

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2021

Findings Date: May 27, 2021

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: F-12025-21

Facility: Atrium Health Surgery Center – Huntersville

FID #: 170239

County: Mecklenburg

Applicants: Atrium Health Huntersville ASC, LLC

The Charlotte-Mecklenburg Hospital Authority

Project: Cost overrun for Project I.D. #F-11349-17 (convert facility from a hospital-based outpatient surgery center to a separately-licensed freestanding ASF)

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

The Charlotte-Mecklenburg Hospital Authority (“CMHA”) was issued a certificate of need on August 29, 2017 to develop Atrium Health Surgery Center – Huntersville (AHSC-Huntersville) by converting a hospital-based outpatient surgery center located on the campus of Atrium Health University City (AH University City) into a separately licensed ambulatory surgical facility (ASF). CMHA was the sole applicant listed on the certificate of need. The approved capital expenditure on the certificate of need was \$355,000.

In this application, CMHA is joined by an additional applicant – Atrium Health Huntersville ASC, LLC (collectively referred to as “Atrium” or “the applicant”), a wholly-owned subsidiary of CMHA. In this application, ownership of AHSC-Huntersville will transfer to Atrium Health Huntersville ASC, LLC and the applicant proposes a cost overrun of \$1,392,300.

The applicant does not propose to:

- develop any beds or services or acquire any medical equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2021 SMFP

Therefore, Criterion (1) is not applicable to this review.

(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 ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

In Section A, page 22, the applicant states:

“...the reorganization of ownership to Atrium Health Huntersville ASC, LLC does not materially change the ownership of the facility outside of CMHA wholly-controlled entities.”

N.C.G.S. §131E-181(a) states:

“A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).”

N.C.G.S. §131E-189(c) states:

“The Department may immediately withdraw any certificate of need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. Transfers resulting from...other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause.”

CMHA, the sole applicant and certificate holder for Project I.D. #F-11349-17, proposes to transfer ownership or control of the project and the certificate of need to a different entity.

While the overall corporate ownership of AHSC-Huntersville will not change, CMHA proposes a change in direct ownership and control of the facility, project, and the certificate of need issued pursuant to Project I.D. #F-11349-17 prior to the completion of the project or operation of the facility. In supplemental information requested by the Agency, CMHA states the reason it proposes to transfer ownership of the existing project and certificate of need is to allow for potential opportunities for physician ownership in AHSC-Huntersville. CMHA states physician ownership would not be an option if CMHA retained direct ownership of the facility and states it plans to retain majority ownership in AHSC-Huntersville through the subsidiary entity.

Based on the information provided in the application as submitted and the supplemental information requested by the Agency, the Agency finds that CMHA has provided prior written notice of its intent to transfer ownership of AHSC-Huntersville and the certificate of need for Project I.D. #F-11349-17 and that good cause exists for the transfer.

Patient Origin

On page 49, the 2021 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 55 of the 2021 SMFP shows Mecklenburg County as its own OR service area. Thus, the service area for this project is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 45, the applicant states there are no changes to the projected patient origin approved in Project I.D. #F-11349-17 because there are no changes to the service components or geographic area of patient origin that was approved in Project I.D. #F-11349-17.

Project I.D. #F-11349-17 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Analysis of Need

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project I.D. #F-11349-17, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

Comparison of Capital Expenditures			
	Project I.D. #F-11349-17	New Proposed	New Total
Construction/Renovation Contracts	\$250,000	\$994,400	\$1,244,400
Architect/Engineering Fees	\$25,000	\$161,000	\$186,000
Furniture	\$0	\$18,100	\$18,100
Consultant Fees	\$55,000	\$50,000	\$105,000
Other	\$25,000	\$168,800	\$193,800
Total	\$355,000	\$1,392,300	\$1,747,300

In Section C, pages 42-46, the applicant explains why it believes the cost increase is necessary to serve the patients it proposes to serve, which are summarized below.

The applicant states the costs have increased from what was previously approved in Project I.D. #F-11349-17 for the following reasons:

- **Construction Costs:** the applicant states construction costs increased because of design modifications required by the Construction Section to bring the space up to code requirements, including items like enclosing and fire rating storage rooms as well as requirements for medical gas station outlets and vacuum station inlets, all of which are necessary for the development of the proposed project.
- **Architect and Engineering Fees:** the applicant states architect and engineering fees increased because of the time between when the certificate of need for the previous application was approved in 2017 and the present, as well as engineering analysis and the design modifications which increased the construction cost.
- **Furniture Costs:** the applicant states these costs are “move management” costs and not actual new furniture.
- **Consultant Fees:** the applicant states consultant fees increased due to the necessity of filing the cost overrun application and the associated legal and CON fees.
- **Other Fees:** the applicant states the other fees include overhead, contingency, and internal allocation. The applicant states these fees increased to support the proposed project.

