"THE BELOW CONSTITUTED SUMMARY IS PREPARED BY THE STAFF OF THE SOUTH CAROLINA HOUSE OF REPRESENTATIVES AND IS NOT THE EXPRESSION OF THE LEGISLATION'S SPONSOR(S) OR THE HOUSE OF REPRESENTATIVES. IT IS STRICTLY FOR THE INTERNAL USE AND BENEFIT OF MEMBERS OF THE HOUSE OF REPRESENTATIVES AND IS NOT TO BE CONSTRUED BY A COURT OF LAW AS AN EXPRESSION OF LEGISLATIVE INTENT".

REPORT OF THE REVENUE POLICY SUBCOMMITTEE

(White, Limehouse, Bingham, Pitts & Herbkersman - Staff Contact: Rena N. Grant)

HOUSE BILL 3250

H. 3250 -- Reps. G.M. Smith, Clyburn, Merrill and Anthony: A BILL TO AMEND SECTION 44-7-130, AS AMENDED, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO TERMINOLOGY FOR THE CERTIFICATE OF NEED PROGRAM

Summary of Bill: H. 3250 as pre-filed includes the following provisions:

- 2012 recommendations of the CON Review Panel (please see attachment)
- Recommendations of the SC Hospital Association
 The SC Hospital Association made the following recommendations to the CON Ad Hoc:
 Removal of CON for the following items:
 - o Adding new beds in an existing licensed acute care, rehab, and psychiatric hospital. This would only apply to additions that are within the existing footprint of the licensed facility.
 - Expanding a service for which CON has been previously awarded. For example, if a hospital
 wanted to add capacity to a service such as open heart surgery the hospital would not have
 get another CON in order to expand.
 - Remove the CON requirement for conversion of acute care beds to psychiatric beds with certain limitations.

Eliminate the monetary threshold for purchasing medical equipment to be used for diagnosis or treatment. Clarification of "like equipment". Under the current statute, a CON is not required when upgrading or replacing "like equipment

Increasing the current capital expenditure threshold from \$2M to \$5M and indexing it annually to medical care consumer price index.

- Elimination of the State Health Plan (SHP)
- Streamlining measures for the CON process (many contained in the 2012 Recommendations of the CON Review Panel)

Estimated Revenue Impact:

Pending

Subcommittee Recommendation:



Recommendations of the CON Review Panel September 12, 2012

The following recommendations are made by the CON review panel:

1. The capital threshold is too low.

Recommendation:

Raise capital threshold to \$5million, 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.

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.

Recommendation:

- a. Eliminate the monetary threshold on equipment used for diagnosis or treatment; b. 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 Adminsitration (FDA) at the time of the SC Health Plan approval; and
- c. 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 Heath. The Department should pursue authority to register MRI units for the sole purpose of ensuring quality through accreditation.
- 3. The reference to CON decisions should be removed from the Revenue Bond Act (§44-7-1590.C) to eliminate appeals directly to the Circuit Court.

Recommendation:

Amend 44-7-1590 (C) of the Hospital Revenue Bond Act, as follows, to eliminate language that allows any interested party to appeal the Department's CON approval to Circuit Court.

(C) Any interested party, within twenty days after the date of the publication of the notice, but not afterwards, may challenge the action so taken by the state board, or the county board, or the Department of Health and Environmental Control, by action de novo in the court of common pleas in any county where the hospital facilities are to be located.

4. Frivolous lawsuits should be discouraged.

Recommendation:

Change the wording of §44-7-220 as follows:

