

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 30, 2020

Findings Date: September 30, 2020

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

Project ID #: F-11906-20

Facility: Gateway Surgery Center

FID #: 060202

County: Cabarrus

Applicant: Gateway Ambulatory Surgery Center, LLC

Project: Acquire and relocate no more than 2 ORs from Atrium Health Cabarrus to its existing ASF in Concord for a total of no more than 6 ORs

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Gateway Ambulatory Surgery Center, LLC (GASC) proposes to relocate two operating rooms (ORs) from Atrium Health Cabarrus (AH Cabarrus) to Gateway Surgery Center (Gateway). Gateway is an existing freestanding ambulatory surgical facility (ASF) with four ORs. Upon completion of the proposed project, Gateway will be licensed for a total of six ORs.

Need Determination

The applicant does not propose to add any beds, services, or medical equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2020 SMFP applicable to the review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2020 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are 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 proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, pages 14-15, the applicant provides a written statement of its plan to assure improved energy efficiency and water conservation, including the use of LED lighting with occupancy sensors, low-flow plumbing, and a digital building automation system. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficient and water conservation.

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 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate two ORs from AH Cabarrus to Gateway, its existing ASF with four ORs, for a total of six ORs upon project completion.

Gateway is currently licensed for four ORs and two GI endoscopy rooms. On May 6, 2020, the Agency determined that a request from Gateway to renovate existing space to develop two procedure rooms was exempt from review pursuant to N.C. Gen. Stat. §131E-184(g). The applicant proposes to develop the two relocated ORs in the two procedure rooms it was approved to develop. Upon completion of the proposed project and the renovations that are exempt from review, Gateway will be licensed for six ORs, two GI endoscopy rooms, and no procedure rooms. In Section C, page 17, the applicant states it included the capital costs associated with developing the procedure rooms where the ORs will relocate to in its proposed capital expenditure.

Patient Origin

On page 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” In Figure 6.1 on page 57 of the 2020 SMFP, Cabarrus County is shown as a single county OR service area. Thus, the service area for this review consists of Cabarrus County. Facilities may also serve residents of counties not included in the service area.

The tables below show current and projected patient origin.

Current (FFY 2019) & Projected (CYs 2022-2024) Patient Origin – Gateway ORs								
County	Current (FFY 2019)		Projected FY 1 (CY 2022)		Projected FY 2 (CY 2023)		Projected FY 3 (CY 2024)	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Cabarrus	4,344	59.84%	4,619	59.84%	4,707	59.84%	4,795	59.84%
Mecklenburg	560	7.71%	595	7.71%	607	7.71%	618	7.71%
Rowan	1,263	17.40%	1,343	17.40%	1,369	17.40%	1,394	17.40%
Stanly	794	10.94%	844	10.94%	860	10.94%	876	10.94%
Others	298	4.11%	317	4.11%	323	4.11%	329	4.11%
Total	7,259	100.00%	7,718	100.00%	7,866	100.00%	8,013	100.00%

Source: Section C, pages 21-22

Note: "Others" includes patients from other NC counties and other states

Current (FFY 2019) & Projected (CYs 2022-2024) Patient Origin – Gateway GI Endo Rooms								
County	Current (FFY 2019)		Projected FY 1 (CY 2022)		Projected FY 2 (CY 2023)		Projected FY 3 (CY 2024)	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Cabarrus	2,563	63.63%	2,883	63.63%	2,941	63.63%	3,000	63.63%
Mecklenburg	203	5.04%	228	5.04%	233	5.04%	238	5.04%
Rowan	692	17.18%	778	17.18%	794	17.18%	810	17.18%
Stanly	415	10.30%	467	10.30%	476	10.30%	486	10.30%
Others	155	3.85%	174	3.85%	178	3.85%	181	3.85%
Total	4,028	100.00%	4,530	100.00%	4,622	100.00%	4,715	100.00%

Source: Section C, pages 21 and 23

Note: "Others" includes patients from other NC counties and other states

In Section C, page 23, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical patient origin.

