

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 20, 2024

Findings Date: August 20, 2024

Project Analyst: Yolanda W. Jackson

Co-Signer: Lisa Pittman

Project ID #: G-12523-24

Facility: North Elam Ambulatory Surgery Center

FID #: 200291

County: Guilford

Applicant(s): North Elam Ambulatory Surgery Center, LLC

The Moses H. Cone Memorial Hospital

Project: Cost overrun for Project ID # G-11895-20 (develop an ambulatory surgical facility)

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

North Elam Ambulatory Surgery Center, LLC and The Moses H. Cone Memorial Hospital (hereinafter referred to as “the applicant”) proposes a cost overrun (COR) for Project ID # G-11895-20. That project approved the development of a new separately licensed ambulatory surgical facility (ASF), North Elam Ambulatory Surgery Center (North Elam ASC) on the Wesley Long Hospital campus, by re-licensing five existing hospital-based operating rooms (ORs) at Wesley Long Surgery Center currently on the Cone Health license.

A certificate of need was issued on August 21, 2020, for Project ID# G-11895-20 and authorized a capital cost of \$7,715,777. The current application proposes a capital cost increase of \$11,205,972 over the previously approved capital cost for a total combined capital cost of \$18,921,749. The cost overrun application is necessary due to additional equipment needs to replace aging equipment, increased cost for construction to comply with current space

standards and FGI (Facility Guidelines Institute) guidelines, and the addition of one sterile processing unit (SPU). The application proposes no material change in scope from the originally approved project.

Need Determination

There were no need determinations in the 2020 State Medical Facilities Plan (SMFP) applicable to Project ID # G-11895-20 and the applicant proposes no changes in the current application which would affect that determination. The applicant does not propose to increase the number of operating rooms, add any new health services, or acquire equipment for which there is a need determination in the 2024 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

In the current COR application, the combined projected capital cost to develop the project is greater than \$5 million; thus, Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities* in the 2024 SMFP applies to this review.

Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities*, on page 30 of the 2024 SMFP, states:

“Any person proposing a capital expenditure greater than \$4 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 this project is greater than \$5 million. In Section B, page 28, the applicant states:

“North Elam ASC is committed to assuring improved energy efficiency and water conservation in its construction and renovation projects. In an effort to reduce future operating costs, provide a healthier work environment, and reduce the overall environmental impact of the project, North Elam ASC will use a number of sustainable building and renovation strategies for the freestanding ASF currently under development pursuant to Project ID # G-11895-20.”

In Section B, page 28, the applicant states it will develop and implement an Energy Efficiency and Sustainability plan for the proposed project that conforms to or exceeds the energy efficiency and water conservation standards in the latest edition of the NC State Building Codes and that the plan will not adversely affect patient or resident health, safety, or infection control.

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 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 COR for Project ID # G-11895-20 (develop an ambulatory surgical facility).

A certificate of need was issued on August 21, 2020, for Project ID # G-11895-20 and authorized a capital cost of \$7,715,777. The current application proposes a capital cost increase of \$11,205,972 over the previously approved capital cost for a total combined capital cost of \$18,921,749. The cost overrun application is necessary due to additional equipment needs to

replace aging equipment, increased cost for construction to comply with current space standards and FGI (Facility Guidelines Institute) guidelines, and the addition of one sterile processing unit (SPU). The application proposes no material change in scope from the originally approved project.

Patient Origin

On page 47, the 2024 SMFP states, “An OR’s service area is the single or multicounty grouping shown in Figure 6.1.” In Figure 6.1, page 53 of the 2024 SMFP, Guilford and Caswell counties are shown as a multicounty operating room service area. Thus, the service area for this application is Guilford and Caswell counties. Facilities may also serve residents of counties not included in the service area.

In Project ID # G-11895-20, 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 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, as reported on Form F.1b in Section Q.

North Elam ASC - Previously Approved and Proposed Capital Cost			
	Previously Approved (G-11895-20)	Projected Changes to Capital Cost (G-12523-24)	New Total Projected Capital Cost
Construction/Renovation Contract(s)	\$6,385,048	\$3,706,507	\$10,091,555
Architect/Engineering Fees	\$510,800	\$518,220	\$1,029,020
Medical Equipment	\$470,197	\$4,682,843	\$5,153,040
Non-Medical Equipment	\$0	\$2,003,390	\$2,003,390
Furniture	\$158,181	\$52,249	\$210,430
Consultant Fees (CON and Legal)	\$191,551	\$242,763	\$434,314
Total Capital Cost	\$7,715,777	\$11,205,972	\$18,921,749

In Section C, pages 43-44, the applicant explains why it believes the proposed increase in capital cost is necessary to develop the proposed project:

- **Construction Contract Costs:** The applicant states that the increase in construction costs is attributable to cost escalation of both labor and materials since the previous application was approved, an update to building code requirements and revisions to the FGI guidelines. The updated project will include expansion of all five ORs to meet new standards, development of an in-house SPU, and an increase in the the size of pre- and post-operative care bays. The applicant planned to outsource sterile processing of surgical equipment when the original application was submitted; however, the applicant states that an in-house SPU will allow North Elam ASC to maintain high quality control, avoid the risk of compliance violations, lower operational costs, and maintain operational efficiencies.

