GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2001

H HOUSE BILL 1254

Short Title: C.O.N. Modifications. (Public)

Sponsors: Representatives Pope; and C. Wilson.

Referred to: Health.

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April 12, 2001

1		A BILL TO BE ENTITLED			
2	AN ACT TO MODIFY THE CERTIFICATE OF NEED LAW.				
3	The General Assembly of North Carolina enacts:				
4	SECTION 1. G.S. 131E-175 is repealed.				
5	SECT	TION 2. G.S. 131E-176 reads as rewritten:			
6	"§ 131E-176. D	efinitions.			
7	As used in tl	nis Article, unless the context clearly requires otherwise, the following			
8	terms have the n	neanings specified:			
9	•••				
10	<u>(7a1)</u>	"Established practice" means an entity (i) that delivers a health service			
11		through a physician or physicians that are licensed by the North			
12		Carolina Medical Board and (ii) which is solely owned by a physician			
13		or physicians that are licensed by the North Carolina Medical Board.			
14	<u>(7a2)</u>	"Exempt" means a project, health service, or health service facility that			
15		is exempt from certificate of need review pursuant to G.S. 131E-184.			
16	•••				
17	(15a)	"Multispecialty ambulatory surgical program" means a formal program			
18		for providing on a same-day basis surgical procedures for at least three			
19		of the following specialty areas: urology, gastroenterology,			
20		pulmonology, podiatry, physiatry, pain management, gynecology,			
21		otolaryngology, plastic surgery, general surgery, ophthalmology,			
22		orthopedic, orthopedic surgery, or oral surgery.			
23	•••				
24	(16)	"New institutional health services" means any of the following:			
25		a. The construction, development, or other establishment of a new			
26		health service facility.			
27		b. The obligation by any person of a capital expenditure exceeding			

two million dollars (\$2,000,000) to develop or expand a health

1		service or a health service facility, or which relates to the
		provision of a health service. The cost of any studies, surveys,
2 3		designs, plans, working drawings, specifications, and other
		activities, including staff effort and consulting and other
4 5		services, essential to the acquisition, improvement, expansion,
6		or replacement of any plant or equipment with respect to which
7		
		an expenditure is made shall be included in determining if the
8 9		expenditure exceeds two million dollars (\$2,000,000).
	C.	Any change in bed capacity as defined in G.S. 131E-176(5).
10	d.	The offering of dialysis services or home health services by or
11		on behalf of a health service facility if those services were not
12		offered within the previous 12 months by or on behalf of the
13		facility.
14	e.	A change in a project that was subject to certificate of need
15		review and for which a certificate of need was issued, if the
16		change is proposed during the development of the project or
17		within one year after the project was completed.completed,
18		unless the proposed change would qualify as an exempt project,
19		health service, or health service facility pursuant to G.S. 131E-
20		184. For purposes of this subdivision, a change in a project is a
21		change of more than fifteen percent (15%) of the approved
22		capital expenditure amount or the addition of a health service
23		that is to be located in the facility, or portion thereof, that was
24		constructed or developed in the project.
25	f.	The development or offering of a health service as listed in this
26		subdivision by or on behalf of any person:
27		1. Bone marrow transplantation services.
28		2. Burn intensive care services.
29		3. Neonatal intensive care services.
30		4. Open-heart surgery services.
31		5. Solid organ transplantation services.
32	f1.	The acquisition by purchase, donation, lease, transfer, or
33		comparable arrangement of any of the following equipment by
34		or on behalf of any person:
35		1. Air ambulance.
36		2. Cardiac angioplasty equipment.
37		3. Cardiac catheterization equipment.
38		4. Gamma knife.
39		5. Heart-lung bypass machine.
40		6. Lithotriptor.
41		7. Magnetic resonance imaging scanner.
42		8. Positron emission tomography scanner.
43	g.	to k. Repealed by Session Laws 1987, c. 511, s. 1.

