

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2005**

**SESSION LAW 2005-346
HOUSE BILL 1060**

AN ACT TO CHANGE THE DEFINITION OF "CRITICAL ACCESS HOSPITAL"
TO CONFORM TO FEDERAL LAW; AND RELATING TO REGULATION OF
GASTROINTESTINAL ENDOSCOPY ROOMS IN LICENSED HEALTH
SERVICE FACILITIES.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 131E-76(1a) reads as rewritten:

"§ 131E-76. Definitions.

As used in this article, unless otherwise specified:

...

(1a) "Critical access hospital" means a hospital which has been designated as a critical access hospital by the North Carolina Department of Health and Human Services, Office of Research, Demonstrations and Rural Health Development. To be designated as a critical access hospital under this subdivision, the hospital must ~~meet the requirements of federal law for certification as a critical access hospital.~~ be certified as a critical access hospital pursuant to 42 CFR Part 485 Subpart F. The North Carolina Department of Health and Human Services, Office of Research, Demonstrations, and Rural Health Development may designate a hospital located in a Metropolitan Statistical Area as a rural hospital for the purposes of the critical access hospital program if the hospital is located in a county with twenty-five percent (25%) or more rural residents as defined by the most recent United States decennial census."

SECTION 2. G.S. 131E-76 is amended by inserting the following new subdivisions, in alphabetical order, to read:

"§ 131E-76. Definitions.

As used in this article, unless otherwise specified:

...

- (8) '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.
- (9) '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."

SECTION 3. G.S. 131E-77(e) reads as rewritten:

"(e) The Department shall issue the license to the operator of the hospital who shall not transfer or assign it except with the written approval of the Department. The license shall designate the number and types of inpatient beds, the number of operating rooms, and the number of gastrointestinal endoscopy rooms."

SECTION 4. G.S. 131E-146 reads as rewritten:

"§ 131E-146. Definitions.

As used in this Part, unless otherwise specified:

- (1) "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 only admit patients for a period of less than 24 hours and must provide at least one designated operating room as defined in subdivision (1c) of this section or at least one gastrointestinal endoscopy room as defined in subdivision (1b) of this section and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. 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 4, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1a) and which are performed in a physician or dentist's office does not make that office an ambulatory surgical facility.
- (1a) "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~~, surgery or gastrointestinal endoscopy, to be medically unnecessary.
- (1b) "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.
- (1c) "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.

(2) "Commission" means the North Carolina Medical Care Commission."

SECTION 5. G.S. 131E-175 is amended by adding the following new subdivisions to read:

"§ 131E-175. Findings of fact.

The General Assembly of North Carolina makes the following findings:

...

(11) That physicians providing gastrointestinal endoscopy services in unlicensed settings should be given an opportunity to obtain a license to provide those services to ensure the safety of patients and the provision of quality care.

(12) That demand for gastrointestinal endoscopy services is increasing at a substantially faster rate than the general population given the procedure is recognized as a highly effective means to diagnose and prevent cancer."

SECTION 6.(a) G.S. 131E-176(1b) and 131E-176(1c) read as rewritten:

"§ 131E-176. Definitions.

...

(1b) "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 only admit patients for a period of less than 24 hours and must provide at least one designated operating room or gastrointestinal endoscopy room, as defined in Article 5 Part 1 and Article 6, Part 4 of this Chapter, and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. 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 ~~(1b)~~–(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.

(1c) "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~~, surgery or gastrointestinal endoscopy, to be medically unnecessary."

SECTION 6.(b) G.S. 131E-176(16)u. reads as rewritten:

"(16) "New institutional health services" means any of the following:

...

u. The construction, development, establishment, increase in the number, or relocation of an operating room or ~~operating rooms~~, gastrointestinal endoscopy room in a licensed health service facility, other than the relocation of an operating room or ~~operating rooms~~ 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 operating rooms are~~ or gastrointestinal endoscopy room is currently located."

SECTION 6.(c) G.S. 131E-176(16) is amended by adding the following new sub-subdivision to read:

"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."

SECTION 6.(d) G.S. 131E-176 is amended by adding the following new subdivisions to read:

"(7d) '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.

(18c) '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."

SECTION 7. G.S. 131E-178(a) reads as rewritten:

"(a) No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department; provided, however, ~~no hospital licensed pursuant to Article 5 of this Chapter that was established to serve a minority population that would not otherwise have been served and that continues to serve a minority population may be required to obtain a certificate of need for transferring up to 65 beds to nursing care facility beds.~~ no person who provides gastrointestinal endoscopy procedures in one or more gastrointestinal endoscopy rooms located in a nonlicensed setting, shall be required to obtain a certificate of need to license that setting as an ambulatory surgical facility with the existing number of gastrointestinal endoscopy rooms, provided that:

- (1) The license application is postmarked for delivery to the Division of Facility Services by December 31, 2006;
- (2) The applicant verifies, by affidavit submitted to the Division of Facility Services within 60 days of the effective date of this act, that the facility is in operation as of the effective date of this act or that the completed application for the building permit for the facility was submitted by the effective date of this act;
- (3) The facility has been accredited by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities by the time the license application is postmarked for delivery to the Division of Facility Services of the Department; and
- (4) The license application includes a commitment and plan for serving indigent and medically underserved populations.

All other persons proposing to obtain a license to establish an ambulatory surgical facility for the provision of gastrointestinal endoscopy procedures shall be required to obtain a certificate of need. 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."

SECTION 8. G.S. 131E-182(a), as amended by Senate Bill 740, 2005 General Assembly, reads as rewritten:

"(a) The Department in its rules shall establish schedules for submission and review of completed applications. The schedules shall provide that applications for similar proposals in the same service area will be reviewed together. However, there shall not be a review scheduled prior to February 1, 2006, for submission and review of certificate of need applications that propose an increase in the number of licensed gastrointestinal endoscopy rooms. An applicant for a certificate of need to establish a licensed gastrointestinal endoscopy room shall show that it is performing or reasonably projects to perform at least 1,500 gastrointestinal endoscopy procedures per gastrointestinal endoscopy room per year."

SECTION 9. Nothing in Sections 2 through 10 of this act shall be construed to represent legislative intent as to the circumstances under which Medicare or Medicaid certification may be obtained for a provider of ambulatory surgery services.

SECTION 10. This act is effective when it becomes law. Section 8 of this act expires on the effective date of administrative rules adopted consistent with the provisions of this act regarding the number of gastrointestinal endoscopy procedures performed or projected to be performed.

In the General Assembly read three times and ratified this the 29th day of August, 2005.

s/ Charlie S. Dannelly
Deputy President Pro Tempore of the Senate

s/ James B. Black
Speaker of the House of Representatives

s/ Michael F. Easley
Governor

Approved 12:28 p.m. this 31st day of August, 2005