Analysis of Need

In Section C, pages 24-35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services:

- There is a need for increased access to ASF ORs in the applicant's primary service area (which it defines as Cabarrus, Mecklenburg, Rowan, and Stanly counties). The applicant states that, between 2015 and 2019, while statewide ASF OR cases grew at a rate of 1.6 percent per year, Gateway's OR cases grew at a rate of 2.3 percent per year. The national average of freestanding ASF ORs is 5.2 per 100,000 people (as of 2017); however, in 2019, the four counties that make up the applicant's primary service area had an average of 2.6 freestanding ASF ORs per 100,000 people. The applicant states Gateway is the only freestanding multispecialty ASF in Cabarrus County, and two adjacent counties— Rowan and Stanly counties – have no freestanding ASFs at all. (pages 24-26)
- The applicant states surgical cases performed in ASF ORs are generally less expensive than those performed in hospital ORs. Additionally, insurance companies, including Medicare, pay lower reimbursement rates for surgical cases performed in ASF ORs, which lowers the cost of care for patients. (pages 27-28)

- The applicant states the population in Cabarrus, Mecklenburg, Rowan, and Stanly counties is among the fastest growing in the state; the population in those four counties will grow at a rate of 1.7 percent per year over the next four years, according to the NC Office of State Budget and Management (NC OSBM). Additionally, the population groups that make up the largest number of ASF patients comprise approximately 25 percent of the area population. The applicant further states that according to NC OSBM, the population of people over age 65, which is the typical age range for the two most frequent surgeries performed at Gateway, is growing faster than the overall population of the applicant's primary service area. (pages 28-30)
- The health status of the population of each of the four counties in the primary service area shows many residents have health conditions which require increased access to ASFs. The applicant states Gateway is at the western edge of a large portion of Cabarrus County designated by the US Department of Health and Human Services as a Medically Underserved Area. The applicant states both Rowan and Stanly counties also have areas designated as Medically Underserved Areas by the US Department of Health and Human Services. (pages 31-34)
- During the last two years, the SMFP has calculated projected deficits in ORs at Gateway and projected surpluses in ORs at AH Cabarrus; the applicant states relocating two ORs will help balance the deficits and surpluses. The applicant states patients find Gateway's location accessible and relocating the ORs to Gateway would reduce the amount of time needed to increase access to ASF ORs compared with developing a new facility. (page 35)

The information is reasonable and adequately supported for the following reasons:

- The applicant provides reliable local, statewide, and national sources of data and information to support its statements about the area's need for additional access to ASF ORs.
- The applicant uses information from the SMFP to support the need to relocate two ORs from AH Cabarrus to Gateway.
- The applicant provides reasonable and adequately supported information about the health status of the area population, projected population growth in the area, and potential cost savings of surgical cases performed in ASF ORs.

Projected Utilization

On Form C in Section Q, the applicant provides historical and projected utilization, as shown in the table below.

Gateway Surgery Center – Historical and Projected Utilization – CYs 2019-2024						
	Historical	Interim		Projected FYs 1-3		
	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
# GI Endoscopy Rooms	2	2	2	2	2	2
# GI Endoscopy Procedures	4,267	3,806	4,441	4,530	4,622	4,715
# GI Endoscopy Rooms Needed (1)	1.42	1.27	1.48	1.51	1.54	1.57
# of ORs	4	4	4	6	6	6
Standard Hours per OR per Year (2)	1,312	1,312	1,312	1,312	1,312	1,312
# Surgical Cases	7,368	6,533	7,571	7,718	7,866	8,013
Final Surgical Case Time (minutes) (3)	45	45	45	45	45	45
Total Surgical Hours (4)	5,526	4,900	5,678	5,789	5,900	6,010
# of ORs Needed (5)	4.21	3.73	4.33	4.41	4.50	4.58

