HOUSE SELECT COMMITTEE ON
THE CERTIFICATE OF NEED PROCESS
AND RELATED HOSPITAL ISSUES

FINAL REPORT
TO THE
2013 HOUSE OF REPRESENTATIVES

DECEMBER 2012
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Legislative Proposals

2013-MGz-16
AN ACT TO ELIMINATE THE MONETARY THRESHOLD FOR EXPEDITED CERTIFICATE OF NEED REVIEW; TO INCREASE THE MONETARY THRESHOLDS TRIGGERING CERTIFICATE OF NEED REVIEW FOR CAPITAL EXPENDITURES AND THE PURCHASE OF MAJOR MEDICAL EQUIPMENT; TO EXEMPT REPLACEMENT EQUIPMENT FROM CERTIFICATE OF NEED REVIEW REGARDLESS OF COST; TO REQUIRE AFFECTED PERSONS SEEKING TO FILE A PETITION FOR A CONTESTED CASE OR AN APPEAL CHALLENGING CERTIFICATE OF NEED APPROVAL TO DEPOSIT A SEPARATE BOND FOR EACH APPROVED APPLICATION THAT IS THE SUBJECT OF THE PETITION OR APPEAL, TO INCREASE THE AMOUNT OF THE MAXIMUM BOND REQUIREMENT, AND TO GIVE THE COURT OF APPEALS GREATER DISCRETION IN IMPOSING A HIGHER BOND AMOUNT; TO REQUIRE THE COURT TO AWARD COSTS AND A REASONABLE ATTORNEY FEE TO ANY CERTIFICATE OF NEED APPLICANT WHOSE APPROVED NEW INSTITUTIONAL HEALTH SERVICE IS THE SUBJECT OF A CONTESTED CASE PETITION DETERMINED TO BE FRIVOLOUS OR FILED TO DELAY THE APPLICANT; AND TO PROHIBIT THE STAYING OF A FINAL DECISION IN A CERTIFICATE OF NEED CASE DURING THE PENDENCY OF AN APPEAL, AS RECOMMENDED BY THE HOUSE SELECT COMMITTEE ON CERTIFICATE OF NEED PROCESS AND RELATED HOSPITAL ISSUES.
TO THE MEMBERS OF THE 2013 HOUSE OF REPRESENTATIVES:

Attached for your consideration is the interim report of the House Select Committee on the Certificate of Need Process and Related Hospital Issues established by the Speaker of the House of Representatives pursuant to G.S. 120-19.6(a1) and Rule 26 of the Rules of the House of Representatives of the 2011 General Assembly.

Respectfully submitted,

Representative Fred Steen
Co-Chair

Representative John Torbett
Co-Chair
HOUSE SELECT COMMITTEE ON THE CERTIFICATE OF NEED PROCESS AND RELATED HOSPITAL ISSUES.

TO THE HONORABLE MEMBERS OF THE NORTH CAROLINA HOUSE OF REPRESENTATIVES

Section 1. The House Select Committee on the Certificate of Need Process and Related Hospital Issues (hereinafter "Committee") is established by the Speaker of the House of Representatives pursuant to G.S. 120-19.6(a1) and Rule 26 of the Rules of the House of Representatives of the 2011 General Assembly.

Section 2. The Committee consists of the 11 members listed below, appointed by the Speaker of the House of Representatives. Members serve at the pleasure of the Speaker of the House of Representatives. The Speaker of the House of Representatives may dissolve the Committee at any time.

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Section 3. The Committee may study all of the following:


2. The legal requirements and process governing Department of Health and Human Services determinations on applications for CON, including an analysis of exceptions granted under policy AC-3 of the State Medical Facilities Plan as implemented by the Department of Health and Human Services.
(3) Issues relating to publicly owned hospitals, including determining the appropriate role of State-owned hospitals and the appropriate manner for public hospital authorities created under G.S. 131E-17 to operate beyond the boundaries of the local government that created the authority.

(4) Whether a hospital operating under a Certificate of Public Advantage should be required to comply with the same rules, policies, and limitations to each county in which it operates.

(5) The extent to which a publicly owned hospital should engage in business with an entity having a Certificate of Public Advantage or operating under an exemption under the CON laws of the State.

(6) Any other matter reasonably related to subdivisions (1) through (4) of this section, in the discretion of the Committee.

Section 4. The Committee shall meet upon the call of its Co-Chairs. A quorum of the Committee shall be a majority of its members.

Section 5. The Committee, while in the discharge of its official duties, may exercise all powers provided for under G.S. 120-19 and Article 5A of Chapter 120 of the General Statutes.

Section 6. Members of the Committee shall receive per diem, subsistence, and travel allowance as provided in G.S. 120-3.1.

