

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2024

Findings Date: January 29, 2024

Project Analyst: Cynthia Bradford

Co-Signer: Micheala Mitchell

Project ID #: J-12438-23

Facility: Duke Gastroenterology of Raleigh

FID #: 200638

County: Wake

Applicant(s): Duke Health Integrated Practice, Inc.

Duke University Health System, Inc.

Project: Cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms)

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.

NA

Duke Health Integrated Practice, Inc., and Duke University Health System, Inc., collectively referred to as “the applicant”, propose a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

On December 30, 2020, Private Diagnostic Clinic, PLLC, was issued a certificate of need for Project ID#, J-11934-20 with an approved capital expenditure of \$3,507,916. Private Diagnostic Clinic, PLLC, subsequently transferred all of its assets to Duke Health Integrated Practice, Inc. (DHIP). The current application proposes a capital cost increase of \$1,901,084, a 35% increase over the previously approved capital expenditure, for a total combined expenditure of \$5,409,000. Duke University Health System (DUHS) states that Project ID J-

11934-20 was approved during the height of the COVID-19 pandemic and was initially delayed. In 2021 and 2022, the applicant was in discussions for an acquisition of a faculty practice plan that further delayed project development until July 1, 2023. These delays created cause for updated construction, equipment, and furniture estimates.

Need Determination

There was no need determination in the 2020 State Medical Facilities Plan (SMFP) applicable to Project ID# J-11934-20 and the applicant proposes no changes in the current application which would affect that determination. The applicant does not propose any changes for which there is a need determination in the 2023 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

Project J-11934-20 was found to be consistent with *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* as published in the 2020 SMFP.

For this review, *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, as published on page 30 of the 2023 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 for 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 capital expenditure of this project is greater than \$5 million. In Section B, page 26, the applicant states: “...this cost overrun will not change DUH’s response to questions regarding Policy GEN-4 or compliance with this policy.” The applicant also references the original application for further information.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

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

C

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

Project ID# J-11934-20 proposed to develop a new ambulatory surgical facility with no more than four gastroenterology (GI) endoscopy procedure rooms. A certificate of need was issued on December 30, 2020, and authorized a capital expenditure of \$3,507,916. The current application proposes a capital cost increase of \$1,901,804, a 35% increase over the previously approved capital expenditure, for a total combined expenditure of \$5,409,720. DUHS states that development of this project was delayed due to the onset of COVID-19 which affected operational and financial priorities and complicated construction projects due to supply and labor issues. Equipment and furniture costs are also higher now due to inflation.

Patient Origin

In Project ID# J-11934-20, 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 affect that determination.

Analysis of Need

In Section Q, Form F.1 and F.1b, the applicant provides a summary of the capital cost approved in Project ID# J-11934-20, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

Duke Gastroenterology of Raleigh – Previously Approved & Proposed Capital Cost			
	Previously Approved (J-11934-20)	New Combined Total Projected Capital Cost	Difference (J-12438-23)
Construction/Renovation Contract(s)	\$1,600,000	\$2,400,000	\$800,000
Architect/Engineering Fees	\$150,000	\$354,000	\$204,000
Medical Equipment	\$1,493,433	\$1,600,000	\$106,567
Non-Medical Equipment	\$169,483	\$450,000	\$280,517
Furniture	\$0	\$200,000	\$200,000
Consulting Fees	\$55,000	\$0	(\$55,000)
Other (Contingency)	\$40,000	\$405,000	\$365,000
Total Capital Cost	\$3,507,916	\$5,409,000	\$1,901,084

In Section C, pages 38-40, the applicant explains why it believes the proposed increase in capital cost is necessary to develop the proposed project:

- Following the issuance of the CON for Project ID# J-11934-20, construction was delayed due to the onset of COVID-19 pandemic.
- The COVID-19 pandemic caused a series of extenuating circumstances:
 - Increased construction costs due to supply chain and labor issues;
 - Substantially impacted operational and financial priorities;
 - Increased equipment and furniture costs due to inflation

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

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

Projected Utilization

In Section C, page 40, the applicant confirms that projected utilization is not expected to be different from what was projected in the previously approved project. In Project ID# J-11934-20, the Agency determined the applicant had adequately identified the projected utilization for the facility. The applicant proposes no changes in the current application which would affect that determination.