- (1) Number of GI Endoscopy Rooms Needed equals GI Endoscopy Procedures divided by 1,500 procedures per room.
- (2) From Table 6A in the 2020 SMFP.
- (3) From Table 6B in the 2020 SMFP.
- (4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (5) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, pages 112-120, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Surgical Cases

- The applicant analyzed its historical utilization from CY 2016-2019 to determine the most appropriate growth rate to use to project utilization. The applicant considered using its 3-year Compound Annual Growth Rate (CAGR) of 2.53 percent but instead decided to use a linear trendline to project utilization.
- On page 113, the applicant states:

“The applicant then applies the trendline equation...to the years 2020 through 2024. The applicant multiplies the slope of 147.4 by the number of years since the beginning of the trendline and adds the intercept of 6,834 to estimate total projected surgical cases.”

The Project Analyst notes that the applicant’s projected annual growth rate for CYs 2020-2024 using a trendline was under two percent, which is a lower growth rate than the applicant’s historical CAGR.

- The applicant projected the impact of COVID-19 on its projected utilization for 2020 by using existing data on surgical cases from January through April 2020, projecting a reduced number of surgical cases in May 2020 based on the average number of surgical cases in March and April 2020, and assuming there would be no reduction in surgical cases due to COVID-19 from June through December 2020.
- The applicant projected its total surgical hours by multiplying its projected surgical cases by 1.19 hours, the average ambulatory case time for a Group 6 facility as listed in the 2020 SMFP. The applicant states the average ambulatory case time in the 2020 SMFP is more

in line with future surgical case times at Gateway due to renovations giving Gateway the ability to perform more complex surgical cases and due to increased time between surgical cases required for infection control as a result of COVID-19.

In Section C, page 38, the applicant states:

“CDC guidelines issued in April 2020 in response to the COVID19 pandemic recommend that facilities allow enough time between cases for the air handling system to completely clear air in the room, before initiating the terminal clean between cases.... Operating rooms typically have 15 air changes per hour. GSC adopted this guideline and other cleaning precautions in April 2020, and time between cases immediately increased by 20 to 30 minutes.” (emphasis in original)

The applicant provides supporting information about the CDC guidelines in Exhibit C.1.

- The applicant calculates its actual operational hours per year at Gateway based on its historical operating hours at Gateway and assumes a utilization capacity of 75 percent of potential hours to project any surpluses or deficits of ORs at Gateway during the first three full fiscal years of operation.

The applicant’s assumptions, methodology, and projected utilization for ORs are summarized in the table below.

Gateway Surgery Center – Historical and Projected Utilization – CYs 2019-2024						
	Historical	Interim		Projected FYs 1-3		
	CY 2019	CY 2020*	CY 2021	CY 2022	CY 2023	CY 2024
# of ORs	4	4	4	6	6	6
# Surgical Cases	7,368	6,533	7,571	7,718	7,866	8,013
Projected Growth Rate	<i>Linear Trendline</i>					
Final Case Time (hours) (1)	1.19	1.19	1.19	1.19	1.19	1.19
Total Surgical Hours (2)	8,768	7,774	9,009	9,184	9,361	9,535
Gateway Annual Hours of Operation	1,644	1,644	1,644	1,644	1,644	1,644
Projected Deficit/(Surplus) (3)	1.33	0.73	1.48	(0.41)	(0.31)	(0.20)

Note: There are minor discrepancies between calculations and what the applicant provides in Section Q; the correct calculations are displayed in the table above. These discrepancies did not impact the outcome of these findings in any way.

* Utilization projections for CY 2020 are calculated differently than projected utilization in other CYs due to the impact of COVID-19.

- (1) Based on Group 6 average case time from Table 6B in the 2020 SMFP.
- (2) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (3) Projected Deficit/(Surplus) equals Total Surgical Hours divided by the Standard Hours per OR per Year, which is then subtracted from the number of ORs.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant projects future growth in surgical cases based on projected growth rates that are either consistent with or lower than its own historical growth rates.

