

## **CON REVIEW PANEL RECOMMENDATIONS**

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## I. RECOMMENDATIONS APPROVED BY THE BOARD

**Recommendation #1: The capital threshold is too low. Raise capital threshold to \$5 million, and apply it only to capital costs associated with patient care activities, or an increase in square footage of greater than ten percent. For items that otherwise do not require CON, the threshold does not apply.**

- *Increase monetary threshold from \$2,000,000 to \$5,000,000: Regulation*
- *Apply threshold only to capital costs associated with patient care activities and increases in square footage of greater than ten percent: Statute*
- *Do not apply threshold to items that are exempt or for which CON is non-applicable: Statute*

**Recommendation #2: The existing equipment threshold should be eliminated, but the Department should ensure quality for medical equipment through processes in the Bureau of Radiological Health. New and emerging technology (NET) with a total project cost of greater than \$1.5 million should be reviewed, with the threshold being revised annually according to the Medical Care Consumer Price Index inflation rate.**

- *Eliminate the monetary threshold on equipment used for diagnosis or treatment: Statute\**
- *Establish a \$1.5 million threshold, revised annually, for new and emerging technology (NET), based on the Medical Care Consumer Price Index. NET is defined as equipment not having received approval by the Food and Drug Administration (FDA) at the time of the SC Health Plan approval: Statute\**
- *The Department should require accreditation for CT and MRI units by CMS accepted accreditation programs. This accreditation should occur as a condition of registration by the Bureau of Radiological Health. The Department should pursue authority to register MRI units for the sole purpose of ensuring quality through accreditation: Statute*

*\* In the meantime, raise the monetary threshold on equipment used for diagnosis or treatment from \$600,000 to \$1.5 million: Regulation*

**Recommendation #4: Frivolous lawsuits should be discouraged.**

- *There should be a "loser pays" provision in CON for lawsuits: Statute*

**Recommendation #19: CON extension requests should allow more flexibility within the required 90 day submission period.**

- *Clarify the Board's authority to waive the requirement that a holder of a CON seeking an extension from the Board submit the request 3 months prior to expiration of the CON: Regulation*

## II. REGULATORY REVISIONS TO IMPLEMENT RECOMMENDATIONS<sup>1</sup>

**Recommendation #1: Increase capital threshold from \$2 million to \$5 million**

**Recommendation #2: Increase threshold for equipment from \$600,000 to \$1.5 million, to be adjusted annually based upon the Medical Care Consumer Price Index, as published by the United States Department of Labor, Bureau of Labor Statistics.**

**Recommendation #19: Allow more flexibility within the required 90 day submission period for requests for CON extensions.**

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### *Amendments to Regulation 61-15, Certification of Need for Health Facilities and Services*

#### **Section 102. Applicability:**

1. A person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Health and Environmental Control before undertaking any of the following:

...

c. An expenditure by or on behalf of a health care facility in excess of ~~two~~ five million dollars (\$~~2~~5,000,000) which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure exempted in Section 104. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the development, acquisition, improvement, expansion, or replacement of any plant or equipment must be included in determining if the expenditure exceeds the prescribed amount;

...

f. The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of ~~six hundred thousand dollars (\$600,000);~~ one and a half million dollars (\$1,500,000). The Department shall adjust the threshold of one and a half million dollars annually on July 1 or, if July 1 is a Saturday, Sunday, or holiday, the next non-holiday business day following July 1, based upon the Medical Care Consumer Price Index, and shall publish notice of the adjusted amount in the next-following edition of the State Register. The adjusted amount shall become effective as of the date of publication in the State Register.

...

#### **Section 601. Voidance and Extension Procedures:**

4. However, the Board may grant further extensions of the Certificate of Need of up to nine months each if it determines that substantial progress has been made. A request to the Board must be made at least three months prior to the expiration of the Certificate of Need and must contain justification for such extension. The Board may, in its discretion, waive the three-month requirement for submitting a request for an extension.

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<sup>1</sup> Some recommendations adopted by the Board require statutory change. If statutory changes occur, further regulatory revisions will be required for consistency between statute and regulation.