Section 7. The expenses of the Committee including per diem, subsistence, travel allowances for Committee members, and contracts for professional or consultant services shall be paid upon the written approval of the Speaker of the House of Representatives pursuant to G.S. 120-32.02(c) and G.S. 120-35 from funds available to the House of Representatives for its operations.

Section 8. The Legislative Services Officer shall assign professional and clerical staff to assist the Committee in its work. The Director of Legislative Assistants of the House of Representatives shall assign clerical support staff to the Committee.

Section 9. The Committee may submit an interim report on the results of the study, including any proposed legislation, on or before May 1, 2012, by filing a copy of the report with the Office of the Speaker of the House of Representatives, the House Principal Clerk, and the Legislative Library. The Committee shall submit a final report on the results of its study, including any proposed legislation, to the members of the House of Representatives prior to the convening of the 2013 General Assembly by filing the final report with the Office of the Speaker of the House of Representatives, the House Principal Clerk, and the Legislative Library. The Committee terminates upon the convening of the 2013 General Assembly or upon the filing of its final report, whichever occurs first.

Effective this the 24th day of August, 2011

Thom Tillis
Speaker
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The development of health care facilities and provision of health care services in North Carolina has been subject to State-level regulation and determinations of need since the late 1970's. This health care planning process seeks to ensure that rural areas and underserved populations have adequate access to health care; to encourage safety and high quality in the health care services provided; and to reduce health care costs through the elimination of unnecessarily duplicative expensive facilities, equipment, and services. To accomplish these goals, the statutes require the development of annual projections of need for various types of health care facilities and services. The resulting document is known as the State Medical Facilities Plan (SMFP). To implement the SMFP, the General Assembly enacted the Certificate of Need Law, which provides the process by which persons may apply for a license to construct or expand health care facilities or to provide services in accordance with the determined need.

In addition to the SMFP and the CON law, the State has also taken steps to enhance the availability of quality health care services by allowing hospitals and other persons to enter into cooperative agreements for the provision of health care that would otherwise be subject to State antitrust scrutiny. Such agreements are subject to the issuance, by the State, of a Certificate of Public Advantage (COPA). The COPA spells out conditions of operation imposed upon the parties to the agreement that, in theory, should counterbalance any competitive advantage gained in the health care marketplace under the cooperative agreement. Only one COPA has been issued since the enactment of the statute in 1993.

Although the Certificate of Need law has been amended several times since enacted, it has been a number of years since the General Assembly undertook a serious review of the program. Further, there is concern that our Certificate of Public Advantage law has not adequately offset the competitive advantage gained under the cooperative agreement, and it is unclear if Article 9A provides a definitive process to initiate the termination of an agreement.

The House Select Committee on the Certificate of Need Process and Related Hospital Issues was created and charged with the review of the State health planning process, including the State's CON program and the implementation of the COPA law, to determine whether these programs are adequately serving their intended purpose of ensuring the availability of quality, cost effective health care services to North Carolina citizens. The Committee began its work in September of 2011 and filed an interim report on its proceedings with the General Assembly. This report covers the activities of the Committee from September of 2012 through its termination.

1. G.S. 131E-177
2. Article 9, Chapter 131E of the General Statutes
3. Article 9A, Chapter 131E of the General Statutes.
4. 1991, Legislative Research Commission: Committee on Care Provided by Rest Homes, Intermediate Care Facilities, and Skilled Nursing Homes; Necessity for Certificates of Need; and Continuing Care Issues.
COMMITTEE PROCEEDINGS

Below is a brief summary of the Committee's proceedings. A more detailed record of the Committee's work can be found in the Committee's notebook, located in the Legislative Library. For meetings September 2011 – April 2012, please see the Interim Report dated April 2012.

September 13, 2012

The House Select Committee on Certificate of Need and Related Hospital Issues met on Thursday, September 13, 2012, in Room 544, LOB at 1:00 p.m. First Amy Jo Johnson and Jan Paul, staff attorneys in the Research Division, presented a review of topics before the committee. Next Drexdal Pratt, Director, Division of Health Services Regulation, Department of Health and Human Services gave an update on activities at the Division of Health Service Regulation since the Committee's last meeting. Before adjourning the meeting, Representative Torbett opened the meeting for a period of public comment.