- The applicant uses its own historical experience to project the available surgical hours at Gateway.
- The applicant provides reasonable and adequately supported information to support its use of a higher surgical case time than it has historically reported when projecting utilization and provides supporting documentation in Exhibit C.1.

Access

In Section C, page 44, the applicant states:

“GASC will accept patients at GSC, regardless of gender, gender [identity], race, ethnicity, age, income, or disability status. GSC is also certified by Medicare and Medicaid and provides services to both populations. GSC has a generous charity care policy as well.”

In Section C, pages 43-44, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Gateway Medically Underserved Patients – FY 3 (CY 2024)	
Medically Underserved Groups	Percentage of OR Patients
Low income persons	14.64%
Racial and ethnic minorities	19.20%
Women	34.70%
Persons with disabilities	16.00%
Persons aged 65 and older	30.97%
Medicare beneficiaries	30.97%
Medicaid recipients	13.91%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.

- Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.
- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate two ORs from AH Cabarrus to Gateway, its existing ASF with four ORs, for a total of six ORs upon project completion.

AH Cabarrus is currently licensed for two dedicated C-Section ORs, two other dedicated inpatient ORs, 17 shared ORs, and six GI endoscopy procedure rooms. After two shared ORs are relocated from AH Cabarrus to Gateway, AH Cabarrus will convert the remaining space into two procedure rooms (for procedures other than GI endoscopies) and be licensed for 15 shared ORs instead of 17 shared ORs.

In Section D, page 51, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. On page 51, the applicant states:

“...the remaining operating room capacity will enable Atrium Health Cabarrus to meet the needs of patients. ..., the operating room capacity remaining will be more than sufficient to meet forecast demand. In the unlikely event that demand would exceed these forecasts, North Carolina Licensure policy would permit Atrium Health-Cabarrus medical staff to develop and approve policies for use of the two procedure rooms for specific surgical cases.”

On Form D in Section Q, the applicant provides historical and projected utilization of the ORs at AH Cabarrus, as shown in the table below.

AH Cabarrus – Historical and Projected OR Utilization – CYs 2019-2022				
	Historical	Interim		FY 1
	FY 2019	CY 2020	CY 2021	CY 2022
# Inpatient ORs	4	4	4	4
# Shared ORs	17	17	17	15
Total # of ORs	21	21	21	19
Inpatient Surgical Cases	5,106	5,450	6,177	6,225
Inpatient Surgical Hours (205 min) (1)	17,446	18,620	21,105	21,268
Outpatient Surgical Cases	5,459	5,122	5,538	5,583
Outpatient Surgical Hours (118.5 min) (1)	10,782	10,116	10,938	11,026
Total Surgical Hours (2)	28,227	28,735	32,043	32,294
Standard Hours per OR per Year (3)	1,755	1,755	1,755	1,755
# of ORs Needed	16.08	16.37	18.26	18.40

- (1) From Table 6B in the 2020 SMFP.
- (2) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (3) From Table 6A in the 2020 SMFP.
- (4) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, pages 121-127, the applicant provides the assumptions and methodology used to project utilization at AH Cabarrus, which are summarized below.

- The applicant analyzed historical utilization at AH Cabarrus from FY 2015-2019 to determine the most appropriate growth rate to use to project utilization. Like it did with its projections for Gateway, the applicant considered whether to use AH Cabarrus’ FY 2015-2019 historical CAGR or a linear trendline to project utilization and decided to use the historical FY 2015-2019 CAGR for AH Cabarrus. The applicant applied the historical inpatient CAGR of 0.77 percent and the historical outpatient CAGR of 0.81 percent to AH Cabarrus’ historical surgical cases. The applicant then converted its FY projections to CY projections.
- The applicant projected the impact of COVID-19 on projected utilization for 2020 by using existing data on inpatient and outpatient surgical cases from January through April 2020, projecting a reduced number of inpatient and outpatient surgical cases in May 2020 based on the average number of inpatient and outpatient surgical cases in March and April 2020, and assuming there would be no reduction in inpatient and outpatient surgical cases due to COVID-19 from June through December 2020.
- The applicant calculated any projected OR surpluses or deficits by using the average inpatient and outpatient case times from the 2020 License Renewal Application (LRA) for AH Cabarrus to project total surgical hours and then dividing the projected number of surgical hours by the Standard Hours per OR per Year for a Group 3 facility as reported in Table 6A of the 2020 SMFP.

