

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013

FILED SENATE
Mar 5, 2013
S.B. 202
PRINCIPAL CLERK

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SENATE DRS85048-MG-65 (02/21)

Short Title: Enact CON Reform.

(Public)

Sponsors: Senator Randleman (Primary Sponsor).

Referred to:

1 A BILL TO BE ENTITLED
2 AN ACT TO EXEMPT DIAGNOSTIC CENTERS FROM CERTIFICATE OF NEED
3 REVIEW AND TO AMEND CERTIFICATE OF NEED LAWS PERTAINING TO
4 SINGLE-SPECIALTY AMBULATORY SURGERY OPERATING ROOMS.

5 The General Assembly of North Carolina enacts:

6 **SECTION 1.** G.S. 131E-175 is amended by adding new subdivisions to read:

7 "(13) That the relocation of a hospital's operating rooms to a location separate
8 from the campus upon which the hospital's inpatient acute care beds and
9 emergency department are located results in a costly and unnecessary
10 economic burden to the public.

11 (14) That physicians who provide single-specialty ambulatory surgery services in
12 unlicensed settings should be afforded an opportunity to obtain a license to
13 provide these services in order to ensure patient safety and the provision of
14 quality care.

15 (15) That the demand for ambulatory surgery is increasing due to advances in
16 technology and anesthesia, and single-specialty ambulatory surgery
17 operating rooms are recognized as a highly effective means of expanding
18 access while achieving cost savings regardless of the availability and
19 potential underutilization of hospital-based operating rooms."

20 **SECTION 2.** G.S. 131E-176(7a) is repealed.

21 **SECTION 3.** G.S. 131E-176(9b) reads as rewritten:

22 "(9b) 'Health service facility' means a hospital; long-term care hospital;
23 psychiatric facility; rehabilitation facility; nursing home facility; adult care
24 home; kidney disease treatment center, including freestanding hemodialysis
25 units; intermediate care facility for the mentally retarded; home health
26 agency office; chemical dependency treatment facility; ~~diagnostic center;~~
27 hospice office, hospice inpatient facility, hospice residential care facility;
28 and ambulatory surgical facility."

29 **SECTION 4.** G.S. 131E-176(14e) reads as rewritten:

30 "(14e) 'Kidney disease treatment center' means a facility that is certified as an
31 end-stage renal disease facility by the Centers for Medicare and Medicaid
32 Services, Department of Health and Human Services, pursuant to 42 C.F.R.
33 § 405.494."

34 **SECTION 5.** G.S. 131E-176(16)l. is repealed.

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

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



1 ...

2 u. The construction, development, establishment, increase in the

3 number, or relocation of an operating ~~room~~ room, including a

4 single-specialty ambulatory surgery operating room, or

5 gastrointestinal endoscopy room in a licensed health service facility,

6 other than the relocation of an operating room or gastrointestinal

7 endoscopy room within the same building or on the same grounds or

8 to grounds not separated by more than a public right-of-way adjacent

9 to the grounds where the operating room or gastrointestinal

10 endoscopy room is currently located.

11"

12 **SECTION 7.** G.S. 131E-176(24c) reads as rewritten:

13 "(24c) ~~Reserved for future codification.~~ "Single-specialty ambulatory surgery

14 operating room" means a designated operating room located in a licensed

15 ambulatory surgical facility that is used to perform same-day surgical

16 procedures in one of the single-specialty areas identified by the American

17 College of Surgeons. For the purpose of this subdivision, "same-day surgical

18 procedures" includes pain injections by orthopedists, physiatrists, and

19 anesthesiologists."

20 **SECTION 8.** G.S. 131E-178 reads as rewritten:

21 **"§ 131E-178. Activities requiring certificate of need.**

22 (a) ~~No~~ Except as otherwise provided in subsections (a1) and (a2) of this section, no

23 person shall offer or develop a new institutional health service without first obtaining a

24 certificate of need from the Department; provided, however, no Department.