September 27, 2012

The House Select Committee on the Certificate of Need Process and Related Hospital Issues met Thursday, March 15, 2012, in Room 544 of the Legislative Office Building at 10:00 a.m. Craig Smith, Chief, Certificate of Need Section, Division of Health Services Regulation, Department of Health and Human Services gave a presentation detailing the scope of the Certificate of Need Law and all new health service regulations included within the law. Next, the Committee heard two presentations from Dave French, MBA, MHA, President, Strategic Healthcare Consultants. Mr. French's initial presentation gave a history of the 2005 changes in the Certificate of Need Law that involved GI Endoscopy Centers. The presentation also explored potential cost savings and justifications for making changes to the Certificate of Need Law proposed by Mr. French. Changes suggested would allow for single-specialty ambulatory surgery centers. Mr. French followed this presentation with another detailing the current regulations under Certificate of Need law for diagnostic service centers. Finally, Hugh Tilson, Senior Vice President, North Carolina Hospital Association made a presentation to the Committee discussing various hospital quality improvement activities that have taken place. This presentation included a demonstration of the North Carolina Hospital Association's website, which contains reports on the various activities of which Mr. Tilson spoke.

October 11, 2012

The House Select Committee on Certificate of Need and Related Hospital Issues met on Thursday, October 11, 2012, in Room 643, LOB at 10:00 a.m. First, Hugh Tilson, Senior Vice President, North Carolina Hospital Association (NCHA) gave a follow-up presentation on the information available via the NCHA website. Next, Lanier Cansler, President, Cansler Collaborative Resources, Inc., Former Secretary, North Carolina Department of Health and Human Resources gave a presentation on planning for the future of healthcare in North Carolina. After the Committee heard from Lanier Cansler, Dr. Thomas Ricketts, Professor, Health Policy and Administration, Deputy Director, Cecil G Sheps Center for Health Services Research gave a
presentation on the supply and demand of physicians in North Carolina. Finally, Earl Jones, Chairman, Good Hope Hospital, Pat Cameron, Chairman, Good Hope Mental Health, Patsy Caron, Mayor of Erwin, and Jim Burgin, Commissioner, Harnett County updated the Committee on the impact of the CON law on the citizens of Harnett County.

October 25, 2012

The House Select Committee on Certificate of Need Process and Related Hospital Issues met Thursday, October 25, 2012, in Room 544 of the Legislative Office Building at 1pm. The Committee heard three presentations. The first speaker was Noah H. Huffstetler, III, Attorney and Partner at Nelson Mullins. Mr. Huffstetler discussed reasons to maintain the State's Certificate of Need program, noted several improvements that had been made by the Division of Health Service Regulation, Department of Health and Human Services, over the past year, and made a number of recommendations for improvements to the program. The next speaker was Dave French, MBA, MHA, President of Strategic Health Care. His presentation detailed the cost savings and justification for changing the Certificate of Need law to allow single-specialty ambulatory surgical centers. The final speaker, Hugh Tilson, Senior Vice President of the North Carolina Hospital Association, provided the hospital perspective on the changes proposed by Mr. French, and noted hospitals rely on commercially insured patients to cover the cost of providing care to the uninsured and those covered by government programs.

November 15, 2012

The House Select Committee on Certificate of Need Process and Related Hospital Issues met Thursday, November 15, 2012, in Room 643 of the Legislative Office Building at 10:00 am. First, the Committee heard from the following presenters on the Certificate of Public Advantage Audit:

- Christopher B. Taylor, CPA, Assistant Secretary, North Carolina Medical Care Commission
- K. D. (Kip) Sturgis, Assistant Attorney General, North Carolina Department of Justice
- David Motsinger, CPA, Partner, Dixon Hughes Goodman LLP

Next, Jan Paul, Staff Attorney, Research Division gave an update on the recent Court of Appeals decision in Novant Health v. NC DHHS. Lastly, Chairman Torbett requested that the Committee work on finalizing recommendations for the Committee report. The Committee discussed its recommendations and the Chair directed staff to assemble a draft report for the Committee's consideration at the December meeting.

December 6, 2012

The House Select Committee on Certificate of Need Process and Related Hospital Issues met Thursday, December 6, 2012, in Room 544 of the Legislative Office Building at 10:00 am. The Committee discussed and voted on a draft of the final report.
FINDINGS AND RECOMMENDATIONS

Finding:
The development of health care facilities and provision of health care services in North Carolina has been subject to State-level regulation and determinations of need since the late 1970's. The Committee heard a variety of presentations and public comment that touched upon the need for alterations to the new institutional health services covered by Certificate of Need. The Committee finds that an in-depth review of services regulated under the Certificate of Need law is necessary.

Recommendation:
1. The Committee recommends a full and a complete review of all new institutional health services regulated under Certificate of Need law to determine the need and rationale for each included service regulation.

2. The Committee recommends the General Assembly enact legislation exempting diagnostic centers from Certificate of Need Review and amending the Certificate of Need laws pertaining to single-specialty ambulatory surgery operating rooms.

