Operating Room (OR) Methodology Workgroup

January 14, 2025

Workgroup Charge

1. Reviewing Session Law 2023-7 passed by the North Carolina General Assembly and signed by Governor Roy Cooper on March 27, 2023.

- 2. Examining the impact of the CON exemption of QUASFs on the current SMFP OR need determination methodology.
- 3. Making a recommendation to the SHCC regarding whether to:
 - a. retain the current OR methodology, with QUASFs removed from the need determination calculations; or
 - b. propose a new OR methodology, with QUASFs removed from the need determination calculations; or
 - c. eliminate the OR need determination methodology in its entirety.

Over-Arching Questions

- What are the pros and cons of
 - Retaining the OR methodology
 - Revising the OR methodology
 - Not having an OR methodology
- In counties with populations >125,000 what do we do with ORs in existing and new ASFs?
- How will we track new QUASFs?
- What does the new law mean?

New Certificate of Need Statutory Provisions

Effective November 21, 2025:

- The definition of "health service facility" in the CON Law will exclude "qualified urban ambulatory surgical facilities." See, § 131E-176 (9b).
- The definition of "new institutional health service" in the Certificate of Need (CON) Law will exclude "qualified urban ambulatory surgical facilities." See, § 131E-176 (16) b.
- The definition of "qualified urban ambulatory surgical facility" is:
 - An ambulatory surgical facility that meets all of the following criteria:
 - a. Is licensed by the Department to operate as an ambulatory surgical facility
 - b. Has a single specialty or multispecialty surgical program
 - c. Is located in a county with a population greater than 125,000 according to the 2020 federal decennial census or any subsequent federal decennial census. See, § 131E-176 (21a).

Qualified urban ambulatory surgical facilities (QUASFs) include new and existing ASFs.

Requirements for QUASFs

Requirement	Need Determination Methodology Recommendation Options		
	Keep (exclude QUASFs)	Revise	Eliminate (no ND for any hospital or ASF ORs)
CON required to develop or expand	×	×	×
CON required to relocate ORs to another QUASF	×	×	×
CON required to relocate ORs to a hospital	√	✓	✓
Service area need determination required to develop or expand	×	×	×
Obligated to 4% charity care requirement	✓	✓	✓
Required to report operational data on license renewal applications, annually	✓	√	✓
Required to report discharge data, quarterly	✓	√	✓

Requirements for ASFs

		Need Determination Methodology Recommendation Options		
Requirement	Keep (exclude QUASFs)	Revise	Eliminate (no ND for any hospital or ASF ORs)	
CON required to develop or expand	✓	✓	✓	
CON required to relocate ORs to a hospital or another ASF	✓	✓	✓	
Service area need determination required to develop or expand (excluding relocated ORs)	✓	?*	×	
Obligated to 4% charity care requirement	×	×	×	
Required to report operational data on license renewal applications, annually	✓	✓	✓	
Required to report discharge data, quarterly	✓	✓	✓	

^{*} The requirement will depend on the workgroup's recommendation and the SHCC's subsequent approval of it.

Requirements for Hospitals

Requirement	Need Determination Methodology Recommendation Options		
	Keep (exclude QUASFs)	Revise	Eliminate (no ND for any hospital or ASF ORs)
CON required to develop or expand	✓	✓	✓
CON required to relocate ORs to an ASF	✓	✓	✓
Service area need determination required to develop or expand (excluding relocating ORs)	✓	?*	×
Obligated to 4% charity care requirement	×	×	×
Required to report operational data on license renewal applications, annually	✓	✓	✓
Required to report discharge data, quarterly	✓	✓	✓

^{*} The requirement will depend on the workgroup's recommendation and the SHCC's subsequent approval of it.