- § 44-7-220. Administrative Law Court review of Certificate of Need decisions.
- (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) If the relief requested in the 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 or the Supreme Court affirms the Administrative Law Court's decision or dismisses the appeal, the Court of Appeals or the Supreme Court 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.
- (C)(1) Furthermore, if at the conclusion of the contested case or judicial review, upon motion the Administrative Law Court, or the Court of Appeals, or the Supreme Court shall determine whether the contested case or subsequent appeal was frivolous. If upon such motion the Administrative Law Court, the Court of Appeals, or the Supreme Court finds that the contested case or a subsequent appeal was frivolous, the Administrative Law Court or shall, and the Court of Appeals or the Supreme Court may, 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 contested case or appeal" means any one of the following:
- (a) a reasonable person in the same circumstances would believe that under the facts, the contested case or a 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) a reasonable person in the same circumstances would believe that the procurement, initiation, or continuation of the contested case or subsequent appeal was intended merely to harass or injure the other party; or
- (c) a reasonable person in the same circumstances would believe that 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.
- (a) taken solely for purposes of delay or harassment;
- (b) where no question of law is involved;
- (c) where the contested case or judicial review is without-merit.

This provision shall not be construed to prohibit any party from seeking sanctions pursuant to the South Carolina Frivolous Civil Proceedings Sanctions Act, under Section 15-36-10.

- (D) In no event shall attorney's fees or costs be assessed against the Department in any contested case or appeal involving a Certificate of Need application, an exemption request under Section 44-7-170, or a request for a determination as to the applicability of Section 44-7-160.
- 5. Create more transparency. Eliminate the requirement to public notice CON intent in the local newspaper, as this is an antiquated requirement.

Recommendation:

- a. DHEC should pursue removing the statutory requirement for newspaper postings, replacing it with a requirement to provide a letter of intent to be filed with DHEC.
- 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.
- 6. No regulatory deadline exists for submitting Final Completion Reports.

Recommendation:

- a. DHEC should better define Total Project Cost and tie the total project cost to a finite period. DHEC should change the definitions of cost overrun and substantial change to better define these terms.
- b. DHEC should establish a timeline for final completion reports and tie it back to the newly defined Total Project Cost. Deadlines should be flexible for large projects.
- c. DHEC should simplify the final completion report requirements and require reporting only on items relevant to the project.
- 7. There should be no time limit for implementation for NAs or exempted projects.

Recommendation:

Remove timelines for exemptions and non-applicability project implementation.

8. There are no repercussions for providers who do not submit Joint Annual Reports (JARs) by the deadline.

Recommendation:

DHEC should amend licensing regulations to require timely submission of JARs, tie JARs submission to licensing requirements, and add penalties for not submitting JARs in a timely fashion.

9. DHEC staff lacks accounting and clinical background experience, but also lacks funds to obtain these resources. Currently, fees taken in by the program exceed the appropriation from the general fund. Additional funds would allow hiring of staff with this type expertise.

Recommendation:

DHEC should propose a statutory change allowing all CON fees to be retained by the CON program. Additional revenue that this generates should be used to obtain the needed outside resources.

10. Batching.

Recommendation:

DHEC should develop and implement a batching process for reviewing CON applications.

11. Eliminate the public hearing and revise the project review meeting process.

<u>Recommendation:</u> Revise §44-7-210(A) and Regulation 61-15 to eliminate the public hearing process and to continue the Project Review meeting process with the establishment of minimum timelines for participation and response by the applicant and the opposition. (Suggested: Opponents present written opposition within certain time frame and attend Project Review meeting. Applicant has 2-3 weeks to respond and no more. Each party has one attempt to present their case.) DHEC should limit project review meetings to competing applications.

12. Mandatory Electronic Filing of CON Application.

<u>Recommendation</u>: Amend Regulation 61-15 to require that a CON applicant submit an original paper application and one copy in electronic form (on CD, via e-mail, or other electronic means).

13. Develop categories of projects eligible for "Expedited Review."

<u>Recommendation</u>: DHEC should develop an expedited review process for some types of CON projects. A list of projects eligible for expedited review should be developed in this process.

14. The Final Review Conference process at the DHEC Board for CON decisions lengthens the appeals process.

<u>Recommendation</u>: Amend §44-1-60 and §44-7-210 to remove the final review conference process at the DHEC Board for CON decisions.

15. Project Review Criteria is in need of change.

<u>Recommendation</u>: DHEC should pursue revised Project Review Criteria. Criteria should be narrowed down to 10 to 12 items for consideration.