25 (a1) Any person proposing to obtain a license to establish an ambulatory surgical facility

26 for the provision of gastrointestinal endoscopy procedures shall be required to obtain a

27 certificate of need to license that setting as an ambulatory surgical facility, with the existing

28 number of gastrointestinal endoscopy rooms, except for a person who (i) provides

29 gastrointestinal endoscopy procedures in one or more gastrointestinal endoscopy rooms located

30 in a nonlicensed setting, shall be required to obtain a certificate of need to license that setting as

31 an ambulatory surgical facility with the existing number of gastrointestinal endoscopy rooms,

32 provided that setting and (ii) meets all of the following criteria:

- 33 (1) The person's license application is postmarked for delivery to the Division of
- 34 Health Service Regulation by December 31, 2006;
- 35 (2) The applicant verifies, by affidavit submitted to the Division of Health
- 36 Service Regulation within 60 days of the effective date of this act, that the
- 37 facility is in operation as of the effective date of this act or that the
- 38 completed application for the building permit for the facility was submitted
- 39 by the effective date of this act;
- 40 (3) The facility has been accredited by The Accreditation Association for
- 41 Ambulatory Health Care, The Joint Commission on Accreditation of
- 42 Healthcare Organizations, or The American Association for Accreditation of
- 43 Ambulatory Surgical Facilities by the time the license application is
- 44 postmarked for delivery to the Division of Health Service Regulation of the
- 45 Department; and
- 46 (4) The license application includes a commitment and plan for serving indigent
- 47 and medically underserved populations.

48 All other persons proposing to obtain a license to establish an

49 ambulatory surgical facility for the provision of gastrointestinal endoscopy

50 procedures shall be required to obtain a certificate of need. The annual State

1 Medical Facilities Plan shall not include policies or need determinations that
2 limit the number of gastrointestinal endoscopy rooms that may be approved.
3 (a2) Any person proposing to obtain a license to establish single-specialty ambulatory
4 operating rooms in an ambulatory surgery facility shall be required to obtain a certificate of
5 need, except for a person who (i) provides single-specialty ambulatory surgery procedures in
6 one or more operating rooms located in a nonlicensed setting and (ii) meets all of the following
7 criteria:

- 8 (1) The person's license application is postmarked for delivery to the Division of
9 Health Service Regulation by December 31, 2013;
- 10 (2) The applicant verifies, by affidavit submitted to the Division of Health
11 Service Regulation within 60 days of the effective date of this act, that the
12 facility is in operation as of the effective date of this act or that the
13 completed application for the building permit for the facility was submitted
14 by the effective date of this act;
- 15 (3) The facility has been accredited by The Accreditation Association for
16 Ambulatory Health Care, The Joint Commission on Accreditation of
17 Healthcare Organizations, or The American Association for Accreditation of
18 Ambulatory Surgical Facilities by the time the license application is
19 postmarked for delivery to the Division of Health Service Regulation of the
20 Department; and
- 21 (4) The license application includes at least all of the following:
 - 22 a. A commitment, plan, and policies and procedures for serving
23 indigent and medically underserved populations.
 - 24 b. Projected charges for the 20 most common surgical procedures to be
25 performed in the proposed single-specialty ambulatory surgery
26 operating rooms.

27 All other persons proposing to obtain a license to establish
28 single-specialty ambulatory operating rooms within an ambulatory surgical
29 facility shall be required to obtain a certificate of need. The annual State
30 Medical Facilities Plan shall not include policies or need determinations that
31 limit the number of single-specialty ambulatory surgery operating rooms that
32 may be approved. However, the Department shall not approve an application
33 for a single-specialty ambulatory surgery operating room in any ambulatory
34 surgical facility within (i) a county in which a licensed critical access
35 hospital, as defined in 42 C.F.R. § 400.202, is located or (ii) a county with a
36 population of less than 100,000, unless the application includes written
37 support from each licensed acute care hospital within that county. The
38 annual State Medical Facilities Plan also shall not include policies or need
39 determinations that limit the relocation and replacement of existing
40 operating rooms, including single-specialty ambulatory operating rooms.
41 However, the Department shall not approve an application for the relocation
42 of a hospital's operating rooms to a location separate from the campus upon
43 which the hospital's inpatient acute care beds and emergency department are
44 located if approval would result in the hospital obtaining reimbursement for
45 surgery procedures at a rate higher than the rate paid to ambulatory surgery
46 centers under a government-sponsored health insurance or medical
47 assistance program.

48 (b) No person shall make an acquisition by donation, lease, transfer, or comparable
49 arrangement without first obtaining a certificate of need from the Department, if the acquisition
50 would have been a new institutional health service if it had been made by purchase. In
51 determining whether an acquisition would have been a new institutional health service, the

1 capital expenditure for the asset shall be deemed to be the fair market value of the asset or the
2 cost of the asset, whichever is greater.

3 (c) No person shall incur an obligation for a capital expenditure which is a new
4 institutional health service without first obtaining a certificate of need from the Department. An
5 obligation for a capital expenditure is incurred when:

6 (1) An enforceable contract, excepting contracts which are expressly contingent
7 upon issuance of a certificate of need, is entered into by a person for the
8 construction, acquisition, lease, or financing of a capital asset;

9 (2) A person takes formal action to commit funds for a construction project
10 undertaken as his own contractor; or

11 (3) In the case of donated property, the date on which the gift is completed.