- Architect/Engineering Fees: The applicant states that the fees increased because of design changes necessary to develop the project in compliance with construction guidelines and the addition of the SPU.
- Medical Equipment Costs: The applicant states that the additional equipment is necessary to replace aging equipment and that there has been significant inflation and cost escalation since 2020 for a majority of the medically equipment necessary to outfit North Elam ASC, such as the new equipment for the SPU.
- Non-Medical Equipment Costs: The applicant states these fees increased because of inflation and approximately one-half of these expenses are associated with items not included in the previously approved equipment list that have since been deemed necessary for operation of North Elam ASC, such as new equipment for the SPU. The applicant states that the SPU requires two pass-through washers, one under counter washer in the decontamination area, and two steam sterilizers to accommodate high acuity cases. The applicant states that these support resources will ensure that the facility can perform the projected number of surgical cases by maintaining sufficient sterilization equipment.
- Furniture Costs: The applicant states that furniture costs increased due to market inflation.
- Consultant Fees: The applicant states that consultant fees increased because there were additional costs necessary to plan for the proposed project, including the preparation of a second CON application.

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 C.8-1 and F.1., including copies of project line drawings and a certified construction cost letter dated May 15, 2024, and signed by the project architect.
- 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 # G-11895-20, 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 ID # G-11895-20, 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 ID # G-11895-20 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 ID # G-11895-20 and there are no changes proposed in this application which would affect that determination.
- The application for Project ID # G-11895-20 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 # G-11895-20, 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.

C

The applicant proposes a COR for Project ID #G-11895-20 (develop an ambulatory surgical facility).

In Section E, pages 52-53, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need.

Halt Development of North Elam ASC

The applicant states that one alternative to filing the COR application is to halt the development of the previously approved project. The applicant states halting the develop of North Elam ASC would not be fiscally responsible nor in the best interest of residents of Guilford County and the service area and would result in higher patient charges and operational expenses if North Elam ASC remains as a hospital-based surgery center. The applicant states that halting development would also negatively impact Cone Health's goal of increasing access and affordability and will hinder physician integration. For those reasons, the applicant determined halting development of the proposed project was not the most effective alternative.

Continue Development Without the Addition of a Sterile Processing Unit

The applicant states that another alternative was to outsource the sterile processing function through Wesley Long Hospital's Sterile Processing Department (SPD) rather than purchasing the recommended sterilization equipment to support operating rooms identified in Project ID# G-11895-20 or continue as planned with the development of the SPU but outsource a majority rather than all sterile processing to Cone Health Wesley Long Hospital. These options would mean that limited SPU operations would be available at North Elam ASC and could potentially slow down operating room turnover due to waiting on equipment and surgical instrument sterilization to be completed through Wesley Long Hospital. The applicant considered both options and determined that while the initial cost with both approaches would be lower, long-term cost to patients could be higher. The applicant states that in-house sterile processing will allow for operational and financial efficiency without the need for additional staff or contracted services and that these cost savings and operational efficiencies will be passed on to the patient by creating a lower cost surgery model. Therefore, outsourcing the sterile processing function was determined to not be the most effective alternative.

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 # G-11895-20.

- The applicant demonstrates that halting development of North Elam ASC is a less effective alternative than the proposed COR.
- The applicant demonstrates that outsourcing the sterile processing function is less effective than the addition of an in-house sterile processing.
- 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. North Elam Ambulatory Surgery Center, LLC and The Moses H. Cone Memorial Hospital (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project ID # G-11895-20. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The total combined capital expenditure for both projects is \$18,921,749, an increase of \$11,205,972 over the capital expenditure of \$7,715,777 previously approved in Project ID #G-11895-20.**
- 3. The certificate holder shall develop a freestanding multispecialty ambulatory surgical facility by re-licensing no more than five hospital-based operating rooms from Wesley Long Surgery Center on the Cone Health Wesley Long Hospital campus.**
- 4. Upon project completion, North Elam Ambulatory Surgery Center shall be licensed for no more than five operating rooms.**
- 5. Upon completion of this project and Project ID # G-11895-20, the certificate holder shall take the necessary steps to delicense Wesley Long Surgery Center's five operating rooms on the Cone Health License #H0159.**
- 6. The certificate holder shall not acquire as part of this project and Project ID # G-11895-20 any equipment that is not included in the combined proposed capital**

expenditure in Section Q of the application and that would otherwise require a certificate of need.