The applicant’s assumptions, methodology, and projected utilization are summarized in the table below.

AH Cabarrus – Interim and Projected OR Utilization – CYs 2020-2024					
	Interim		Projected		
	CY 2020*	CY 2021	CY 2022	CY 2023	CY 2024
# Inpatient ORs	4	4	4	4	4
# Shared ORs	17	17	15	15	15
Total # of ORs	21	21	19	19	19
Inpatient Surgical Cases	5,450	6,177	6,225	6,273	6,321
Inpatient Surgical Cases Growth Rate	--	--	0.77%	0.77%	0.77%
Inpatient Surgical Hours (189.5 min) (1)	17,212	19,509	19,660	19,812	19,965
Outpatient Surgical Cases	5,122	5,538	5,583	5,628	5,673
Outpatient Surgical Cases Growth Rate	--	--	0.82%	0.82%	0.82%
Outpatient Surgical Hours (123.9 min) (1)	10,576	11,436	11,529	11,622	11,715
Total Surgical Hours (2)	27,788	30,946	31,189	31,433	31,680
Standard Hours per OR per Year (3)	1,755	1,755	1,755	1,755	1,755
Projected Deficit/(Surplus) (4)	(5.17)	(3.37)	(1.23)	(1.09)	(0.95)

* Utilization projections for CY 2020 are calculated differently than projected utilization in other CYs due to the impact of COVID-19.

- (1) From the 2020 LRA for AH Cabarrus.
- (2) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (3) From Table 6A in the 2020 SMFP.
- (4) Projected Deficit/(Surplus) equals Total Surgical Hours divided by the Standard Hours per OR per Year, which is then subtracted from the number of ORs.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects future growth in surgical cases based on projected growth rates that are consistent with historical growth rates.
- The applicant demonstrates adequate access will still exist at AH Cabarrus following the relocation of two shared ORs for the population presently served.

In Section D, pages 56-58, the applicant discusses the effect of the relocation on medically underserved groups and describes the access medically underserved groups currently being served by AH Cabarrus will have to both Gateway and AH Cabarrus.

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 needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion.
 - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion.
- (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 to relocate two ORs from AH Cabarrus to Gateway, its existing ASF with four ORs, for a total of six ORs upon project completion.

In Section E, pages 59-61, the applicant describes the alternatives considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states maintaining the status quo would not increase access to ASF services for the community, would not allow for more surgical options in a lower cost setting, and prevents certain patients from timely access due to block scheduling. Therefore, the applicant rejected this alternative as less effective.
- Develop Another ASF – The applicant states building a new ASF would far exceed the cost of the proposed project. Therefore, the applicant rejected this alternative as more costly.
- Expand the Size of Gateway – The applicant states expanding the square footage of the existing facility would require more renovations, more capital cost, and more operating costs, and relocating two ORs can be done without any of those additional obstacles. Therefore, the applicant rejected this alternative as more costly.
- Relocate a Different Number of ORs – The applicant states relocating one OR versus two ORs would result in an increased cost due to having to disrupt the services twice – once for each OR – rather than just once for two ORs. The applicant also states the growth in population, particularly in age groups likely to need ASF services, supports relocating two ORs now. Therefore, the applicant rejected this alternative as less effective and more costly.

On page 61, the applicant states that its proposal is the most effective alternative because it is the least costly way to meet the increasing demand for ASF services, helps maintain a patient-friendly and physician-friendly schedule, and accommodates expected utilization with increased case times.