1		1.	The purchase, lease, or acquisition of any health service facility,
2			or portion thereof, or a controlling interest in the health service
3			facility or portion thereof, if the health service facility was
4 5			developed under a certificate of need issued pursuant to G.S. 131E-180.
6		m.	Any conversion of nonhealth service facility beds to health
7			service facility beds.
8		n.	The construction, development or other establishment of a
9			hospice, hospice inpatient facility, or hospice residential care
10			facility; facility.
11		ο.	The opening of an additional office by an existing home health
12			agency within its service area as defined by rules adopted by the
13			Department; or the opening of any office by an existing home
14			health agency outside its service area as defined by rules
15			adopted by the Department.
16		p.	The acquisition by purchase, donation, lease, transfer, or
17			comparable arrangement by any person of major medical
18			equipment.
19		q.	The relocation of a health service facility from one service area
20			to another.
21		r.	The conversion of a specialty ambulatory surgical program to a
22			multispecialty ambulatory surgical program or the addition of a
23			specialty to a specialty ambulatory surgical program.
24		S.	The furnishing of mobile medical equipment to any person to
25			provide health services in North Carolina, which was not in use
26			in North Carolina prior to the adoption of this provision, if such
27			equipment would otherwise be subject to review in accordance
28			with G.S. 131E-176(16)(f1.) or G.S. 131E-176(16)(p) if it had
29			been acquired in North Carolina.
30		t.	The relocation or expansion of part or all of an ambulatory
31			surgical facility which requires a new license under Part D of
32			Article 6 of this Chapter, or the relocation and addition of part
33			or all of a hospital operating room to a building other than one
34			within which it is currently located.
35	•••		
36	(24c)	_	ialty ambulatory surgical program" means a formal program for
37		•	ding on a same-day basis surgical procedures for only the
38		_	alty areas identified on the ambulatory surgical facility's 1993
39			cation for Licensure as an Ambulatory Surgical Center and
40			rized by its certificate of need.need where a certificate of need is
41		reauir	red pursuant to this Article."

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

SECTION 3. G.S. 131E-178 reads as rewritten:

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- (a) No-Unless exempt from review pursuant to G.S. 131E-184, 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.
- (b) No-Unless exempt from review pursuant to G.S. 131E-184, 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-Unless exempt from review pursuant to G.S. 131E-184, 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:
 - (1) 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;
 - (2) A person takes formal action to commit funds for a construction project undertaken as his own contractor; or
 - (3) In the case of donated property, the date on which the gift is completed.
- (d) 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.
- (e) 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.site for a new institutional health service that is not exempt from review pursuant to G.S. 131E-184."

SECTION 4. G.S. 131E-181 reads as rewritten:

"§ 131E-181. Nature of certificate of need.

- (a) A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).
- (b) A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need. The Department shall require any recipient of a certificate of need, or its successor, whose service is in operation to submit to the Department evidence that the recipient, or its successor, is in material compliance with the representations made in its application for the certificate of need which granted the recipient the right to operate that service. In determining whether the recipient of a certificate of need, or its successor, is operating a service which materially differs from the representations made in its application for that certificate of need, the Department shall consider cost increases to the recipient, or its successor, including, but not limited to, the following:
 - (1) Any increase in the consumer price index;
 - (2) Any increased cost incurred because of Government requirements, including federal, State, or any political subdivision thereof; and
 - (3) Any increase in cost due to professional fees or the purchase of services and supplies.
- (c) Whenever a certificate of need is issued more than 12 months after the application for the certificate of need began review, the Department shall adjust the capital expenditure amount proposed by increasing it to reflect any inflation in the Department of Commerce's Construction Cost Index that has occurred since the date when the application began review; and the Department shall use this recalculated capital expenditure amount in the certificate of need issued for the project.
- (d) A project authorized by a certificate of need is complete when the health service or the health service facility for which the certificate of need was issued is licensed and certified and is in material compliance with the representations made in the certificate of need application.
- (e) Any recipient of a certificate of need received on or before the effective date of the amendments to G.S. 131E-184 that qualifies for exempt status pursuant to G.S. 131E-184, as amended, may serve the Department with written notice of a request for exemption. The Department shall grant the exemption where the request for exemption shows that the applicant qualifies for exempt status pursuant to any provision of G.S. 131E-184.
- (f) A recipient of a certificate of need that requests exempt status pursuant to subsection (e) of this section shall comply with the requirements of subsections (b), (c), and (d) of this section until the Department issues the exemption. The requirements of

subsections (b), (c), and (d) shall cease to apply to a recipient of a certificate of need on the date the exemption is issued by the Department pursuant to G.S. 131E-184."

SECTION 5. G.S. 131E-182 reads as rewritten:

"§ 131E-182. Application.

- (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 health service area will be reviewed together.
- (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.
- (b1) An application for exemption from certificate of need review submitted pursuant to G.S. 131E-184 shall be made on forms provided by the Department. The application forms shall require any information that the Department deems necessary, by rule, to conduct the review. An applicant shall be required to furnish only that information that is necessary to determine whether the proposed project, health service, or health service facility meets the requirements for exempt status consistent with the review criteria implemented under G.S. 131E-184.
- (c) All fees established by the Department for submitting an application for a certificate of need are due when the application is submitted. These fees are not refundable, regardless of whether a certificate of need is issued."

SECTION 6. G.S. 131E-183 reads as rewritten:

"§ 131E-183. Review criteria.