### III. CON REVIEW PANEL RECOMMENDATIONS THAT CAN BE ADMINISTRATIVELY IMPLEMENTED<sup>1</sup>

Recommendation # 5(b) and (c):

**5. Create more transparency. Eliminate the requirement to public notice CON intent in the local newspaper, as this is an antiquated requirement.**

Recommendation:

- b. *DHEC should develop a method of posting letters of intent on the DHEC web page.*
- c. *DHEC should pursue an online process for CON applications, that includes the ability of affected persons to submit comments and/or express opposition.*

Recommendation 5(b) can be easily implemented by posting letters of intent on DHEC's website. However, the Department normally does not receive these letters until after publication in the newspaper. We can let the regulated community know that we have the ability to post these online, and when we do receive one, we can post it. We cannot require applicants to send us these letters of intent; we can only tell them that we'll post them if we do.

Recommendation 5(c) could be implemented in the future. It cannot be implemented at this time due to the resources needed. However, the program has included this in its request within the e-permitting system that the agency is developing.

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<sup>1</sup> Includes recommendations by the CON Review Panel not adopted by the Board at the January 10, 2013 Board meeting.



**South Carolina General Assembly**  
120th Session, 2013-2014

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~~Indicates Matter Stricken~~

Indicates New Matter

**S. 568**

**STATUS INFORMATION**

General Bill

Sponsors: Senators Peeler, Cleary and S. Martin

Document Path: I:\council\bill\nbd\11180ac13.docx

Introduced in the Senate on March 21, 2013

Currently residing in the Senate

Summary: Certificate of Need

**HISTORY OF LEGISLATIVE ACTIONS**

Date	Body	Action Description with journal page number
3/21/2013	Senate	Introduced and read first time ( <a href="#">Senate Journal-page 9</a> )
3/21/2013	Senate	Referred to Committee on Medical Affairs ( <a href="#">Senate Journal-page 9</a> )
4/18/2013	Senate	Committee report: Favorable Medical Affairs ( <a href="#">Senate Journal-page 9</a> )
4/19/2013		Scrivener's error corrected

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**VERSIONS OF THIS BILL**

[3/21/2013](#)

[4/18/2013](#)

[4/19/2013](#)

(Text matches printed bills. Document has been reformatted to meet World Wide Web specifications.)

~~Indicates Matter Stricken~~

Indicates New Matter

**COMMITTEE REPORT**

April 18, 2013

**S. 568**

Introduced by Senators Peeler and Cleary

S. Printed 4/18/13--S. [SEC 4/19/13 3:54 PM]

Read the first time March 21, 2013.

## THE COMMITTEE ON MEDICAL AFFAIRS

To whom was referred a Bill (S. 568) to amend Section 44-7-130, as amended, Code of Laws of South Carolina, 1976, relating to the definition of terms used in the State Certificate of Need, etc., respectfully

### REPORT:

That they have duly and carefully considered the same and recommend that the same do pass:

HARVEY S. PEELER, JR. for Committee.

### A BILL

TO AMEND SECTION 44-7-130, AS AMENDED, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO THE DEFINITION OF TERMS USED IN THE STATE CERTIFICATE OF NEED AND HEALTH FACILITY LICENSURE ACT, SO AS TO ADD THE DEFINITION FOR "NEW AND EMERGING TECHNOLOGY"; TO AMEND SECTION 44-7-160, AS AMENDED, RELATING TO CIRCUMSTANCES AND ACTIVITIES REQUIRING A CERTIFICATE OF NEED (CON), SO AS TO FURTHER SPECIFY HEALTH CARE FACILITY EXPENDITURES REQUIRING A CON AND TO MAKE TECHNICAL CORRECTIONS; TO AMEND SECTION 44-7-220, AS AMENDED, RELATING TO THE APPELLATE REVIEW OF CERTIFICATE OF NEED DECISIONS, SO AS TO PROVIDE FOR ATTORNEY FEES AND COSTS IN CERTAIN CIRCUMSTANCES AND TO DEFINE "FRIVOLOUS APPEAL"; TO AMEND SECTION 13-7-10, RELATING TO THE DEFINITION OF TERMS USED IN THE ATOMIC ENERGY AND RADIATION CONTROL ACT, SO AS TO REVISE THE DEFINITION OF "NONIONIZING RADIATION"; TO AMEND SECTION 13-7-45, AS AMENDED, RELATING TO THE COLLECTION OF FEES FOR LICENSING, REGISTRATION AND CERTIFICATION OF USERS OF THE SOURCES OF IONIZING RADIATION AND THE USE OF THESE FEES, SO AS TO PROVIDE THAT ACCREDITATION OR CERTIFICATION IS A REQUIREMENT OF APPLICATION AND REGISTRATION OF MAGNETIC RESONANCE IMAGING EQUIPMENT AND COMPUTED TOMOGRAPHY EQUIPMENT AND THAT THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL SHALL DETERMINE THE ACCREDITATION OR CERTIFICATION AGENCIES AND TO PROVIDE THAT THE DEPARTMENT SHALL ESTABLISH REGISTRATION FEES FOR RADIOFREQUENCY RADIATION WITHIN MAGNETIC RESONANCE IMAGING DEVICES USED TO OBTAIN HUMAN BODY IMAGES.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Section 44-7-130 of the 1976 Code, as last amended by Act 61 of 2011, is further amended by adding an appropriately numbered item at the end to read:

"( ) 'New and emerging technology' or 'NET' means equipment, used for diagnosis or treatment, not yet having received approval by the Food and Drug Administration as of the adoption of the South Carolina Health Plan in effect at the time."

SECTION 2. Section 44-7-160 of the 1976 Code, as last amended by Act 278 of 2010, is further amended to read:

"Section 44-7-160. A person or health care facility, as defined in this article, is required to obtain a Certificate of Need from the department before undertaking any of the following:

- (1) the construction or other establishment of a new health care facility;
- (2) a change in the existing bed complement of a health care facility through the addition of one or more beds or change in the classification of licensure of one or more beds;
- (3) an expenditure by or on behalf of a health care facility in excess of an amount to be prescribed by regulation which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure and which is associated with patient care activities or an increase in square footage of greater than ten percent, ~~except those expenditures exempted in Section 44-7-170(B)(1) in Section 44-7-170 that are exempt or to which this article does not apply.~~ The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the development, acquisition, improvement, expansion, or replacement of any plant or equipment must be included in determining if the expenditure exceeds the prescribed amount;
- (4) a capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the South Carolina Health Plan;
- (5) the offering of a health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan;
- (6) the acquisition of ~~medical equipment which is to be~~ new and emerging technology used for diagnosis or treatment if the total project cost is in excess of that prescribed by regulation."

SECTION 3. Section 44-7-220 of the 1976 Code, as last amended by Act 278 of 2010, is further amended to read:

"Section 44-7-220. (A) A party who is aggrieved by the Administrative Law Court's final decision may seek judicial review of the final decision in accordance with Section 1-23-380.

(B)(1) If a party does not prevail in a contested case at the Administrative Law Court when requesting the reversal of the department's decision to approve a Certificate of Need application or an exemption under Section 44-7-170 or a determination that Section 44-7-160 is not applicable, the Administrative Law Court shall award the party whose project is the subject of the appeal reasonable attorney's fees and costs incurred in the contested case.

(2) If a party does not prevail in an appeal to the Court of Appeals when requesting the reversal of the Administrative Law Court's decision to approve a Certificate of Need application or an exemption under Section 44-7-170 or a determination that Section 44-7-160 is not applicable, the Court of Appeals shall award the party whose project is the subject of the contested case reasonable attorney's fees and costs incurred in the appeal.

(C) If the relief requested in the an appeal is the reversal of the Administrative Law Court's decision to approve the Certificate of Need application or approve the request for exemption under Section 44-7-170 or approve the determination that Section 44-7-160 is not applicable, the party filing the appeal shall

deposit a bond with the Clerk of the Court of Appeals within five calendar days after filing the petition to appeal. The bond must be secured by cash or a surety authorized to do business in this State in an amount equal to five percent of the total cost of the project or one hundred thousand dollars, whichever is greater, up to a maximum of one million five hundred thousand dollars. If the Court of Appeals affirms the Administrative Law Court's decision or dismisses the appeal, the Court of Appeals shall award to the party whose project is the subject of the appeal all of the bond ~~and also may award reasonable attorney's fees and costs incurred in the appeal~~. If a party appeals the denial of its own Certificate of Need application or of an exemption request under Section ~~44-7-170~~ or appeals the determination that Section ~~44-7-160~~ is applicable and there is no competing application involved in the appeal, the party filing the appeal is not required to deposit a bond with the Court of Appeals.

~~(E)~~(1) ~~Furthermore~~, If at the conclusion of the contested case or judicial review the Administrative Law Court or the Court of Appeals finds that the contested case or a subsequent appeal was frivolous, the Administrative Law Court or the Court of Appeals ~~may~~ shall award damages incurred as a result of the delay, as well as reasonable attorney's fees and costs, to the party whose project is the subject of the contested case or judicial review.