Finding:
The Committee heard concerns that the specified capital expenditures amounts for certain projects and activities need to be adjusted based upon inflation. The statutory expenditure thresholds have not been changed since 1993 regarding expedited reviews, major medical equipment, and replacement equipment. The capital expenditure threshold for new institutional health services has been set at two million dollars since 1987. The Committee finds that many of the monetary thresholds are outdated or no longer relevant.

Recommendations:
3. The Committee recommends the General Assembly increase the capital expenditure threshold for new institutional health services from two million dollars to four million dollars.

4. The Committee recommends the General Assembly eliminate the monetary threshold for expedited reviews.

5. The Committee recommends the General Assembly eliminate replacement equipment from the Certificate of Need process.
6. The Committee recommends the General Assembly increase the monetary threshold for major medical equipment from seven hundred fifty thousand dollars to one and a half million dollars.

Finding:
The Committee heard from parties who had an approved Certificate of Need application and, due to a change in circumstances, encountered difficulty making alterations to its Certificate of Need. This need for alterations is only increased during difficult economic situations. The Committee finds that looking into methods by which a modification to an approved Certificate of Need application could be made is prudent.

Recommendation:
7. The Committee recommends studying ways to make it easier and more efficient to modify or change an approved Certificate of Need, particularly in light of an applicant's change in financial situation, and under which instances this should apply.

Finding:
Pursuant to G.S. 131E-177, the Department of Health and Human Services is designated as the State Health Planning and Development Agency. The State Health Coordinating Council (SHCC) is responsible for directing the development of the annual State Medical Facilities Plan. The SHCC was established via executive order by the Governor and contains appointments from the Governor. The SHCC is subject to ethics guidelines also established via Governor executive order. The Committee received comment expressing a need for more transparency and accountability by the State Health Coordinating Council and its decisions affecting the development of the State Medical Facilities Plan. The Committee finds, while it is necessary for the State Health Coordinating Council members to have experience and expertise in the health care industry, there are concerns of member conflicts of interest, the potential for undue influence by a single individual, and public perception. The Committee finds that these concerns could be lessened by changing the current appointment process of members to the State Health Coordinating Council.

Recommendations:
8. The Committee recommends a codification of the State Health Coordinating Council. The appointments to the Council should be divided amongst the legislative and executive branches.

9. Upon codification of the State Health Coordinating Council, the members should adhere to ethical standards and conflict of interest provisions set by the General Assembly. These ethical standards should strive to eliminate any appearance of undue influence.
Finding:
The Department of Health and Human Services is authorized by statute to establish policies and rules for project review. Policy AC-3 of the North Carolina State Medical Facilities Plan exempts from the need determinations of the State Medical Facilities Plan certain projects for which Certificates of Need are sought by academic medical center teaching hospitals. The academic medical center is required to demonstrate that the expansion is necessary and that its need cannot be achieved effectively at any non-academic medical center teaching hospital provider which currently offers the service for which the exemption is requested and which is within 20 miles of the academic medical center teaching hospital. Presentations and discussion brought into question the issue of whether the Policy AC-3 was equitable, or whether it created an unfair and unnecessary competitive advantage for academic medical centers. Discussion was centered on eliminating the AC-3 policy, codifying it, or studying it. The Committee was informed that Policy AC-3 was revised in the 2012 State Medical Facilities Plan, which added additional requirements for a Policy AC-3 exemption, and that there has been insufficient time and opportunity to determine whether the policy changes will alleviate or eliminate the issues of concern.

Recommendation:

10. The Committee recommends that the Division of Health Services Regulation monitor and review Policy AC-3 for a period of one year, and then report and make recommendations to the 2013 General Assembly and the General Assembly’s Legislative Oversight Committee on Health and Human Services.

Finding:
The Committee heard concerns that the Certificate of Need appeals process is often lengthy, and that some appeals might be brought solely for purposes of delay. The Committee finds that changes in the appeals process should be made in order to streamline the appeals process, to redefine the parties having standing to appeal, and to deter the bringing of frivolous, harassing, or meritless appeals.

Recommendations:

11. The Committee recommends a study to assess the need for a reduction in the appeals process time frames in Certificate of Need cases and to determine methods by which to accomplish this goal.

12. The Committee recommends the General Assembly enact legislation to award the prevailing party costs and attorneys’ fees in Certificate of Need contested cases.

13. The Committee recommends the General Assembly enact legislation giving the appellate court greater discretion to impose a higher appeal bond amount in Certificate of Need cases.
14. The Committee recommends the General Assembly enact legislation requiring the posting of a separate appeal bond for each approved application that is the subject of a petition for contested case hearing or appeal of a Certificate of Need determination.

15. The Committee recommends a study to determine whether prohibiting the staying of a final decision in a Certificate of Need Case during the pendency of an appeal would expedite the CON process.