The applicant provided updated floor plans and line drawings showing the proposed design changes in Exhibit C.8-1.

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

- The applicant explains in detail the necessity for the increase in capital cost.
- The applicant explains why the changes to design that are proposed (and the accompanying cost increases) are necessary to develop the proposed project in a manner compliant with the building codes.
- The applicant provides line drawings of the proposed changes in Exhibit C.8-1.

Projected Utilization

In Section C, pages 45-46, the applicant states:

“..., this cost overrun proposal in and of itself will not result in any change to projected utilization as it does not involve any change in service components from the previously approved application. This position is consistent with Agency Findings issued on January 26, 2021 in the conditional approval of Project ID # E-11987-20,

which was a cost overrun for previously approved Project ID # E-11298-17 to develop a new separately licensed ASF through the conversion of an existing hospital-based outpatient surgery center in Burke County. ...

...

Consistent with the Agency Findings excerpted above, Atrium Health Huntersville ASC, LLC believes that it is not required to demonstrate a second time the need to develop the new, separately licensed ASF it was approved to develop pursuant to Project ID # F-11349-17 nor is it necessary to provide revised projected utilization to demonstrate the need it has for the proposed increase in projected capital costs to develop the previously approved project.” (emphasis in original)

Agency findings for different applications involving different facts are not binding precedent on the Agency. While the application referenced above and the current application both involve Atrium-related facilities, there are numerous facts that are different between the two applications. Further, there may be times when updated projected utilization is necessary to demonstrate need for a proposed cost overrun. While the application under review does not need updated projected utilization to demonstrate the need for this proposed project, that is based on an analysis of the information in this application as submitted and the facts of this situation and not because a previous set of findings determined a different project with different facts did not need updated projected utilization.

On page 46, the applicant states:

“However, out of an abundance of caution, Atrium Health Huntersville ASC, LLC has elected to provide updated utilization projections in this cost overrun application for no reason other than to be consistent with more recent operating room projections for Atrium Health Huntersville Surgery that were included in a November 2020 CON submission that is currently under review, as discussed in Form C Assumptions and Methodology. The updated utilization projections included in this cost overrun application are not provided in an attempt to demonstrate again the need for the project that was approved pursuant to Project ID # F-11347-17. [sic]”

On Form C.3b in Section Q, the applicant projected utilization for the first three fiscal years of operation following project completion, as shown in the table below.

Projected Utilization – AHSC-Huntersville				
	Partial FY (Apr – Dec 2022)	FY 1 – CY 2023	FY 2 – CY 2024	FY 3 – CY 2025
# of ORs	1	1	1	1
# of Surgical Cases	734	998	1,019	1,040
Outpatient Case Time (1)	39.5	39.5	39.5	39.5
Surgical Hours (2)	483	657	671	685
Group Assignment	5	5	5	5
Standard Hours/OR (3)	1,312	1,312	1,312	1,312
# of ORs Needed (4)	0.37	0.50	0.51	0.52
# of Procedure Rooms	3	3	3	3
# of Procedures	825	1,123	1,147	1,171

- (1) The Final Case Time in minutes for new Group 5 facilities in the 2021 SMFP.
 (2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
 (3) From Table 6B in the 2021 SMFP.
 (4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant states it used the same assumptions and methodology it used in Project I.D. #F-12008-20, submitted to the Agency on November 16, 2020 and which required the applicant to project utilization for all Atrium ORs in Mecklenburg County through CY 2030.
- The applicant calculated CY 2020 “normalized” utilization for AHSC-Huntersville as the starting point of projected utilization. The applicant states it calculated the “normalized” utilization by calculating the historical utilization by month of the year, using year-to-date utilization through September 2020, and using the data and calculations to annualize year-to-date volume. The applicant states it chose this approach rather than averaging the year-to-date utilization by month and multiplying it by 12 months to avoid possible over- or underrepresentation of utilization due to impacts of the pandemic.
- The applicant adjusted its CY 2020 “normalized” utilization by shifting 315 surgical cases to procedure rooms based on historical shifts after the completion of Project I.D. #F-11106-15, which relocated one OR to Charlotte Surgery Center – Wendover.
- The applicant calculated the CY 2016-2019 3-year Compound Annual Growth Rate (CAGR) for surgical cases at AHSC-Huntersville. The 3-year CAGR was 2.1 percent.
- The applicant applied the 2.1 percent growth rate to project future surgical cases.
- The applicant used the 2021 SMFP Group 5 Facility Final Case Time of 39.5 minutes. The applicant states it determined the facility would be a Group 5 facility based on historical OR utilization by specialty.