16. Revise Appeals Process for Non-Applicability Determinations (NAD's) and Exemptions.

Recommendation:

Revise §44-7-170 as follows:

§ 44-7-170. Institutions and transactions not subject to review.

(A) This article does not apply to:

- (1) an expenditure by or on behalf of a health care facility for nonmedical projects for services such as refinancing existing debt, parking garages, laundries, roof replacements, computer systems, telephone systems, heating and air conditioning systems, upgrading facilities which do not involve additional square feet or additional health services, replacement of like equipment with similar capabilities for which a Certificate of Need was not issued, or similar projects as described in regulations;
- (2) facilities owned and operated by the South Carolina Department of Mental Health and the South Carolina Department of Disabilities and Special Needs, except an addition of one or more beds to the total number of beds of the departments' health care facilities existing on July 1, 1988;
- (3) educational and penal institutions maintaining infirmaries for the exclusive use of student bodies and inmate populations;
- (4) any federal health care facility sponsored and operated by this State;

- (5) community-based housing designed to promote independent living for persons with mental or physical disabilities. This does not include a facility defined in this article as a "health care facility";
- (6) kidney disease treatment centers including, but not limited to, free standing hemodialysis centers and renal dialysis centers;
- (7) health care facilities owned and operated by the federal government;
- (8) the offices of a licensed private practitioner whether for individual or group practice, without regard to employment status, except as provided for in Section 44-7-160(1) and (6);
- (9) an expenditure as described in Section 44-7-160(3) or (6) which does not require Certificate of Need review solely because the expenditure does not exceed an amount prescribed by regulation.
- (10) the acquisition by a person of medical equipment to be used solely for research, the offering of an institutional health service by a person solely for research, or the obligation of a capital expenditure by a person to be made solely for research if it does not:
- (a) affect the charges imposed by the person for the provision of medical or other patient care services other than the services that are included in the research;
- (b) change the bed capacity of a health care facility; or
- (c) substantially change the medical or other patient care services provided by the person.

 A written description of the proposed research project must be submitted to the department in order for the department to determine if these conditions are met.
- A Certificate of Need is required in order to continue use of the equipment or service after the equipment or service is no longer being used solely for research;
- (11) the replacement of like equipment for which a Certificate of Need has been issued which does not constitute a material change in service or a new service.
- (B) For projects enumerated in subsection (A)(9), the department shall prescribe by regulation the conditions under which a person is required to obtain a written determination of non-applicability from the department.
- (C) Before undertaking a project enumerated in subsection (B), a person shall obtain a written exemption from the department as may be more fully described in regulation.
- 17. The definition of affected person needs to be amended to remove out of state parties from appealing CON decisions unless they have a presence in the State.

Recommendation:

Amend the definition of affected person in §44-7-130(1) as follows:

(1) "Affected person" means the applicant, a person residing within the geographic area served or to be served by the applicant, persons who provide similar services to the proposed project in the health service area in which the project is to be located, persons who before receipt by the department of the proposal being reviewed have formally indicated an intention to provide in the future similar services to the proposed project in the health service area in which the project is to be located, persons who pay for health services in the health service area in which the project is to be located and who have notified the department of their interest in Certificate of Need applications, the State Consumer Advocate, and the State Ombudsman. A person operating a health care facility or providing a health service in a state other than South Carolina who does not operate a health care facility in the proposed service area which provides similar services or provides a health service similar to that being sought by the applicant is not deemed to be an affected person.

18. Shorten the appeals process by limiting discovery.

Recommendation:

Reduce the discovery limits to those provided for in the Rules of the Administrative Law Court (RPALC 21(A)) by the addition of Section 44-7-210(G) as follows:

- (G) Notwithstanding any other provision of law, including Section 1-23-650(C), in a contested case arising from the department's decision to grant or deny a Certificate of Need application under Section 44-7-160(3) (6), grant or deny a request for exemption under Section 44-7-170(B), or the issuance of a determination regarding the applicability of Section 44-7-160(3) or (6), the following apply:
- (1) each party shall conduct no more than three depositions of persons identified as witnesses who may testify at the contested case hearing, unless otherwise provided for by the Administrative Law Court;
- (2) each party is permitted to take only the deposition of a person listed as a witness who may testify at the contested case hearing, unless otherwise provided for by the Administrative Law Court;
- (3) each party is permitted to serve only ten interrogatories pursuant to Rule 33 of the South Carolina Rules of Civil Procedure; and
- (4) each party is permitted to serve only ten requests for admission, including subparts.

