for Metrolina Vascular Access Care (MVAC), as reported on Form F.1b in Section Q.

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Site Preparation	$350,000	$177,477	$527,477
Construction/Renovation Contracts	$1,575,000	$584,040	$2,159,040
Architect/Engineering Fees	$100,000	66,000	$166,000
Medical Equipment	$74,000	$0	$74,000
Non-medical Equipment	$106,000	$112,622	$218,622
Furniture	$20,000	$8,000	$28,000
Consultant Fees	$45,00	$0	$45,000
Interest During Construction	$42,677	$74,711	$117,388
Contingency and Development Fees	$350,000	$117,091	$467,091
Pre-opening Expenses	$237,323	$60,059	$297,382
Total Capital Cost	**$2,900,000**	**$1,200,00**	**$4,100,000**

In Section K.5, page 72, the applicant states that the project involves upfit of 9,052 square feet of space in a new medical office building, which is an increase of 2,156 over the total square footage of 6,896 proposed in Project I.D. # F-11612-18. Line drawings are provided in Exhibit K-5.

In Section K.5, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on page 73 of the application.

In Section K.5, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the

public for the proposed services based on the information and representations made by the applicant on page 73 of the application.

On page 73, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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.

(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 I.D. # F-11612-18, the Agency determined the applicant had 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 in that project.

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 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

In Project I.D. # F-11612-18, 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 I.D. # F-11612-18, the Agency determined the applicant had 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.

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 I.D. # F-11612-18, the Agency determined the applicant had 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 in that project.

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 I.D. # F-11612-18, the Agency determined the applicant had adequately demonstrated that 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 in that project.

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 cost overrun and change of scope (COR/COS) for Project I.D. # F-11612-18. That project approved the development of a new ambulatory surgical facility in Charlotte with one operating room and one procedure room focused on vascular access procedures for patients with end stage renal disease.

A certificate of need was issued on April 30, 2019 for Project I.D. # F-11612-18 and authorized a capital cost of $2,900,000. The current application proposes a capital cost increase of $1,200,00 over the previously approved capital cost for a total combined capital cost of $4,100,000. The COR/COS application is necessary due to increased construction costs for approximately 2,000 square feet of additional space and an increase in non-medical equipment costs associated with the additional space.

On page 49, the 2021 SMFP states, *"An OR's service area is the single or multicounty grouping shown in Figure 6.1."* In Figure 6.1, page 55 of the 2021 SMFP, Mecklenburg County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # F-11612-18, the Agency determined the applicant had 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 upon 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 in that project.

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.

(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.

NA

Neither the applicant nor any related entities own, operate, or manage an existing health service facility located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

(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.

NA

In Project I.D. # F-11612-18, the Agency determined the application was conforming to all applicable Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100, which were in effect at that time. The applicant proposes no changes in this application which would affect that determination. Therefore, there are no Criteria and Standards applicable to this review.