1. Retain Current OR Methodology with QUASFs Removed from the Calculations

- Unknown impact on future OR need determinations
- Providers will have restricted ability to expand OR capacity compared to QUASFs
- Missed opportunity: unknown when the next opportunity will be to change OR methodology
- Pop growth rate limits future growth in current methodology
 - County-based pop growth rates not consistent with hx growth
- Hospital case times likely to increase
 - Limit to max increase of 10% on case time could suppress need determinations

2. Propose a New OR Methodology with QUASFs Removed from the Calculations

- Unknown probability of future OR need determinations
- Providers likely to have restricted ability to expand OR capacity compared to QUASFs
- Update to performance standards?
- Update growth rates consistent with historical growth?
- Would two methodologies be required for example one for counties with >125,000 population and one for counties with less than 125,000 population?
- Hospital case times likely to increase
 - Remove limit of 10% increase in case time per year?

3. Eliminate OR Methodology Entirely

- More leveled playing field with QUASFs
- Ability to submit CONs for additional ORs as needed
- Update to performance standards?
- Potential for inundation of OR CONs at outset
- Impact on counties with <125K population?

Overview of Health Planning for ASCs

- Georgia only has a need methodology for ASC ORs as hospital-based surgery is exempt.
- Georgia did not change its OR/ASC need methodology for ambulatory surgery services throughout this time period.
 - The inventory of ORs in the need methodology does not include exempt single-specialty or JV ASCs.
 - The OR utilization in the methodology does not include exempt single-specialty or JV ASCs.
 - The OR utilization in the methodology includes dedicated outpatient ORs and an allocation of hospital shared ORs, even though the ASC methodology is not applicable to hospital-based ambulatory surgery projects.
 - The goal appeared to have been that outpatient surgery in all CON regulated environments (hospital and ASC) should be considered before identifying the need for more ASCs.

Specifics of the Need Methodology

- The Georgia ASC need methodology has a two-part test:
 - Calculate the number of outpatient OR rooms needed compared to the inventory of rooms available.
 - Calculate the aggregate utilization of the existing ORs, which must exceed 80%.
- Capacity calculations are much simpler that North Carolina.
 - Capacity of an OR (regardless of setting) is considered to be 1,250.
 - Calculations are done by planning region and not by county.
- The actual need calculation has not shown a need for any ASC operating rooms anywhere in the State since March of 2013.
- Unlike North Carolina, the Georgia ASC rules allow for an applicant to apply for an exception to the need methodology, so a limited number of ASCs have been approved despite the lack of need in under the need methodology.

Summary of Regulatory History

- All CON exempt and non-exempt ASCs and hospitals are required to provide annual survey data much like the North Carolina LRAs on the utilization of their respective operating rooms.
- Single-Specialty ASCs and JV ASCs are required to file a request for Determination of Non-Reviewability (DET), which confirms the exempt status of such ASCs.
 - This provides public notice the plans to develop such ASC.
 - It also provides a mechanism to track the inventory of all ASCs in the state.
 - Exempt ASCs are requited to provide a 2% minimum level of charity care. If they do not provide
 Medicaid, then the minimum level charity care is 4%. This is tracked by the Department of Community
 Health.
- Because Georgia has both CON-approved and exempt ASCs and ORs, as opposed to complete CON exemption, it is the most relevant to North Carolina.

Take Aways from Georgia Experience:

- Exempt ASCs have grown faster than CON approved ASCs and hospitals by all measures number of facilities, number of ORs, and number of cases.
 - See analysis below from 2008-2012 (first five years of full exemption)
 - As of January 2025, there are more than 550 approved and/or operating exempt ASCs in Georgia
- Complex to plan for only part of the ORs in the market.
 - Within 9 years of exemption of single specialty ASCs (2004), and 4 years of exemption of JV ASCs (2008), the ASC need methodology showed no need statewide.
 - No need has been shown for ASC ORs since 2013.
- Hospitals, while considered in the inventory of ORs available, are permitted to expand existing surgical services without having to meet the need methodology. North Carolina does not currently have this option for hospitals.
- Georgia has an exception allowing for applications even if there is no calculated need. In reality, it is very difficult to qualify for the exception to need. North Carolina does not currently have a similar exception or provision.
- Recommend considerations for not penalizing hospitals as exempt ASCs proliferate.