The limitations provided for in this subsection are intended to make the contested case process more efficient, less burdensome, and less costly to the parties in Certificate of Need cases. Because substantial information is contained in applications, requests for determinations of non-applicability, and requests for exemptions as well as supplemental submissions made by the applicant or requestor and affected persons during application or request review, a party requesting additional discovery bears the burden of demonstrating that (1) the probative value of additional information obtained through more extensive discovery outweighs the accompanying burdens of time and expense, and (2) failure to allow for additional discovery would cause substantial prejudice to the requesting party. Upon making this showing, the Administrative Law Court may, by court order, lift these limitations beyond the parameters set forth in this

subsection only in exceptional circumstances. In addition, nothing in this Section shall prohibit the parties from jointly defining and stipulating to the limits on discovery and proposing those limits to the Administrative Law Court.

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

Recommendation:

Amend Regulation 61-15 §601(4) as follows:

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 ninety days prior to the expiration of the Certificate of Need and must contain justification for such extension; however, if an extension request is submitted to the Board less than ninety days prior to the expiration of the Certificate of Need, the Board may, in its discretion, consider the request.

20. DHEC does not have access to the data it needs to review CON applications.

Recommendation:

The panel endorses the concept of DHEC having access to data collected by the South Carolina Office of Research and Statistics (SCORS) in order to review CON applications, and the concept of making health care data public through public use data files. DHEC should pursue a statutory change to gain access to data held by SCORS for the purpose of reviewing CON applications.

21. Data on utilization of ASCs is not always relevant.

Recommendation:

The State Health Planning Committee and the Board should include within the SC Health Plan a utilization requirement based on minutes of OR utilization for purposes of determining needs at an ASC.

South Carolina General Assembly

121st Session, 2015-2016

H. 3250

STATUS INFORMATION

General Bill

Sponsors: Reps. G.M. Smith, Clyburn, Merrill and Anthony

Document Path: 1:\council\bills\bh\26214vr15.docx

Introduced in the House on January 13, 2015 Currently residing in the House Committee on **Ways and Means**

Summary: Certificate of Need program

HISTORY OF LEGISLATIVE ACTIONS

Date	Body	Action Description with journal page number
12/18/2014	House	Prefiled
12/18/2014	House	Referred to Committee on Ways and Means
1/13/2015	House	Introduced and read first time (House Journal-page 170)
1/13/2015	House	Referred to Committee on Ways and Means (House Journal-page 170)