- 7. North Elam Ambulatory Surgery Center 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.**
- 8. 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 Section Q of this application, in Project ID # G-11895-20, and in any supplemental responses 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.**
- 9. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for this project and Project ID # G-11895-20 that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 10. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 11. 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.**
- 12. 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 March 3, 2025.**
- 13. 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 #G-11895-20 (develop an ambulatory surgical facility).

Capital and Working Capital Costs

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project ID # G-11895-20, the changes proposed in this application, and the new projected capital cost as shown in the table below.

North Elam ASC - Previously Approved and Proposed Capital Cost			
	Previously Approved (G-11895-20)	Projected Changes to Capital Cost (G-12523-24)	New Total Projected Capital Cost
Construction/Renovation Contract(s)	\$6,385,048	\$3,706,507	\$10,091,555
Architect/Engineering Fees	\$510,800	\$518,220	\$1,029,020
Medical Equipment	\$470,197	\$4,682,843	\$5,153,040
Non-Medical Equipment	\$0	\$2,003,390	\$2,003,390
Furniture	\$158,181	\$52,249	\$210,430
Consultant Fees (CON and Legal)	\$191,551	\$242,763	\$434,314
Total Capital Cost	\$7,715,777	\$11,205,972	\$18,921,749

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

- The applicant provides detailed explanations about what the proposed increases in capital and working capital costs are to justify the proposed increases.
- The applicant considers the impact of factors such as inflation due to the new timeline to develop the proposed project.

In Project ID #G-11895-20, the applicant stated start-up costs would be \$732,663 and initial operating costs would be \$1,098,994, for a total working capital of \$1,831,657. The Agency determined Project ID #G-11895-20 was conforming to this criterion. In Section F, page 64, the applicant projects total start-up costs and initial operating costs of \$777,062 and \$4,662,374, respectively, for a total of \$5,439,436 in working capital, \$3,607,779 above the previously approved working capital of \$1,831,657. On page 64, the applicant explains the increase in working capital is due to the impact of inflation with the new project timeline.

Availability of Funds

In Project ID # G-11895-20, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount of \$7,715,777. The current application proposes a capital cost increase of \$11,205,972 over the previously approved capital cost for a combined total capital cost of \$18,921,749.

In Section F, pages 62-63, the applicant states the increase in projected capital costs will be funded through the accumulated reserves of The Moses H. Cone Memorial Hospital.

Exhibit F.5-1 contains a letter dated June 17, 2024, from the Chief Financial Officer of Cone Health stating that The Moses H. Cone Memorial Hospital will provide the funding for the projected increase in capital costs from accumulated reserves.

Exhibit F.5-2 contains the audited financial statements for The Moses H. Cone Memorial Hospital and affiliates for the years ending September 30, 2022, and 2023. As of September 30, 2023, The Moses H. Cone Hospital had adequate cash and assets to fund the proposed increase in the projected capital cost.

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 needs of the project and a commitment to use that funding accordingly.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility

In Project ID # G-11895-20, the applicant projected revenues would exceed operating expenses during each of the first three full fiscal years of operation. The Agency determined Project ID # G-11895-20 had demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges.

In Section Q, Form F.2b, the applicant projects revenues will exceed operating expenses in each of the first three operating years as shown in the table below:

	1st Full FY	2nd Full FY	3rd Full FY
	FY2027	FY2028	FY2029
Total OR Cases	3,218	3,581	3,986
Total Gross Revenue	\$53,242,302	\$61,034,493	\$69,967,099
Total Net Revenue	\$14,612,339	\$16,750,904	19,202,456
Average Net Revenue per Case	\$4,541	\$4,678	\$4,817
Total Operating Costs	\$11,999,519	13,021,541	\$14,591,259
Operating Expense per Case	\$3,729	\$3,636	\$3,661
Net Income (Loss)	\$2,612,820	3,729,363	\$4,611,197

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Forms F.2b and F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly identifies the sources of data used to project revenues and expenses.
- The applicant makes adjustments to revenues based on an annual inflation rate of 3.0 percent.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

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 and working 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 and working 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.

The applicant proposes a COR for Project ID # G-11895-20 (develop an ambulatory surgical facility).

On page 47, the 2024 SMFP states, “An OR’s service area is the single or multicounty grouping shown in Figure 6.1.” In Figure 6.1, page 53 of the 2024 SMFP, Guilford and Caswell counties are shown as a multicounty operating room service area. Thus, the service area for this application is Guilford and Caswell counties. Facilities may also serve residents of counties not included in the service area. The 2020 SMFP identified the same multicounty OR service area for Project ID #G-11895-20.