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 application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

- 1. Gateway Ambulatory Surgery Center, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Gateway Ambulatory Surgery Center, LLC shall relocate no more than two operating rooms from Atrium Health Cabarrus to Gateway Surgery Center.**
- 3. Upon completion of the project, Gateway Surgery Center shall be licensed for no more than six operating rooms and two gastrointestinal endoscopy procedure rooms; upon completion of the project, Atrium Health Cabarrus shall be licensed for no more than two dedicated C-Section operating rooms, two dedicated inpatient operating rooms, and 15 shared operating rooms.**
- 4. Gateway Ambulatory Surgery Center, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Sections F and Q of the application and that would otherwise require a certificate of need.**
- 5. For the first three years of operation following completion of the project, Gateway Ambulatory Surgery Center, LLC 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.**
- 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, Gateway Ambulatory Surgery Center, LLC 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.**

7. Gateway Ambulatory Surgery Center, LLC 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 to relocate two ORs from AH Cabarrus to Gateway, its existing ASF with four ORs, for a total of six ORs upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 146, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contracts	\$1,075,000
Medical Equipment	\$906,884
Non-Medical Equipment	\$235,747
Financing Costs/Interest	\$23,625
A & E/Consultant Fees	\$225,000
Contingency	\$1,352,038
Total	\$3,818,295

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 66, the applicant states there will be no working capital costs because Gateway is already an operational and licensed ASF.

Availability of Funds

In Section F, page 63, the applicant states the capital cost will be funded with a loan. Exhibit F.2 contains a term sheet dated March 3, 2020 from Pinnacle Financial Partners, outlining terms of a possible loan for \$5,080,000 for the proposed project and other CON-exempt

renovations. Exhibit F.2 also includes a letter dated June 10, 2020 from a managing member of GASC, committing up to \$3.9 million of the \$5,080,000 loan to develop the proposed project. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects that revenues will exceed operating expenses during the first three full fiscal years following project completion, as shown in the table below.

Gateway OR Revenues & Operating Expenses – FYs 1-3 (CYs 2022-2024)			
	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Total Surgical Cases	7,718	7,866	8,013
Total Gross Revenues (Charges)	\$77,528,830	\$81,264,870	\$85,119,341
Total Net Revenue	\$22,178,943	\$23,723,357	\$25,320,675
Average Net Revenue per Surgical Case	\$2,874	\$3,016	\$3,160
Total Operating Expenses (Costs)	\$16,415,613	\$17,044,906	\$17,719,104
Average Operating Expense per Surgical Case	\$2,127	\$2,167	\$2,211
Net Income	\$5,763,331	\$6,678,451	\$7,601,570

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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 costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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 costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate two ORs from AH Cabarrus to Gateway, its existing ASF with four ORs, for a total of six ORs upon project completion.

On page 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” In Figure 6.1 on page 57 of the 2020 SMFP, Cabarrus County is shown as a single county OR service area. Thus, the service area for this review consists of Cabarrus County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved ORs in Cabarrus County.

Current ORs – Cabarrus County		
Facilities	# of ORs	Projected Deficit / (Surplus)
Atrium Health Cabarrus	19	(1.52)
Gateway Surgery Center	4	0.44
Eye Surgery and Laser Clinic, Inc.	2	0.58
TOTAL	25	(0.50)

Sources: Section G, page 70; 2020 SMFP, Table 6B, page 71

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ambulatory surgical services in Cabarrus County. The applicant states:

“...population growth in Cabarrus and surrounding counties, combined with population health status and increasing demand for outpatient healthcare services will result in sustained need for additional freestanding ambulatory surgery operating rooms.

This project involves relocation of operating rooms from a hospital-based outpatient department to a freestanding ambulatory surgical facility. GSC is an existing and operational multi-specialty ambulatory surgical program. The project does not introduce new operating rooms to the service area, but it will increase the number of freestanding ambulatory surgery center operating rooms.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The proposal would not result in an increase in ORs or freestanding ASFs in Cabarrus County.