View the latest legislative information at the website

VERSIONS OF THIS BILL

12/18/2014

A BILL

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TO AMEND SECTION 44-7-130, AS AMENDED, CODE OF 12 LAWS OF SOUTH CAROLINA, 1976, RELATING TO 13 TERMINOLOGY FOR THE CERTIFICATE OF NEED 14 PROGRAM, SO AS TO ADD THE TERM "NEW AND 15 EMERGING TECHNOLOGY": BY ADDING SECTION 16 44-7-215 SO AS TO ENTITLE THE DEPARTMENT OF 17 HEALTH AND ENVIRONMENTAL CONTROL TO HAVE 18 ACCESS TO CERTAIN DATA MAINTAINED BY THE 19 REVENUE AND FISCAL AFFAIRS OFFICE; TO AMEND 20 SECTION 13-7-10, AS AMENDED, RELATING TO THE 21 DEFINITION OF "NONIONIZING RADIATION", SO AS TO 22 CHANGE THE DEFINITION; TO AMEND SECTION 13-7-45, 23 AS AMENDED, RELATING TO REGULATION OF SOURCES 24 OF IONIZING AND NONIONIZING RADIATION, SO AS TO 25 REQUIRE ACCREDITATION OR CERTIFICATION FOR 26 CERTAIN SOURCES OF RADIATION AND TO CHANGE 27 ALLOWABLE FEES; TO AMEND SECTION 44-1-60, AS 28 AMENDED, RELATING TO THE REVIEW OF CERTIFICATE 29 OF NEED DECISIONS OF THE DEPARTMENT OF HEALTH 30 AND ENVIRONMENTAL CONTROL BY THE BOARD OF 31 HEALTH AND ENVIRONMENTAL CONTROL AND 32 REQUESTS FOR CONTESTED CARE HEARINGS IN 33 CERTIFICATE OF NEED CASES, SO AS TO ELIMINATE 34 BOARD REVIEW; TO AMEND SECTION 44-7-120, RELATING 35 TO THE PURPOSE OF THE CERTIFICATE OF NEED 36 PROGRAM, SO AS TO ELIMINATE THE USE OF A STATE 37 HEALTH PLAN; TO AMEND SECTION 44-7-130, AS 38 AMENDED, RELATING TO CERTIFICATE OF NEED PROGRAM DEFINITIONS, SO AS TO REVISE DEFINITIONS "AFFECTED PERSON", "HEALTH SERVICE", "FREESTANDING OR MOBILE TECHNOLOGY", AND "LIKE 42 NEW AND EMERGING TECHNOLOGY WITH SIMILAR

1 CAPABILITIES": TO AMEND SECTION 44-7-150, AS AMENDED, RELATING TO THE USE OF CERTIFICATE OF 3 NEED FEES, SO AS TO ALLOW THE DEPARTMENT TO 4 RETAIN ALL FEES COLLECTED FOR THE USE OF THE 5 PROGRAM; TO AMEND SECTION 44-7-160, AS AMENDED, 6 RELATING TO CIRCUMSTANCES UNDER WHICH A 7 CERTIFICATE OF NEED IS REQUIRED, SO AS TO CHANGE 8 CERTAIN REQUIREMENTS; TO AMEND SECTION 44-7-170, 9 AS AMENDED, RELATING TO CERTIFICATE OF NEED 10 EXCEPTIONS, SO AS TO ADD NEW EXCEPTIONS AND 11 MAKE CHANGES TO EXISTING EXCEPTIONS; TO AMEND 12 SECTION 44-7-200, AS AMENDED, RELATING TO NOTICE 13 REQUIREMENTS ABOUT CERTIFICATE OF 14 APPLICATIONS, SO AS TO ELIMINATE THE REQUIREMENT 15 FOR PUBLICATION OF NOTICE AND INSTEAD TO 16 REQUIRE THE APPLICANT TO FILE A LETTER OF INTENT 17 WITH THE DEPARTMENT AND TO ELIMINATE THE 18 REFERENCE TO BOARD REVIEW OF DEPARTMENT 19 DECISIONS; TO AMEND SECTION 44-7-210, AS AMENDED, 20 RELATING TO CERTIFICATE OF NEED REVIEW 21 PROCEDURES, SO AS TO ELIMINATE THE REQUIREMENT 22 OF A PUBLIC HEARING, THE APPLICATION OF THE STATE 23 HEALTH PLAN, AND BOARD REVIEW OF DEPARTMENT 24 DECISIONS; TO AMEND SECTION 44-7-220, AS AMENDED, 25 RELATING TO JUDICIAL REVIEW OF ADMINISTRATIVE 26 LAW COURT DECISIONS ON CERTIFICATE OF NEED 27 MATTERS, SO AS TO ADD CERTAIN REQUIREMENTS 28 RELATED TO THE AWARD OF ATTORNEY FEES AND 29 COSTS AND TO CHANGE THE DEFINITION OF FRIVOLOUS 30 APPEAL; TO AMEND SECTION 44-7-230, AS AMENDED, 31 RELATING TO LIMITATIONS ON CERTIFICATES OF NEED, 32 SO AS TO SUBSTITUTE THE TERM "NEW AND EMERGING 33 TECHNOLOGY" FOR "MEDICAL EQUIPMENT" AND TO 34 ELIMINATE THE ROLE OF THE BOARD; TO AMEND 35 SECTION 44-7-240, RELATING TO CONSTRUCTION 36 PROGRAMS IN THE STATE, SO AS TO ELIMINATE 37 REFERENCE TO THE STATE HEALTH PLAN; TO AMEND 38 SECTION 44-7-1590, RELATING TO PROCEDURES FOR 39 APPROVAL OF HOSPITAL BONDS, SO AS TO ELIMINATE 40 THE RIGHT TO CHALLENGE AN ACTION BY THE 41 DEPARTMENT; TO REPEAL SECTION 44-7-180 RELATING 42 TO THE STATE HEALTH PLANNING COMMITTEE AND THE 43 STATE HEALTH PLAN, AND SECTION 44-7-225 RELATING