- The applicant projected procedure room cases by applying the same 2.1 percent growth rate to procedures as it did to surgical cases. The applicant states growth in procedure room cases between CY 2017 and CY 2020 “normalized” had a CAGR of 72.1 percent.

The following table illustrates projected utilization at AHSC-Huntersville.

AHSC-Huntersville Projected OR Utilization				
	PFY Apr-Dec 2022	CY 2023	CY 2024	CY 2025
Total Outpatient Cases	734	998	1,019	1,040
Final Outpatient Case Time (1)	39.5	39.5	39.5	39.5
Total Surgical Hours (2)	483	657	671	685
Average Annual Operating Hours – Group 5 (3)	1,312	1,312	1,312	1,312
Number of ORs Needed (4)	0.37	0.50	0.51	0.52
Number of Existing/Approved ORs	1	1	1	1
(Surplus) / Deficit	(0.63)	(0.50)	(0.49)	(0.48)
Number of Procedure Rooms	3	3	3	3
Number of Procedures	825	1,123	1,147	1,171

Source: Section Q, Form C Methodology and Assumptions

- (1) The Final Case Time in minutes for new Group 5 facilities in the 2021 SMFP.
- (2) Total Hours equals Surgical Cases multiplied by the Average Case Time, then divided by 60.
- (3) From Table 6B in the 2021 SMFP.
- (4) # of ORs Needed equals Surgical Hours divided by the Standard Hours per OR per Year.

As previously stated, in this specific project under review, updated projections for utilizations are not necessary to demonstrate the need for the proposed cost overrun. Nonetheless, projected utilization is reasonable and adequately supported based on the following:

- The applicant relies on the historical experience at the existing facility to project utilization.
- The applicant uses a lower projected growth rate for procedure room cases than the historical growth rate.
- The applicant uses a lower surgical case time than the historical case time.

Access to Medically Underserved Groups

In Section C, page 47, the applicant states it projects no changes to the representations it made in the prior application about providing access to medically underserved groups. The applicant states the applicant is only necessary due to the increase in cost to develop the previously approved project.

Project I.D. #F-11349-17 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.

- (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 proposes a cost overrun and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service in this application.

Further, Project I.D. #F-11349-17 was conforming with this criterion and the applicant proposes no changes in the application as submitted 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 ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

In Section E, pages 53-54, 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. The applicant states the only real alternative to the proposed project was to cease development of the previously approved Project I.D. #F-11349-17. The applicant states that alternative would result in the existing OR remaining under the hospital license and that would prevent the development of a freestanding ASF that could potentially

lower costs to patients and third-party payors. The applicant states that because it would not allow for the development of a freestanding ASF, this was not an effective alternative. The applicant states that its proposal is the most effective alternative because it is already accessible to patients, is already physically separate from all other hospital-based services on the campus, and will allow for development of an ASF with reduced charges for patients and third-party payors because the OR will not be hospital-based.

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 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
- Supplemental information requested by the Agency
- 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. Atrium Health Huntersville ASC, LLC and The Charlotte-Mecklenburg Hospital Authority (hereinafter certificate holder) shall materially comply with the representations in this application, the representations in Project I.D. #F-11349-17, and any supplemental information. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall develop a new freestanding ambulatory surgical facility, Atrium Health Surgery Center – Huntersville, by separately licensing 1 existing OR currently licensed as part of Atrium Health University City.**
- 3. Upon completion of the project, Atrium Health Surgery Center – Huntersville shall be licensed for no more than 1 OR.**
- 4. Upon completion of the project, the certificate holder shall take the necessary steps to delicense 1 OR from Atrium Health University City.**

5. **The approved combined capital expenditure for both Project I.D. #F-11349-17 and this project is \$1,747,300, an increase of \$1,392,300 over the previously approved capital expenditure of \$355,000 in Project I.D. #F-11349-17.**
6. **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.**
7. **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.**
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 the application 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. **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.**
10. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holders 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.