12 (d) Where the estimated cost of a proposed capital expenditure, including the fair
13 market value of equipment acquired by purchase, lease, transfer, or other comparable
14 arrangement, is certified by a licensed architect or engineer to be equal to or less than the
15 expenditure minimum for capital expenditure for new institutional health services, such
16 expenditure shall be deemed not to exceed the amount for new institutional health services
17 regardless of the actual amount expended, provided that the following conditions are met:

18 (1) The certified estimated cost is prepared in writing 60 days or more before
19 the obligation for the capital expenditure is incurred. Certified cost estimates
20 shall be available for inspection at the facility and sent to the Department
21 upon its request.

22 (2) The facility on whose behalf the expenditure was made notifies the
23 Department in writing within 30 days of the date on which such expenditure
24 is made if the expenditure exceeds the expenditure minimum for capital
25 expenditures. The notice shall include a copy of the certified cost estimate.

26 (e) The Department may grant certificates of need which permit capital expenditures
27 only for predevelopment activities. Predevelopment activities include the preparation of
28 architectural designs, plans, working drawings, or specifications, the preparation of studies and
29 surveys, and the acquisition of a potential site."

30 **SECTION 9.** G.S. 131E-182 reads as rewritten:

31 "**§ 131E-182. Application.**

32 (a) The Department in its rules shall establish schedules for submission and review of
33 completed applications. The schedules shall provide that applications for similar proposals in
34 the same service area will be reviewed together. However, the Department is prohibited from
35 scheduling a review prior to February 1, 2013, for certificate of need applications that propose
36 to establish a licensed single-specialty ambulatory operating room within an ambulatory
37 surgery facility.

38 (b) An application for a certificate of need shall be made on forms provided by the
39 Department. The application forms, which may vary according to the type of proposal, shall
40 require such information as the Department, by its rules deems necessary to conduct the review.
41 An applicant shall be required to furnish only that information necessary to determine whether
42 the proposed new institutional health service is consistent with the review criteria implemented
43 under G.S. 131E-183 and with duly adopted standards, plans and criteria. The application form
44 for a certificate of need to establish a single-specialty ambulatory surgery operating room
45 within an ambulatory surgery facility shall require the applicant to (i) include a written
46 commitment, plan, and policies and procedures for serving indigent and medically underserved
47 populations, (ii) furnish the projected charges for the 20 most common surgical procedures to
48 be performed in the proposed operating room, and (iii) demonstrate that it is performing or
49 reasonably expects to perform at least 800 single-specialty ambulatory procedures per licensed
50 single-specialty ambulatory operating room per year.

1 (c) An application fee is imposed on an applicant for a certificate of need. An applicant
2 must submit the fee with the application. The fee is not refundable, regardless of whether a
3 certificate of need is issued. Fees collected under this section shall be credited to the General
4 Fund as nontax revenue. The application fee is five thousand dollars (\$5,000) plus an amount
5 equal to three-tenths of one percent (.3%) of the amount of the capital expenditure proposed in
6 the application that exceeds one million dollars (\$1,000,000). In no event may the fee exceed
7 fifty thousand dollars (\$50,000)."

8 **SECTION 10.** G.S. 131E-184(a) is amended by adding a new subdivision to read:

9 "(10) To develop, acquire, or replace an institutional health service that obtained
10 certificate of need approval prior to the effective date of this act as a
11 diagnostic center. For the purpose of this subdivision, "diagnostic center"
12 means a freestanding facility, program, or provider, including, but not
13 limited to, physicians' offices, clinical laboratories, radiology centers, and
14 mobile diagnostic programs, in which the total cost of all the medical
15 diagnostic equipment utilized by the facility that cost ten thousand dollars
16 (\$10,000) or more exceeds five hundred thousand dollars (\$500,000), unless
17 a new institutional health service other than those defined in
18 G.S. 131E-176(16)b. is offered or developed in the building."

19 **SECTION 11.** Nothing in this act shall be construed to reflect any legislative intent
20 as to the circumstances under which Medicare or Medicaid certification may be obtained for a
21 provider of ambulatory surgery services.

22 **SECTION 12.** This act is effective when it becomes law. Section 9 of this act
23 expires on the effective date of administrative rules adopted consistent with the provisions of
24 this act regarding the number of single-specialty surgery procedures performed or projected to
25 be performed by applicants seeking to establish a licensed single-specialty ambulatory surgery
26 operating room.