

Reference Information

Methodology Assumptions

- Determines need for all ORs in the state (hospitals and ASCs)
- Excludes GI-endoscopy rooms and facilities. SMFP provides inventory of GI-endoscopy only facilities.
- Uses estimated case time (3 hours for inpatient procedures, 1.5 hours for outpatient/ambulatory procedures)
- Uses estimated annual surgical availability (9 hours per day, 260 days per year)
- Full (100%) utilization is considered to be 80% of capacity, or 1,872 hours (9 hours per day x 260 days per year x 80%)
- Need determinations are calculated based on the service area's "planning inventory." The planning inventory excludes several types of ORs
 - Dedicated C-Section rooms (ORs and procedures are excluded)
 - 1 OR is removed for hospitals that are Level I or Level II trauma centers
 - 1 OR is removed for hospitals with a Burn Intensive Care Unit
 - All ORs and procedures in underutilized facilities (a facility that has reported less than 40% utilization for the immediate past two reporting years and that has been in operation long enough to submit 3 License Renewal Applications)
 - Applies to both hospitals and ASCs
 - Does not apply to service areas in which there is only one facility or in which all facilities are underutilized

Planning Process

- License Renewal Applications (LRAs) are received early in the calendar year
- Data entry is complete in March
- Draft tables are presented to Acute Care Services Committee in May
- The publication year of the State Medical Facilities Plan (SMFP) is always two years later than the data collection year.
- The data collection year is on federal fiscal year.
- The earliest any proposed methodology changes can be implemented is in the 2018 SMFP, provided the methodological changes don't require changes to the LRAs. Methodology changes that require additional data collection on the DHSR LRAs would be made on the 2018 LRAs and would be used in the 2019 SMFP.

Definitions

- **Requirement for Certificate of Need (CON)**

“No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department” (emphasis added)

N.C.G.S. §131E-178(a) [Certificate of Need Law]

- **New Institutional Health Service**

“New institutional health services’ means any of the following:

- a. The construction, development, or other establishment of a new health service facility.
- b. Except as otherwise provided in G.S. 131E-184(e), the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. ...

...

- r. The conversion of a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or the addition of a specialty to a specialty ambulatory surgical program.

...

- u. The construction, development, establishment, increase in the number, or relocation of an operating room or gastrointestinal endoscopy room in a licensed health service facility, other than the relocation of an operating room or gastrointestinal endoscopy room within the same building or on the same grounds or to grounds not separated by more than a public right-of-way adjacent to the grounds where the operating room is or gastrointestinal endoscopy room is currently located.

- v. The change in designation, in a licensed health service facility, of an operating room to a gastrointestinal endoscopy room or change in designation of a gastrointestinal endoscopy room to an operating room that results in a different number of each type of room than is reflected on the health service facility’s license in effect as of January 1, 2005.”

N.C.G.S. §176(16) [Certificate of Need Law]

- **Types of facilities with ORs**

- Ambulatory Surgical Facilities (ASFs, ASCs, or AMSUs)
- Hospitals

- **Ambulatory Surgical Facility**

“‘Ambulatory surgical facility’ means a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. ... An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1c) of this section and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.”

N.C.G.S. §131E-146(1) [Ambulatory Surgical Facility Licensure Law]

N.C.G.S. §131E-176(1b) [Certificate of Need Law]

- **Ambulatory Surgical Program**

“‘Ambulatory surgical program’ means a formal program for providing on a same-day basis those surgical procedures which require local, regional or general anesthesia and a period of post-operative observation to patients whose admission for more than 24 hours is determined, prior to surgery or gastrointestinal endoscopy, to be medically unnecessary.”

N.C.G.S. §131E-176(1c) [Certificate of Need Law]

- **Multispecialty Ambulatory Surgical Program**

“‘Multispecialty ambulatory surgical program’ means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.”

N.C.G.S. §131E-176(15a) [Certificate of Need Law]

- **Specialty Ambulatory Surgical Program**

“‘Specialty ambulatory surgical program’ means a formal program for providing on a same-day basis surgical procedures for only the specialty areas identified on the ambulatory surgical facility's 1993 Application for Licensure as an Ambulatory Surgical Center and authorized by its certificate of need.”

N.C.G.S. §131E-176(24f) [Certificate of Need Law]

- **Hospital**

“‘Hospital’ means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered

under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours.”

N.C.G.S. §131E-76(3) [Hospital Licensure Law]

“‘Hospital’ means a public or private institution which is primarily engaged in providing to inpatients, by or under supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The term includes all facilities licensed pursuant to G.S. 131E-77 of the General Statutes, except long-term care hospitals.”

N.C.G.S. §131E-176(13) [Certificate of Need Law]

- **Operating Room**

“‘Operating room’ means a room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room.”

N.C.G.S. §131E-76(6a) [Hospital Licensure Law]

N.C.G.S. §131E-146(1c) [Ambulatory Surgical Facility Licensure Law]

N.C.G.S. §131E-176(18c) [Certificate of Need Law]

- **Gastrointestinal Endoscopy (GI) Rooms**

“‘Gastrointestinal endoscopy room’ means a room used for the performance of procedures that require the insertion of a flexible endoscope into a gastrointestinal orifice to visualize the gastrointestinal lining and adjacent organs for diagnostic or therapeutic purposes.”

N.C.G.S. §131E-76(1e) [Hospital Licensure Law]

N.C.G.S. §131E-146(1b) [Ambulatory Surgical Facility Licensure Law]

N.C.G.S. §131E-176(7d) [Certificate of Need Law]

- **No methodology in the SMFP for GI Endo Rooms**

“The annual State Medical Facilities Plan shall not include policies or need determinations that limit the number of gastrointestinal endoscopy rooms that may be approved.” (emphasis added)

N.C.G.S. §131E-178(a) [Certificate of Need Law]

- **Certificate of Need Process**

- Need methodology shows a need for one or more additional operating rooms in a service area.
- CON schedules a review in Chapter 6 of the SMFP.
- CON applications are due on the 15th of the month prior to the month the review begins (they always begin on the 1st day of the month).
- Need determinations for operating rooms are frequently competitive. Meaning that CON receives multiple applications proposing to develop the additional operating rooms.
- The number of operating rooms in the need determination is a determinative limit on the number of operating rooms that may be approved.
- CON has 90 days to review the applications against the statutory and regulatory review criteria or rules.
- The current rules for operating rooms are based on the current methodology, including the assumptions used in that methodology. The rules may need to be changed depending on what changes, if any, are made to the operating room methodology.
- CON may extend the review an additional 60 days for a total of no more than 150 days.
- Once a decision is mailed to the applicants, the 30-day appeal period begins.
- If there is no appeal, the certificate may be issued.
- If there is an appeal, the Administrative Law Judge (ALJ) has 270 days to make his or her decision.
- The ALJ's decision may be appealed to the N.C. Court of Appeals. They have no time limit for making their decision.
- Decisions made by the N.C. Court of Appeals may be appealed to the N.C. Supreme Court. They also have no time limit for making their decision.
- Once a certificate is issued, the certificate holder is required to make a good faith effort to develop the facility or additional operating rooms in a timely manner consistent with the representations made in the certificate of need application.
- The certificate holder is required to submit periodic progress reports.