11. 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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

Capital and Working Capital Costs

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project I.D. #F-11349-17, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

Comparison of Capital Expenditures			
	Project I.D. #F-11349-17	New Proposed	New Total
Construction/Renovation Contracts	\$250,000	\$994,400	\$1,244,400
Architect/Engineering Fees	\$25,000	\$161,000	\$186,000
Furniture	\$0	\$18,100	\$18,100
Consultant Fees	\$55,000	\$50,000	\$105,000
Other	\$25,000	\$168,800	\$193,800
Total	\$355,000	\$1,392,300	\$1,747,300

In Section C, pages 42-44, and immediately following Form F.1b in Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant explains in detail the items in each category projecting an increase from the originally approved capital expenditure.
- The applicant provides floor plans showing updated designs in Exhibit C.8-1.
- The applicant provides a certified cost estimate signed by an architect in Exhibit F.5-1.

In Section F, page 66, the applicant states it had not projected any working capital costs in Project I.D. #F-11349-17 because it had assumed CMHA would retain ownership and there would not be any initial operating period or start-up expenses. Because this project proposes to change the ownership of AHSC-Huntersville, the applicant provided projected start-up costs of \$276,759 and projected initial operating costs of \$968,656 for a total projected working capital cost of \$1,245,415. In supplemental information requested by the Agency, 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 explains the factors used in projecting the estimated start-up costs and the time period involved.
- The applicant explains the factors used in projecting the initial operating expenses, including that the projections are based on the highest cumulative negative cash flow, and the time period involved.

Availability of Funds

In Section F, pages 65-67, the applicant states the projected increase in capital costs and newly projected working capital costs will be funded with Atrium's accumulated reserves.

In Exhibit F.5-2, the applicant provides a letter dated February 15, 2021 from the Executive Vice President and Chief Financial Officer for Atrium, stating that Atrium has sufficient accumulated reserves to fund the projected capital and working capital costs and committing to providing that funding to develop the proposed project.

Exhibit F.5-3 contains a copy of Atrium's Basic Financial Statements and Other Financial Information for the year ending December 31, 2019. According to the Basic Financial Statements, as of December 31, 2019, Atrium had adequate cash and assets to fund all the capital needs of the proposed project.

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

- The applicant provides a letter from the appropriate Atrium official confirming the availability of the funding proposed for the capital and working capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. In Form F.2b, the applicant projects revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – AHSC-Huntersville			
	1st Full FY CY 2023	2nd Full FY CY 2024	3rd Full FY CY 2025
Total Combined OR/Procedure Room Cases	2,121	2,166	2,211
Total Gross Revenues (Charges)	\$10,609,644	\$11,154,853	\$11,728,079
Total Net Revenue	\$4,112,260	\$4,323,537	\$4,545,669
Total Net Revenue per Case	\$1,939	\$1,996	\$2,056
Total Operating Expenses (Costs)	\$3,719,626	\$3,850,188	\$3,985,736
Total Operating Expenses per Case	\$1,754	\$1,778	\$1,803
Net Income/(Losses)	\$392,634	\$473,349	\$559,933

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately prior to 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 details the sources of data used to project revenues and expenses.
- The applicant based its projections on its own historical experience.
- 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
- Supplemental information requested by the Agency
- 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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

On page 49, the 2021 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 55 of the 2021 SMFP shows Mecklenburg County as its own OR service area. Thus, the service area for this project is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 68, the applicant states it does not propose to add any service components or services in this application that were not previously approved in Project I.D. #F-11349-17.

Project I.D. #F-11349-17 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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

AHSC-Huntersville Projected Staffing			
Position	CY 2023	CY 2024	CY 2025
Registered Nurses	7.26	7.26	7.26
Certified Nurse Aides/Nursing Assistants	0.49	0.49	0.49
Clerical	0.88	0.88	0.88
Technician	1.02	1.02	1.02
Registered Technician	0.05	0.05	0.05
Supervisory	0.51	0.51	0.51
Enviro/Plant/Food Service	0.41	0.41	0.41
Unit Secretary	0.05	0.05	0.05
Total Staffing	10.67	10.67	10.67

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.3b, which is found in Section Q.

In Section H, page 70, the applicant states it provided updated projected staffing due to the updated utilization projections.

Additionally, Project I.D. #F-11349-17 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.

- (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 ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

Ancillary and Support Services

In Section I, page 72, the applicant states the proposed ownership change and cost overrun will not result in changes to the provision of necessary ancillary and support services. The applicant states:

“The proposed cost overrun project will not result in any changes to the provision of necessary ancillary and support services. As previously discussed, the new separately licensed ASF approved to be developed pursuant to Project ID # F-11349-17 will be owned and operated by Atrium Health Huntersville ASC, LLC rather than CMHA. However, Atrium Health Huntersville ASC, LLC is wholly owned by CMHA; because CMHA is the sole member of Atrium Health Huntersville ASC, LLC, the ownership of the surgery center is not changed outside of CMHA wholly-controlled entities. As such, the proposed project will not result to [sic] any change to the availability of ancillary and support services demonstrated in the previously approved Project ID # F-11349-17.”