In Project ID # G-11895-20, the Agency determined the applicant had adequately demonstrated that the project will 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

In Project ID # G-11895-20, 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

In Project ID # G-11895-20, 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 to develop a sterile processing unit within the ASC, rather than outsourcing this support function as originally proposed in Project ID # G-11895-20. See the discussion regarding the sterile processing unit in Criterion (3) which is incorporated herein by reference. The applicant does not propose a change in support services related to the sterile processing unit. The applicant adequately demonstrates that the necessary ancillary and support services will be made available and that the proposed services will be coordinated with existing health care systems.

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 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 COR for Project ID # G-11895-20 (develop an ambulatory surgical facility).

A certificate of need was issued on August 21, 2020, for Project ID #G-11895-20 and authorized a capital cost of \$7,715,777. The current application proposes a capital cost increase of \$11,205,972 over the previously approved capital cost for a total combined capital cost of \$18,921,749. The cost overrun application is necessary due to additional equipment needs to replace aging equipment and increased cost for construction to comply with current space standards and FGI (Facility Guidelines Institute) guidelines, and the addition of one sterile processing unit (SPU). The application proposes no material change in scope from the originally approved project.

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

North Elam ASC			
Previously Approved and Proposed Capital Cost			
	Previously Approved (G-11895-20)	Projected Changes to Capital Cost (G-12523-24)	New Total Projected Capital Cost
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Total Capital Cost	\$7,715,777	\$11,205,972	\$18,921,749

In Section K, page, 76, the applicant states that the project involves renovating 19,130 square feet of existing space. Line drawings of the facility are provided in Exhibit C.8-1.

The discussions regarding the COR being the most reasonable alternative for developing the proposed project are found in Criterion (3) and Criterion (4) are incorporated herein by reference.

In Section K, page 76, 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 following:

- The applicant states that North Elam ASC will be a separately licensed, freestanding ASF rather than a hospital-based surgical services provider.
- The applicant states that North Elam ASC as a freestanding ASF will offer a more cost-effective alternative to patients in the service area because patients and payors do not incur the charges associated with hospital-based care.

In Section K, pages 76-77, the applicant identifies any applicable energy savings features that will be incorporated into the renovation 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 stated 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

The applicant proposes a COR for Project ID # G-11895-20 (develop an ambulatory surgical facility).

Project ID # G-11895-20 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

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 # G-11895-20, the Agency determined the application was conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination.

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.

- (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 # G-11895-20, the Agency determined the applicant had adequately describes the range of means by which patients will have access to the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project; however, the applicant states that it's projected payor mix is expected to change for Self-Pay and Medicaid due to the recent Medicaid expansion in North Carolina. The applicant is projecting a 50 percent shift from Self-Pay to Medicaid compared to the projected payor mix in the third full FY for Project ID # G-11895-20.

North Elam Ambulatory Surgery Center FY2029	
Payor Source	OR Services as Percentage of Total Patients Served
Self-Pay	2.0%
Charity Care^	0.0%
Medicare*	32.7%
Medicaid*	11.4%
Insurance*	51.8%
Other (TRICARE and Workers Compensation)	2.1%
Total	100%

*Including any managed care plans.

^Cone Health internal data does not include Charity Care as a payor source for patients.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.0% of total services will be provided to self-pay patients, 32.7% to Medicare patients and 11.4% to Medicaid patients.

On page 83, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

The cost overrun will not affect the previously approved application's projected payor mix.

- The projected payor mix is expected to change for Medicaid and Self-Pay only as compared to the projected payor mix for Project ID # G-11895-20 due to the recent Medicaid expansion in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 # G-11895-20, 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.

- (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 # G-11895-20, 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 COR for Project ID #G-11895-20 (develop an ambulatory surgical facility).

On page 47, the 2024 SMFP states, “*An OR’s service area is the single or multicounty grouping shown in Figure 6.1.*” In Figure 6.1, page 53 of the 2024 SMFP, Guilford and Caswell counties are shown as a multicounty operating room service area. Thus, the service area for this application is Guilford and Caswell counties. Facilities may also serve residents of counties not included in the service area. The 2020 SMFP identified the same service area for Project ID # G-11895-20.

In Project ID # G-11895-20, 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.

C

The applicant proposes a COR for Project ID # G-11895-20 (develop an ambulatory surgical facility).

In Section Q, Form O, the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 11 facilities of this type located in North Carolina.

In Section O, page 90, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 11 facilities, the applicant provided 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.

NA

The application does not propose to increase the number of operating rooms in the service area, therefore, the criteria and standards for surgical services and operating rooms do not apply.