Access to Medically Underserved Groups

The application for Project ID# J-11934-20 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 all the reasons described above.

- (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

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service in this application. 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 cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

In Section E, page 46, the applicant states that the needs for the project originally identified still exist. Specifically, the applicant states:

“DUHS is committed to completing this project, as the needs for the project originally identified still exist.... While DUHS will continue to make all reasonable efforts to control construction costs, the increased construction costs reflect national inflationary trends.”

The applicant adequately demonstrates that the cost overrun 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# J-11934-20.
- 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.

Conclusion

The Agency reviewed the:

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

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

- 1. Duke Health Integrated Practice, Inc., and Duke University Health System, Inc. (hereinafter known collectively as the certificate holder) shall materially comply with the representations in this application.**
 - 2. The certificate holder shall develop a new ambulatory surgical facility with no more than four gastroenterology (GI) endoscopy procedure rooms, upon completion of this project and Project ID# J-11934-20.**
 - 3. The total combined capital expenditure for this project and Project ID# J-11934-20 is \$5,409,720, an increase of \$1,901,804 over the previously approved capital expenditure of \$3,507,916 previously approved in Project ID# J-11934-20.**
 - 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on July 1, 2024.**
 - 5. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

Capital and Working Capital Costs

The certificate of need for Project ID# J-11934-20 approved a capital expenditure of \$3,507,916. The applicant states that, to develop the previously approved project, it requires a total capital expenditure of \$5,409,720, which is 35.15% over the originally approved capital expenditure, which does not exceed the 115% statutory limit for capital expenditures in an approved project.

The following table compares the capital cost approved in Project ID# J-11934-20, the changes proposed in this application, and the new projected capital costs, as reported on Form F.1b in Section Q.

Duke Gastroenterology of Raleigh – Previously Approved & Proposed Capital Cost			
	Previously Approved (J-11934-20)	New Combined Total Projected Capital Cost	Difference (J-12438-23)
Construction/Renovation Contract(s)	\$1,600,000	\$2,400,000	\$800,000
Architect/Engineering Fees	\$150,000	\$354,000	\$204,000
Medical Equipment	\$1,493,433	\$1,600,000	\$106,567
Non-Medical Equipment	\$169,483	\$450,000	\$280,517
Furniture	\$0	\$200,000	\$200,000
Consulting Fees	\$55,000	\$0	(\$55,000)
Other (Contingency)	\$40,000	\$405,000	\$365,000
Total Capital Cost	\$3,507,916	\$5,409,000	\$1,901,084

In Section C, pages 38-40, the applicant explains why the proposed increase in capital cost is necessary to develop the proposed project. Construction for the two pharmacy components was delayed due to the COVID-19 pandemic which dramatically impacted operational and financial priorities, and complicated construction projects due to supply chain and labor issues. The delays resulted in increased equipment and furniture costs due to inflation.

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

- The applicant provides detailed explanations about what the proposed increases in capital costs are to justify the proposed increases,
- The applicant explains why the updates to the design are necessary to improve the efficiency and quality of the proposed services.
- The applicant considers the impact of factors such as inflation and interest costs due to the increased timetable to develop the proposed project.

Availability of Funds

In Project ID# J-11934-20, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount of \$3,507,916. The current application proposes a capital cost increase of \$1,901,804 over the previously approved capital cost. In Section F.5, page 53, the applicant states that the increase will be covered by accumulated reserves in the amount \$1,901,804. Total working capital does not change.