Project I.D. #F-11349-17 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Coordination

In Section I, page 73, the applicant states the proposed cost overrun project will not result in changes to coordination with the existing healthcare system. The applicant states:

“...the proposed cost overrun application will not result in changes to coordination with the existing healthcare system. As previously discussed, Atrium Health Huntersville Surgery is currently operated under the acute care hospital license of Atrium Health University City, which has established relationships with area healthcare providers. Atrium Health Huntersville ASC, LLC is wholly owned by CMHA; because CMHA is the sole member of Atrium Health Huntersville ASC, LLC, the ownership of the surgery center is not changed outside of CMHA wholly-controlled entities. As such, the proposed project will not result in changes to these existing relationships as demonstrated in the previously approved Project ID # F-11349-17.”

Project I.D. #F-11349-17 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.

- (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 ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

In Section K, page 78, the applicant states that there have been no changes to the size of the facility from those approved in Project I.D. #F-11349-17. The applicant states it made changes in design and construction plans to meet applicable codes and regulations. The applicant provides line drawings in Exhibit C.8-1.

On page 78, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the need to construct a facility that will meet applicable building codes and regulations.

On pages 78-79, 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 there have been no material changes to the answers it provided in Project I.D. #F-11349-17 regarding this issue.
- The applicant states the project will represent a low-cost alternative for the provision of outpatient services, and because the facility will be part of the larger CMHA system, it will benefit from cost savings measures due to economies of scale.

On pages 79-80, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Project I.D. #F-11349-17 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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

Project I.D. #F-11349-17 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.

- (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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

Project I.D. #F-11349-17 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.

- (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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

In Section L, page 86, the applicant states the proposed cost overrun project will not result in any changes to projected access by medically underserved groups.

Project I.D. #F-11349-17 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.

- (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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

In Section L, page 86, the applicant states the proposed cost overrun project will not result in any changes to projected access by medically underserved groups.

Project I.D. #F-11349-17 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.

- (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 and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

In Section M, page 87, the applicant states the proposed cost overrun project will not result in any changes to the accommodation of clinical needs of area health professional training programs. The applicant states:

“As an existing healthcare facility in the area, Atrium Health Huntersville Surgery, through CMHA, has established affiliations with many health professional training

programs. The approval of this cost overrun application is not expected to have any impact on those relationships.”

Project I.D. #F-11349-17 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 applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(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 ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

On page 49, the 2021 SMFP defines the service area for ORs as “...*the single or multicounty grouping shown in Figure 6.1.*” Figure 6.1 on page 55 of the 2021 SMFP shows Mecklenburg County as its own OR service area. Thus, the service area for this project is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section N, pages 88-89, the applicant states the proposed cost overrun project will not result in changes to the expected effects of the original proposal on competition in the proposed service area. On page 89, the applicant states:

“The proposed cost overrun project will continue to stimulate competition and will appropriately balance access, quality, and cost-effectiveness of health services for Mecklenburg County patients.”

In Section N, page 89, the applicant states the proposed cost overrun project will not result in changes from the original proposal to the impact of enhanced competition on the cost-effectiveness, quality, and access by medically underserved groups.

Project I.D. #F-11349-17 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.

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

C

The applicant proposes a cost overrun and change of ownership to AHSC-Huntersville, approved in Project I.D. #F-11349-17 to develop a separately licensed ASF with 1 OR on the campus of AH University City.

On Form O in Section Q, the applicant identifies hospitals and ASFs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified 13 hospitals and 6 ASFs in North Carolina.

In Section O, pages 91-92, the applicant states that during the 18 months immediately preceding the submittal of the application, there was a single incident related to quality of care at Atrium Health Cleveland which resulted in a finding of immediate jeopardy and a termination action. The applicant states that it submitted documentation and at a subsequent review, the deficiency was determined to be corrected and The Centers for Medicare and Medicaid Services withdrew the immediate jeopardy termination action. Supporting documentation is provided in Exhibit O.4. 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, there was one incident related

to quality of care that occurred in any of the 19 hospitals and ASFs. 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 19 hospitals and ASFs, 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, as published at the time, were applicable to Project I.D. #F-11349-17, and that project was conforming with all applicable administrative rules. The administrative rules have since changed and there is nothing in the proposed application which would make the current Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100 applicable to the current review. Therefore, there are no administrative rules applicable to this review.