16. The Committee recommends an examination and possible redefining of the terms “affected person” and “aggrieved party” in the Certificate of Need laws.

Finding:
Hospital authorities are authorized pursuant to Article 2 of Chapter 131E of the General Statutes. A hospital authority may be created by resolution of the city council or board of county commissioners upon finding that it is in the interest of the public health and welfare to do so. The boundaries of a hospital authority include the city or county creating the authority and the area within 10 miles from the territorial boundaries of the city or county. Hospital authorities may operate outside of this area pursuant to an agreement with another hospital in the county, or if none, with a health care agency. The statutes grant extensive powers to hospital authorities, including the power of eminent domain.

Recommendation:
17. The Committee recommends the General Assembly should examine how to define the territorial boundaries of hospital authorities.

Finding:
North Carolina lags slightly in the number of physicians per capita in the U.S. The supply of physicians, however, is growing faster than the State population and the number of physicians in primary care is also on the increase. Unfortunately, there is a persistent problem with poor distribution of physicians across the State. Two programs that have been successful in increasing the number of physicians in rural and underserved areas are the North Carolina Area Health Education Centers (AHEC) residency program and the State Loan Repayment program. Data shows that North Carolina AHEC trained residents are more likely to practice in the rural areas of the State and are more likely to choose primary care than other specialties. The North Carolina Office of Rural Health and Community Care administers the Loan Repayment Program. That program provides up to $100,000 principle plus interest for loan repayments to new physicians locating their practices in rural areas. A four year commitment is required. The Committee finds that the State needs to encourage new physicians to choose specialties that are in short supply and to locate practices in rural, underserved areas.
Recommendation:
18. The Committee recommends the General Assembly should continue to support the NC AHEC residency program and the NC Office of Rural Health and Community Care Rural Health Loan Repayment Program.

Finding:
Health care costs in North Carolina continue to increase despite efforts by the State to control them. Most regulatory efforts, whether aimed at managing care or limiting the expansion of facilities and technology to a State determined level of need, end up simply shifting costs from one area to another that is more profitable. Lanier Cansler, Former Secretary of the North Carolina Department of Health and Human Services noted that if the State wants to seriously address the issues of affordability and sustainability of healthcare in the State "we must develop a vision of our healthcare delivery system and then every modification to law, reimbursement process, policy, must be focused on achieving that vision."

Recommendation:
19. The General Assembly should study reform of the health care market and the health care delivery system in North Carolina to increase cost effectiveness and quality of care through the encouragement of market driven competition in the provision of health care services.

Finding:
A Certificate of Public Advantage (COPA) was issued by the State in 1995 as a condition of allowing the merger of Memorial Mission Hospital and St. Joseph's Hospital to go forward. The entity that emerged from the merger process is Mission Hospital, Inc., operated by Mission Health Systems, Inc. ("Mission"). The COPA agreement was required by the State to offset the anticompetitive effects of the merger on the Western North Carolina health care market. Since 1995, the COPA agreement has been modified twice. Mission has submitted the reports required under the statutes and has been determined to be in compliance with the terms of the COPA agreement. Nonetheless, hospitals, health care providers, and individuals continue to raise concerns about the increase in Mission's market power and whether the COPA agreement has been effective in balancing the anticompetitive effects of the merger. Further in-depth investigation into the economic impact of Mission's COPA on the health care market, especially in light of recent changes in the structure of the health care industry, may be necessary to resolve these issues and ensure the provision of low cost, high quality health care to the people in Western North Carolina.

Recommendation:
20. The Committee recommends that the hospitals, health care providers, and interested individuals in the region make every effort to resolve their differences regarding the COPA prior to the end of the 2013 Session of the General Assembly. If a satisfactory resolution to the issues is not reached in that time, the Committee recommends that the General Assembly conduct a study of the economic impact of the COPA and the effectiveness of that agreement.
GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013

BILL DRAFT 2013-MGz-16A [v.2] (11/19)

(TO SUCH AS A DRAFT AND IS NOT READY FOR INTRODUCTION)
12/6/2012  2:58:31 PM

Short Title: Enact CON Committee Recommendations. (Public)
Sponsors: Representative Torbett.
Referred to:

A BILL TO BE ENTITLED
AN ACT TO ELIMINATE THE MONETARY THRESHOLD FOR EXPEDITED
CERTIFICATE OF NEED REVIEW; TO INCREASE THE MONETARY THRESHOLDS
TRIGGERING CERTIFICATE OF NEED REVIEW FOR CAPITAL EXPENDITURES
AND THE PURCHASE OF MAJOR MEDICAL EQUIPMENT; TO EXEMPT
REPLACEMENT EQUIPMENT FROM CERTIFICATE OF NEED REVIEW
REGARDLESS OF COST; TO REMOVE DIAGNOSTIC CENTERS FROM
CERTIFICATE OF NEED REVIEW; TO ADD SINGLE-SPECIALTY AMBULATORY
SURGERY OPERATING ROOMS AS A TYPE OF NEW INSTITUTIONAL HEALTH
SERVICE SUBJECT TO CERTIFICATE OF NEED REVIEW, WITH EXCEPTIONS
FOR CERTAIN EXISTING SINGLE-SPECIALTY AMBULATORY SURGERY
OPERATING ROOMS IN UNLICENSED SETTINGS; TO REQUIRE AFFECTED
PERSONS SEEKING TO FILE A PETITION FOR A CONTESTED CASE OR AN
APPEAL CHALLENGING CERTIFICATE OF NEED APPROVAL TO DEPOSIT A
SEPARATE BOND FOR EACH APPROVED APPLICATION THAT IS THE SUBJECT
OF THE PETITION OR APPEAL, TO INCREASE THE AMOUNT OF THE MAXIMUM
BOND REQUIREMENT, AND TO GIVE THE COURT OF APPEALS GREATER
DISCRETION IN IMPOSING A HIGHER BOND AMOUNT; AND TO REQUIRE THE
COURT TO AWARD REASONABLE ATTORNEY FEES AND COSTS TO ANY
CERTIFICATE OF NEED APPLICANT WHOSE APPROVED NEW INSTITUTIONAL
HEALTH SERVICE IS THE SUBJECT OF A CONTESTED CASE PETITION
DETERMINED TO BE FRIVOLOUS OR FILED TO DELAY THE APPLICANT, AS
RECOMMENDED BY THE HOUSE SELECT COMMITTEE ON CERTIFICATE OF
NEED PROCESS AND RELATED HOSPITAL ISSUES.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 131E-175 is amended by adding new subdivisions to read:
"(13) That the relocation of a hospital’s operating rooms to a location separate
from the campus upon which the hospital’s inpatient acute care beds and
emergency department are located results in a costly and unnecessary
economic burden to the public.

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

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

SECTION 2. G.S.131E-176(7a) reads as rewritten:

"(7a) 'Diagnostic center' means a freestanding facility, program, or provider, including but not limited to, physicians’ offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars ($10,000) or more exceeds five hundred thousand dollars ($500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars ($500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater."

SECTION 3. G.S. 131E-176(7b) reads as rewritten:

"(7b) 'Expedited review' means the status given to an application’s review process when the applicant petitions for the review and the Department approves the request based on findings that all of the following are met:

a. The review is not competitive.

b. The proposed capital expenditure is less than five million dollars ($5,000,000).

c. A request for a public hearing is not received within the time frame defined in G.S. 131E-185.

d. The agency has not determined that a public hearing is in the public interest."

SECTION 4. G.S. 131E-176(9b) reads as rewritten:

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

SECTION 5. G.S. 131E-176(14o) reads as rewritten:

"(14o) 'Major medical equipment' means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars ($750,000), one million five hundred thousand dollars ($1,500,000). In determining whether the major medical equipment
costs more than **seven hundred fifty thousand dollars ($750,000)**-**one million five hundred thousand dollars ($1,500,000)**, the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section."

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

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

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. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds **two million dollars ($2,000,000)**.

"...

**SECTION 7.** 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**, including a **single-specialty ambulatory surgery 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 or gastrointestinal endoscopy room is currently located.

"...

**SECTION 8.** G.S. 131E-176(22a) reads as rewritten:

"(22a) 'Replacement equipment' means equipment that **costs less than two million dollars ($2,000,000)** and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than two million dollars ($2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater."

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SECTION 9. G.S. 131E-176(24c) reads as rewritten:

"(24c) Reserved for future codification. 'Single-specialty ambulatory surgery operating room' means a designated operating room located in a licensed ambulatory surgical facility that is used to perform same-day surgical procedures in one of the single-specialty areas identified by the American College of Surgeons. For the purpose of this subdivision, 'same-day surgical procedures' includes pain injections by orthopedists, physiatrists, and anesthesiologists."

SECTION 10.(a) G.S. 131E-178 reads as rewritten:

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

(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 person 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, except for a person who:

1. 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 person's license application is postmarked for delivery to the Division of Health Service Regulation by December 31, 2006;
   2. The applicant verifies, by affidavit submitted to the Division of Health Service Regulation 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 Health Service Regulation 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.

(a2) Any person proposing to obtain a license to establish single-specialty ambulatory operating rooms in an ambulatory surgery facility shall be required to obtain a certificate of need, except for a person who:

1. provides single-specialty ambulatory surgery procedures in one or more operating rooms located in a nonlicensed setting and
2. meets all of the following criteria:
(1) The person's license application is postmarked for delivery to the Division of Health Service Regulation by December 31, 2013.