- (a) This section shall not apply to applications for exemption submitted pursuant to G.S. 131E-184.
- (a1) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.
 - (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, ambulatory surgical operating rooms, or home health offices that may be approved. The need determinations in the State Medical Facilities Plan shall not constitute determinative limitations on the provision of any project, health service, health service facility, health service facility bed, dialysis stations, or ambulatory surgical operating rooms that are exempt from certificate of need review pursuant to G.S. 131E-184.

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(b)

- this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

 (c) Repealed by Session Laws 1987, c. 511, s. 1."
 - Repealed by Session Laws 1987, c. 511, s. 1."

 SECTION 7. G.S. 131E-184 reads as rewritten:

"§ 131E-184. Exemptions from review.

- (a) Except as provided in subsection (b), the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, for any of the following:
 - (1) To eliminate or prevent imminent safety hazards as defined in federal, State, or local fire, building, or life safety codes or regulations.

The Department is authorized to adopt rules for the review of particular types

of applications that will be used in addition to those criteria outlined in subsection (a) of

- (1a) To comply with State licensure standards.
- (1b) To comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State plan for medical assistance approved under Title XIX of that act.
- (2) Repealed by Session Laws 1987, c. 511, s. 1.
- (3) To provide data processing equipment.
- (4) To provide parking, heating or cooling systems, elevators, or other basic plant or mechanical improvements, unless these activities are integral portions of a project that involves the construction of a new health service facility or portion thereof and that is subject to certificate of need review.
- (5) To replace or repair facilities destroyed or damaged by accident or natural disaster.
- (6) To provide any nonhealth service facility or service.
- (7) To provide replacement equipment.
- (8) To acquire an existing health service facility, including equipment owned by the health service facility at the time of acquisition.
- (9) To develop or acquire a physician office building regardless of cost, unless a new institutional health service other than defined in G.S. 131E-176(16)b. is offered or developed in the building.
- (b) Those portions of a proposed project which are not proposed for one or more of the purposes under subsection (a) of this section are subject to certificate of need review, if these non-exempt portions of the project are new institutional health services

under G.S. 131E-176(16): G.S. 131E-176(16) and are not otherwise exempt from review
 pursuant to any of the remaining provisions in this section.
 (c) The Department shall exempt from certificate of need review any conversion

- (c) The Department shall exempt from certificate of need review any conversion of existing acute care beds to psychiatric beds provided:
 - (1) The hospital proposing the conversion has executed a contract with the Department's Division of Mental Health, Developmental Disabilities, and Substance Abuse Services and/or one or more of the Area Mental Health, Developmental Disabilities, and Substance Abuse Authorities to provide psychiatric beds to patients referred by the contracting agency or agencies; and
 - (2) The total number of beds to be converted shall not be more than twice the number of beds for which the contract pursuant to subdivision (1) of this subsection shall provide.
- (d) The Department shall exempt from certificate of need review the projects, health services, and health service facilities identified in this subsection if it receives prior written notice from the applicant requesting the exemption, which notice shall include an explanation of the project, health service, or health service facility that is sufficient to enable the Department to determine if the applicant qualifies for exempt status pursuant to any provision in subdivisions (d)(1) through (d)(5) of this section. The Department shall grant the exemption where the request shows that the applicant qualifies for exempt status pursuant to any provision in subdivisions (d)(1) through (d)(5). For the purpose of this subsection, the following projects, health services, and health service facilities are exempt from certificate of need review:
 - (1) The construction, development, or other establishment by an established practice within its county or by a hospital within its county of any of the following: ambulatory surgical facility, ambulatory surgical program, specialty or multispecialty ambulatory surgical program, and imaging services attendant to a physician's practice, including the acquisition and use of one or more magnetic resonance imaging scanners.
 - (2) 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, by an established practice within its county or by a hospital within its county.
 - (3) The acquisition of major medical equipment, excluding lithotriptor equipment, by purchase, donation, lease, transfer, or comparable arrangement by a hospital that is operating pursuant to a certificate of need.
 - (4) A change in bed capacity or the conversion of nonhealth service facility beds to health service facility beds in a hospital.
 - (5) The expansion or relocation of a hospital if the expansion or relocation is within its county of primary operation.