- The applicant adequately demonstrates that relocating ORs to increase ASF OR capacity is needed in addition to the existing or approved ORs and ASFs in Cabarrus County.

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 based on 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

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

Gateway Current and Projected Staffing (FTEs)				
	Current	Projected		
	As of 12/31/2019	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
CRNAs	1.61	1.70	1.73	1.76
RNs - Endo	1.27	1.33	1.36	1.38
RNs - Other	1.17	1.23	1.25	1.28
RN Coordinator – Endo	1.00	1.00	1.00	1.00
RN Coordinator – Other	0.18	0.18	0.18	0.18
Endo Technicians	3.17	3.33	3.40	3.46
Aides/Orderlies – Endo	0.48	0.50	0.51	0.52
Aides/Orderlies – Other	0.18	0.19	0.20	0.20
Clerical Staff	2.77	2.91	2.97	3.03
Medical Records	0.84	0.88	0.90	0.92
Central Sterile Supply	0.56	0.59	0.60	0.61
Materials Management	0.31	0.32	0.33	0.34
Business Office	0.52	0.55	0.56	0.57
TOTAL	14.05	14.73	14.99	15.26

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, page 74, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 79, the applicant identifies the current medical director. In Exhibit I.2, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

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.

- (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 Section I, pages 76-77, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Extended Recovery
- Anesthesia
- Pre- and Post-Anesthesia, Recovery
- Sterile Processing
- Medical Direction
- Business Office
- Medical Records
- Laundry Service
- Housekeeping
- Materials Management
- Pathology
- Pharmacy

On pages 76-77, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1 and I.2.

In Section I, pages 78-79, the applicant describes the existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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

In Section K, page 81, the applicant states that the project involves renovating 2,005 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 82-83, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibits C.1, F.2, and K.3.

On page 84, 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 and provides supporting documentation in Exhibit C.4.

On page 84, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

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.

- (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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 88, the applicant provides the historical payor mix at Gateway and AH Cabarrus for the proposed services during CY 2019, as shown in the tables below.

Gateway Historical Payor Mix – CY 2019		
Payor Category	Entire Facility	ORs
Self-Pay	0.77%	1.09%
Medicare*	38.82%	30.97%
Medicaid*	10.66%	13.91%
Insurance*	48.58%	52.41%
Other**	1.18%	1.61%
Total	100.00%	100.00%

Note: On page 88, the applicant states it does not consider charity care a payor source.

*Including any managed care plans

**Other includes Workers Comp, TRICARE, VA, & other federal programs

AH Cabarrus Historical Payor Mix – CY 2019		
Payor Category	Entire Facility	ORs
Self-Pay	7.78%	5.43%
Medicare*	48.48%	50.81%
Medicaid*	13.04%	8.53%
Insurance*	27.68%	32.08%
Workers Comp	0.33%	0.48%
Other**	2.69%	2.67%
Total	100.00%	100.00%

Note: On page 88, the applicant states Atrium does not consider charity care a payor source.

*Including any managed care plans

**Other includes TRICARE, VA, & other federal programs

In Section L, page 87, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Gateway during the Last Full FY	Percentage of the Population of Cabarrus County
Female	56.6%	51.3%
Male	43.4%	48.7%
Unknown	0.0%	0.0%
64 and Younger	62.9%	86.8%
65 and Older	37.1%	13.2%
American Indian	Not Available	0.7%
Asian	Not Available	4.4%
Black or African-American	Not Available	19.0%
Native Hawaiian or Pacific Islander	Not Available	0.1%
White or Caucasian	Not Available	73.4%
Other Race	Not Available	2.4%
Declined / Unavailable	0.0%	0.0%

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 89, the applicant states it has no such obligation

In Section L, page 89, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 90, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Gateway Projected Payor Mix – CY 2024		
Payor Category	Entire Facility	ORs
Self-Pay	0.77%	1.09%
Medicare*	38.82%	30.97%
Medicaid*	10.66%	13.91%
Insurance*	48.58%	52.41%
Other**	1.18%	1.61%
Total	100.00%	100.00%

Note: On page 90, the applicant states it does not consider charity care a payor source.