(2) The applicant verifies, by affidavit submitted to the Division of Health Service Regulation within 60 days after 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 Health Service Regulation of the Department; and

(4) The license application includes at least all of the following:
   a. A commitment, plan, and policies and procedures for serving indigent and medically underserved populations.
   b. Projected charges for the 20 most common surgical procedures to be performed in the proposed single-specialty ambulatory surgery operating rooms.

All other persons proposing to obtain a license to establish single-specialty ambulatory operating rooms within an ambulatory surgical facility 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 single-specialty ambulatory surgery operating rooms that may be approved. However, the Department shall not approve an application for a single-specialty ambulatory surgery operating room in any ambulatory surgical facility within a county in which a licensed critical access hospital, as defined in 42 CFR § 400.202, is located. The annual State Medical Facilities Plan also shall not include policies or need determinations that limit the relocation and replacement of existing operating rooms, including single-specialty ambulatory operating rooms. However, the Department shall not approve an application for the relocation of a hospital's operating rooms to a location separate from the campus upon which the hospital's inpatient acute care beds and emergency department are located if approval would result in the hospital obtaining reimbursement for surgery procedures at a rate higher than the rate paid to ambulatory surgery centers under a government sponsored health insurance or medical assistance program.

(b) No person shall make an acquisition by donation, lease, transfer, or comparable arrangement without first obtaining a certificate of need from the Department, if the acquisition would have been a new institutional health service if it had been made by purchase. In determining whether an acquisition would have been a new institutional health service, the capital expenditure for the asset shall be deemed to be the fair market value of the asset or the cost of the asset, whichever is greater.

(c) No person shall incur an obligation for a capital expenditure which is a new institutional health service without first obtaining a certificate of need from the Department. An obligation for a capital expenditure is incurred when:
An enforceable contract, excepting contracts which are expressly contingent upon issuance of a certificate of need, is entered into by a person for the construction, acquisition, lease or financing of a capital asset;

A person takes formal action to commit funds for a construction project undertaken as his own contractor; or

In the case of donated property, the date on which the gift is completed.

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

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

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

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

SECTION 11. G.S. 131E-182 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, the Department is prohibited from scheduling a review prior to February 1, 2013, for certificate of need applications that propose to establish a licensed single-specialty ambulatory operating room within an ambulatory surgery facility.

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

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

SECTION 12. G.S. 131E-184(a) is amended by adding a new subdivision to read:

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

SECTION 13. G.S. 131E-184(e) reads as rewritten:

"(e) The Department shall exempt from certificate of need review a capital expenditure that exceeds the two-four million dollar ($2,000,000) ($4,000,000) threshold set forth in G.S. 131E-176(16)b. if all of the following conditions are met:

1. The proposed capital expenditure would:
   a. Be used solely for the purpose of renovating, replacing on the same site, or expanding an existing:
      1. Nursing home facility,
      2. Adult care home facility, or
      3. Intermediate care facility for the mentally retarded; and
   b. Not result in a change in bed capacity, as defined in G.S. 131E-176(5), or the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.

2. The entity proposing to incur the capital expenditure provides prior written notice to the Department, which notice includes documentation that demonstrates that the proposed capital expenditure would be used for one or more of the following purposes:
   a. Conversion of semiprivate resident rooms to private rooms.
   b. Providing innovative, homelike residential dining spaces, such as cafes, kitchenettes, or private dining areas to accommodate residents and their families or visitors.
   c. Renovating, replacing, or expanding residential living or common areas to improve the quality of life of residents."

SECTION 14. G.S. 131E-188 reads as rewritten:

"§ 131E-188. Administrative and judicial review.
(a) After a decision of the Department to issue, deny or withdraw a certificate of need or exemption or to issue a certificate of need pursuant to a settlement agreement with an applicant to the extent permitted by law, any affected person, as defined in subsection (c) of this section, shall be entitled to a contested case hearing under Article 3 of Chapter 150B of the General Statutes. A petition for a contested case shall be filed within 30 days after the Department makes its decision. When a petition is filed, the Department shall send notification..."
of the petition to the proponent of each application that was reviewed with the application for a certificate of need that is the subject of the petition. Any affected person shall be entitled to intervene in a contested case.

A contested case shall be conducted in accordance with the following timetable:

1. An administrative law judge or a hearing officer, as appropriate, shall be assigned within 15 days after a petition is filed.
2. The parties shall complete discovery within 90 days after the assignment of the administrative law judge or hearing officer.
3. The hearing at which sworn testimony is taken and evidence is presented shall be held within 45 days after the end of the discovery period.
4. The administrative law judge or hearing officer shall make a final decision within 75 days after the hearing.