- 1 (e) An applicant requesting an exemption under any provision in subsection (d)
 2 of this section shall certify all of the following with respect to the project, health
 3 service, or health service facility for which the exemption is requested:
 4 (1) If the project, health service, or health service facility is subject to any
 - (1) If the project, health service, or health service facility is subject to any State licensure requirements, that it will continuously maintain those licenses, except that need-based licensure requirements established by general statute or rules issued pursuant to those statutes shall not apply to projects, health services, or health service facilities that are exempt from review as set forth in this section.
 - (2) If the project, health service, or health service facility is subject to minimum standards established by general statute or the rules issued pursuant to those statutes, that it will continuously maintain those minimum standards.
 - (3) That the project, health service, or health service facility will provide nonselective necessary medical treatment to medically uninsured, medically indigent or low-income persons, Medicaid recipients, and Medicare recipients.
 - (4) That the transference of care of any patient to another health service provider or health service facility shall not be based on the patient's income or the patient's available health insurance coverage."

SECTION 8. Chapter 131E of the General Statutes is amended by adding a new section to read:

"§ 131E-185.1. Review process for applications for exemption.

The Department shall have 60 days from the day the request is received to review a request for exemption submitted pursuant to G.S. 131E-184. The request for exemption may be made at any time. The Department may extend the review period, upon written notice to the applicant, for a period not to exceed 60 days, if it has requested additional substantive information from the applicant."

SECTION 9. Chapter 131E of the General Statutes is amended by adding a new section to read:

"§ 131E-186.1. Decision on applications for exemption.

- (a) Within the prescribed time limits in G.S. 131E-185.1, the Department shall issue a decision to "approve," "approve with conditions," or "deny" an application for exemption from certificate of need review pursuant to G.S. 131E-184.
- (b) Within five business days after it makes a decision on a request for exemption, the Department shall provide written notice to the applicant of all the findings and conclusions on which it based its decision, including the criteria used by the Department in making its decision."

SECTION 10. G.S. 131E-190 reads as rewritten:

"§ 131E-190. Enforcement and sanctions.

(a) Only those new institutional health services which are found by the Department to be needed as provided in this Article and granted certificates of need, or which are found by the Department to be exempt from review, shall be offered or developed within the State.

- (b) No formal commitments made for financing, construction, or acquisition regarding the offering or development of a <u>nonexempt</u> new institutional health service shall be made by any person unless a certificate of need for such service or activities has been granted.
 - (c) Repealed by Session Laws 1993, c. 7, s. 11.
- (d) If any person proceeds to offer or develop a new institutional health service without having first obtained a certificate of need for such services, the penalty for such violation of this Article and rules hereunder may include the withholding of federal and State funds under Titles V, XVIII, and XIX of the Social Security Act for reimbursement of capital and operating expenses related to the provision of the new institutional health service.
- (e) The Department may revoke or suspend the license of any person who proceeds to offer or develop a <u>nonexempt</u> new institutional health service without having first obtained a certificate of need for such services.
- (f) The Department may assess a civil penalty of not more than twenty thousand dollars (\$20,000) against any person who knowingly offers or develops any nonexempt new institutional health service within the meaning of this Article without a certificate of need issued under this Article and the rules pertaining thereto, or in violation of the terms or conditions of such a certificate, whenever it determines a violation has occurred and each time the service is provided in violation of this provision. In determining the amount of the penalty the Department shall consider the degree and extent of harm caused by the violation and the cost of rectifying the damage. A person who is assessed a penalty shall be notified of the penalty by registered or certified mail. The notice shall state the reasons for the penalty. If a person fails to pay a penalty, the Department shall refer the matter to the Attorney General for collection. For the purpose of this subsection, the word "person" shall not include an individual in his capacity as an officer, director, or employee of a person as otherwise defined in this Article.

The clear proceeds of penalties provided for in this subsection shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2.

- (g) No agency of the State or any of its political subdivisions may appropriate or grant funds or financially assist in any way a person, applicant, or facility which is or whose project is in violation of this Article.
- (h) If any person proceeds to offer or develop a <u>nonexempt</u> new institutional health service without having first obtained a certificate of need for such services, the Secretary of Health and Human Services or any person aggrieved, as defined by G.S. 150B-2(6), may bring a civil action for injunctive relief, temporary or permanent, against the person offering, developing or operating any new institutional health service. The action may be brought in the superior court of any county in which the health service facility is located or in the superior court of Wake County.
- (i) If the Department determines that the recipient of a certificate of need, or its successor, is operating a service which materially differs from the representations made in its application for that certificate of need, the Department may bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized for injunctive relief, temporary or permanent, requiring the

recipient, or its successor, to materially comply with the representations in its application. The Department may also bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized to enforce the provisions of this subsection and G.S. 131E-181(b) and the rules adopted in accordance with this subsection and G.S. 131E-181(b)."

6 7 **SECTION 11.** The Division of Facility Services shall collect a fee of ten dollars (\$10.00) for processing each application filed pursuant to this act.

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SECTION 12. This act becomes effective October 1, 2001.