Exhibit F.5(a) contains a letter dated October 10, 2023, from the Interim Chief Financial Officer, Treasurer for Duke University Health System stating that DUHS has as much as \$8,000,000 in accumulated reserves for the completion of these projects including the funds originally committed for this project and additional funds now committed for the cost overrun. Exhibit F.5(b) contains audited consolidated financial statements for June 30, 2023 and 2022. Per this documentation, DUHS has adequate cash and assets to fund the original CON-approved costs and the proposed increase in the projected capital and working capital cost. The applicant adequately demonstrates the availability of sufficient funds for the original CON-approved costs and the proposed increase in the projected capital and working capital cost based on the following:

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

Financial Feasibility

In Project ID# J-11934-20, the applicant projected revenues would exceed operating expenses during the first full fiscal year of operation following project completion. The Agency determined Project ID# J-11934-20 had demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges.

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses beginning in FY 7/1/27- 6/30/28, the third full fiscal year following completion of the project, as shown in the table below.

Duke University Health System ('000s)	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
	FY 2026	FY 2027	FY 2028
Total Gross Revenues	\$20,330,258	\$21,163,103	\$22,029,654
Total Net Revenue	\$6,532,431	\$6,797,120	\$7,070,364
Total Operating Costs	\$6,718,955	\$6,889,770	\$7,061,331
Net Income	(\$186,523)	(\$92,650)	\$9,032

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2(b) 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.
- In Section C, page 40, the applicant confirms that projected utilization is not expected to be different from what was projected in the previously approved project. In Project ID# J-11934-20, the Agency determined the applicant had adequately identified the projected utilization for the facility. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital 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.

C

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

On page 139, the 2023 SMFP defines the service area for NF beds as “*the county in which the bed is located.*” Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 56, the applicant states it does not propose to add any service components or services in this application that were not previously approved in Project ID# J-11934-20.

Project ID# J-11934-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

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 described above.

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

C

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

The application for Project ID# J-11934-20 adequately demonstrated the availability of resources, including health manpower and management personnel to provide the proposed services and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

- (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 for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

The application for Project ID# J-11934-20 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 and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

- (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 for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

In Section K, page 64, the applicant states that the costs of completing this project have increased from what was approved in Project ID# J-11934-20 due to COVID-19. The applicant states it made no changes in design and construction plans. The applicant provides line drawings in Exhibit K.5-2.

On page 64, the applicant states that the proposal will not increase the costs and charges to the public from that approved in Project ID# J-11934-20. The applicant provides documentation of the revised costs in Exhibit K.5-3.

Project ID# J-11934-20 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

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 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

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

Project ID# J-11934-20 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
- Information publicly available during the review and used by the Agency

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

- (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

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

Project ID# J-11934-20 was found 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

- Information publicly available during the review and used by the Agency

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

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

C

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

Project ID# J-11934-20 was found 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
- Information publicly available during the review and used by the Agency

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

- (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

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

Project ID# J-11934-20 was found 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
- Information publicly available during the review and used by the Agency

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

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

C

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

In Section M, page 71, the applicant states the proposed cost overrun will not result in any changes to the accommodation of clinical needs of area health professional training programs.

Project ID# J-11934-20 adequately demonstrated that the proposed health services will accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes a cost overrun for Project J-11934-20 (develop a new ambulatory surgical facility with four GI endoscopy procedure rooms).

The application for Project ID# J-11934-20 adequately demonstrated the expected effects of the proposed services on competition and how any enhanced competition would have a positive impact on cost-effectiveness, quality, and access to the services proposed. The applicant proposes no changes in this application which would affect that determination.

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 reasons described 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

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

In Section O, page 74, the applicant states that, during the 18 months immediately preceding submission of the application, they have no knowledge of incidents related to quality of care at any of its facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all four 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 Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100 were not applicable to Project ID #F-11934-20 because that project did not propose to add new ORs to the existing OR inventory in Wake County. The current proposal also does not propose to add new ORs to the existing OR inventory in Wake County. Therefore, there are no administrative rules applicable to this review.