(5) Repealed by Session Laws 2011-398, s. 46, as amended by Session Laws 2011-326, s. 23, effective January 1, 2012, and applicable to contested cases commenced on or after that date.

The administrative law judge or hearing officer assigned to a case may extend the deadlines in subdivisions (2) through (4) so long as the administrative law judge or hearing officer makes a final decision in the case within 270 days after the petition is filed.

(a1) On or before the date of filing a petition for a contested case hearing on the approval of an applicant for a certificate of need, the petitioner shall deposit a bond for each approved application that is the subject of the petition with the clerk of superior court where any new institutional health service that is the subject of the petition is proposed to be located. The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of the proposed new institutional health service each approved application that is the subject of the petition, but may not be less than five thousand dollars ($5,000) and may not exceed fifty thousand dollars ($50,000). A petitioner who received approval for a certificate of need and is contesting only a condition in the certificate is not required to file a bond under this subsection.

The applicant who received approval for the any new institutional health service that is the subject of the petition may bring an action against a bond filed under this subsection and shall award the applicant reasonable attorney fees and costs incurred in the contested case. At the conclusion of the contested case, if the court does not find that the petition for a contested case was frivolous or filed to delay the applicant, the petitioner shall be entitled to the return of the bond deposited with the superior court upon demonstrating to the clerk of superior court where the bond was filed that the contested case hearing is concluded.

(b) Any affected person who was a party in a contested case hearing shall be entitled to judicial review of all or any portion of any final decision in the following manner. The appeal shall be to the Court of Appeals as provided in G.S. 7A-29(a). The procedure for the appeal shall be as provided by the rules of appellate procedure. The appeal of the final decision shall be taken within 30 days of the receipt of the written notice of final decision, and notice of appeal shall be filed with the Office of Administrative Hearings and served on the Department and all other affected persons who were parties to the contested hearing.
(b1) Before filing an appeal of a final decision granting a certificate of need, the affected person shall deposit a bond with the Clerk of the Court of Appeals. The bond requirements of this subsection shall not apply to any appeal filed by the Department.

(1) The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of each approved application that is the subject of the appeal, but may not be less than five thousand dollars ($5,000) and may not exceed fifty thousand dollars ($50,000); one hundred thousand dollars ($100,000); provided that the applicant who received approval of the certificate of need may petition the Court of Appeals for a higher bond amount for the payment of such costs and damages as may be awarded pursuant to subdivision (2) of this subsection. This amount shall be determined by the Court in its discretion, not to exceed three hundred thousand dollars ($300,000). A holder of a certificate of need who is appealing only a condition in the certificate is not required to file a bond under this subsection.

(2) If the Court of Appeals finds that the appeal was frivolous or filed to delay the applicant, the court shall remand the case to the superior court of the county where a bond was filed for the contested case hearing on the certificate of need. The superior court may award the holder of the certificate of need part or all of the bond. The court shall award the holder of the certificate of need reasonable attorney fees and costs incurred in the appeal to the Court of Appeals. If the Court of Appeals does not find that the appeal was frivolous or filed to delay the applicant and does not remand the case to superior court for a possible award of all or part of the bond to the holder of the certificate of need, the person originally filing the bond shall be entitled to a return of the bond.

(c) The term "affected persons" includes: the applicant; any individual residing within the service area or the geographic area served or to be served by the applicant; any individual who regularly uses health service facilities within that geographic area or the service area; any person who provides services, similar to the services under review, to individuals residing within the service area or the geographic area proposed to be served by the applicant; any person who, prior to receipt by the agency of the proposal being reviewed, has provided written notice to the agency of an intention to provide similar services in the future to individuals residing within the service area or the geographic area to be served by the applicant; third party payers who reimburse health service facilities for services in the service area in which the project is proposed to be located; and any agency which establishes rates for health service facilities or HMOs located in the service area in which the project is proposed to be located."

SECTION 15. Nothing in Sections 1, 7, 9, 10, or 11 of this act shall be construed to reflect any legislative intent as to the circumstances under which Medicare or Medicaid certification may be obtained for a provider of ambulatory surgery services.

SECTION 16. Sections 1, 2, 4, 7, 9, 10, 11 and 12 of this act are effective when they become law. Section 11 of this act expires on the effective date of administrative rules adopted consistent with the provisions of this act regarding the number of single-specialty surgery procedures performed or projected to be performed by applicants seeking to establish a licensed single-specialty ambulatory surgery operating room. The remainder of this act becomes effective October 1, 2013, and applies to certificate of need applications, contested case petitions, and appeals filed on or after that date.