*Including any managed care plans

**Other includes Workers Comp, TRICARE, VA, & other federal programs

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.77 percent of total services will be provided to self-pay patients, 38.82 percent to Medicare patients, and 10.66 percent to Medicaid patients.

On page 90, and on Form F.2 in Section Q, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 91, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 92, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates 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 to relocate two ORs from AH Cabarrus to Gateway, its existing facility with four ORs, for a total of six ORs upon project completion.

On page 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” In Figure 6.1 on page 57 of the 2020 SMFP, Cabarrus County is shown as a single county OR service area. Thus, the service area for this review

consists of Cabarrus County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved ORs in Cabarrus County.

Current ORs – Cabarrus County		
Facilities	# of ORs	Projected Deficit / (Surplus)
Atrium Health Cabarrus	19	(1.52)
Gateway Surgery Center	4	0.44
Eye Surgery and Laser Clinic, Inc.	2	0.58
TOTAL	25	(0.50)

Sources: Section G, page 70; 2020 SMFP, Table 6B, page 71

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

“The proposed project will result in additional freestanding ambulatory surgery capacity that will more efficiently serve patients. By utilizing and reconfiguring existing space for the proposed project, GSC has chosen the most effective option, thereby improving value to the patient, and fostering competition...”

GSC maintains AAAHC accreditation that keeps the quality of its services at or above standards. Hence, with more capacity, GSC, the low-cost surgery provider, will offer an incentive for other providers to reduce patient costs.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 93, the applicant states:

“Relocating the rooms to an existing, accredited, and certified surgery center takes advantage of existing infrastructure and existing relationships with payors. The former reduces construction and fixed capital costs. The latter eliminates the working capital cost of delays associated with long payer certification and rate negotiation processes. Both are cost effective. Incorporating the relocated rooms within an existing building envelope will spread fixed overhead, including basic utilities over more cases, thus reducing unit cost per case.”

Regarding the impact of the proposal on quality, in Section N, page 94, the applicant states:

“GSC is licensed by the state of North Carolina, certified for participation in Medicare and Medicaid, and accredited by the Accreditation Association for Ambulatory Health Care. Each provides additional layers of oversight, maintaining a high bar for competition.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 94, the applicant states:

“GSC will continue to accept patients without regard to source of payment and provide charity for medical necessity. GSC offers ambulatory surgery services at affordable rates. This makes the facility accessible and more affordable to all patients, including underinsured persons who may have high co-pay and deductible insurance plans. In addition to planning for reasonable access by persons who may need full charity support for medical necessities, the facility has also budgeted for self-pay persons who may require discounts. GSC accepts Medicare and Medicaid assignment.

...

The location, ADA compliant building design, and willingness to accept Medicare, Medicaid, hardship patients, and uninsured will all increase access for patients and promote competition in the proposed service area.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, K, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, D, L, and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

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

C

On Form A in Section Q, the applicant identifies the hospitals and surgery centers located in North Carolina owned, operated, or managed by the applicants or a related entity. The applicant identifies a total of 21 of these types of facilities located in North Carolina.

In Section O, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that 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, there is one potential incident related to quality of care at one of the 21 facilities, but there were no confirmed incidents related to quality of care that 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 21 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.
- (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 applicant proposes to relocate two ORs from AH Cabarrus to Gateway, its existing ASF, for a combined total of six ORs upon project completion. The Criteria and Standards for Surgical Services and Operating Rules, promulgated in 10A NCAC 14C .2103, are not applicable to this review because the applicant does not propose to increase the number of ORs in a service area.