(2) As used in this subsection, 'frivolous appeal' means ~~any one of the following~~ a reasonable person in the same circumstances would believe that:

(a) ~~taken solely for purposes of delay or harassment~~ under the fact the contested case or subsequent appeal was clearly not warranted under existing law and that a good faith or reasonable argument did not exist for the extension, modification, or reversal of existing law;

(b) ~~where no question of law is involved~~ the procurement, initiation, or continuation of the contested case or subsequent appeal was intended merely to harass or injure the other party; or

(c) ~~where the contested case or judicial review is without merit~~ the contested case or subsequent appeal was not reasonably founded in fact or was interposed merely for delay or was merely brought for a purpose other than securing proper discovery or adjudication of the claim upon which the proceedings are based.

This subsection must not be construed to prohibit any party from seeking sanctions pursuant to the South Carolina Frivolous Civil Proceedings Sanctions Act pursuant to Section 15-36-10, et seq.

(D) The court must not assess attorney's fees or costs against the department or awarded to the department in any contested case or appeal involving a Certificate of Need application or an exemption request under Section 44-7-170 or a request for a determination as to the applicability of Section 44-7-160."

SECTION 4. Section ~~13-7-10~~(9) of the 1976 Code is amended to read:

"(9) 'Nonionizing radiation' for the purpose of this section ~~shall mean only~~ means ultraviolet radiation used for the purpose of tanning the human body, ~~and shall include ultraviolet radiation with wavelengths in air between two hundred and four hundred nanometers or radiofrequency radiation within a magnetic resonance imaging device used for the purpose of obtaining images of the human body."~~

SECTION 5. Section ~~13-7-45~~ of the 1976 Code, as last amended by Act 355 of 2006, is amended to read:

"Section ~~13-7-45~~. (A)(1) The South Carolina Department of Health and Environmental Control shall promulgate regulations and establish a schedule for the collection of annual fees for the licensing,

registration, and certification of users of the sources of ionizing radiation. The fees collected must be sufficient, in the judgment of the department, to protect the public health and safety and the environment and to recover the costs incurred by the department in regulating the use of ionizing radiation and in performing emergency corrective measures intended to protect the public health and safety or the environment pursuant to the provisions of law.

(2) Accreditation or certification is a requirement of application and registration of magnetic resonance imaging equipment and computed tomography equipment. The department shall determine the appropriate accreditation or certification agencies.

(3) The department shall promulgate regulations and establish a schedule for the collection of an annual fee for the registration of a source of nonionizing radiation ~~which that~~ is used in a commercial establishment for the tanning of human skin or radiofrequency radiation within a magnetic resonance imaging device used for the purpose of obtaining images of the human body. The registration fee must be sufficient in the judgment of the department to protect the public health and safety and the environment and to recover the costs incurred by the department in registering the source of nonionizing radiation and in performing emergency corrective measures intended to protect the public health and safety or the environment pursuant to ~~the provisions of law.~~

~~(3)~~(4) The department ~~shall have~~ has no duty to inspect a source of nonionizing radiation unless it has received credible information indicating a violation of applicable statutes or regulations or the existence of a public health emergency. The department may retain up to ~~thirty~~ fifty thousand dollars from the fees collected to be used for the administration of this program.

(B) In determining the sufficiency of the fees to be charged and collected, the department shall consider an arrangement existing between South Carolina and a registrant, a licensee, a certificant, another state, or a federal agency under which costs incurred by the department in regulating the use of ionizing and nonionizing radiation and in performing emergency corrective measures intended to protect the public health and safety and the environment are recoverable by this State.

(C) A registrant, licensee, or certificant who fails to pay the fees required by ~~regulation of the~~ department within thirty days after payment is due also shall pay a penalty of fifty dollars. If failure to pay the required fees continues for more than sixty days after payment is due, the registrant, licensee, or certificant must be notified by the department by certified mail to be sent to his last known address that his registration, license, or certificate is revoked and that activities permitted under the authority of the registration, license, or certificate must end immediately. The registration, license, or certificate may be reinstated by the department upon payment of the required fees, the penalty of fifty dollars, and an additional penalty of one hundred dollars if the registrant, licensee, or certificant is otherwise in good standing, in the judgment of the department, and presents to the department a satisfactory explanation for his failure to pay the required fees."

SECTION 6. This act takes effect upon approval by the Governor.

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