- 1 TO JUDICIAL CONSIDERATION OF THE STATE HEALTH
- 2 PLAN IN MATTERS BEFORE THE COURT; AND TO
- 3 REQUIRE THE BOARD TO REVIEW CERTAIN PROJECTS
- 4 FOR WHICH A CERTIFICATE OF NEED WAS REQUIRED
- 5 BUT NOT OBTAINED BETWEEN JULY 1, 2013, AND APRIL
- 6 14, 2014, TO DETERMINE WHETHER THE PROJECTS MEET
- 7 THE REQUIREMENTS FOR ISSUANCE OF A CERTIFICATE
- 8 OF NEED, AND TO ISSUE CERTIFICATES OF NEED IN
- 9 APPROPRIATE CASES.

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11 Be it enacted by the General Assembly of the State of South 12 Carolina:

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14 SECTION 1. Section 44-7-130 of the 1976 Code, as last amended 15 by Act 173 of 2014, is further amended by adding an appropriately 16 numbered item at the end to read:

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"()'New and emerging technology' means equipment, used for diagnosis or treatment, not yet having received approval by the Food and Drug Administration as of the date that the applicant files a letter of intent pursuant to Section 44-7-200."

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23 SECTION 2. Article 3, Chapter 7, Title 44 of the 1976 Code is 24 amended by adding:

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"Section 44-7-215. Notwithstanding another provision of law, the department shall have access to data maintained by the Revenue and Fiscal Affairs Office relevant to Certificates of Need."

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30 SECTION 3. Section 13-7-10(9) of the 1976 Code, as last 31 amended by Act 552 of 1990, is further amended to read:

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"(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."

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41 SECTION 4. Section 13-7-45(A) of the 1976 Code, as last 42 amended by Act 355 of 2006, is further amended to read:

- "(A)(1) The South Carolina Department of Health and 2 Environmental Control shall promulgate regulations and establish a schedule for the collection of annual fees for the licensing, 4 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."

SECTION 5. Section 44-1-60 (E)(2) and (G) of the 1976 Code, as last amended by Act 278 of 2010, is further amended to read:

"(E)(2)The staff decision becomes the final agency decision fifteen calendar days after notice of the staff decision has been mailed to the applicant, unless a written request for final review accompanied by a filing fee is filed with the department by the applicant, permittee, licensee, or affected person. There is no right

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to a final review regarding a decision on an application submitted for a Certificate of Need pursuant to Section 44-7-200. 2

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- (G)(1) Except as otherwise provided in item (2), an applicant, permittee, licensee, or affected person may file a request with the Administrative Law Court for a contested case hearing within thirty calendar days after:
- (1)(a) notice is mailed to the applicant, permittee, licensee, 9 and affected persons that the board declined to hold a final review 10 conference; or
- (2)(b) the sixty calendar day deadline to hold the final 12 review conference lapses and no conference has been held; or
- (3)(c) the final agency decision resulting from the final 13 14 review conference is received by the parties.
- (2) In the case of a Certificate of Need decision, an applicant, a holder of a certificate, and an affected person, within thirty days after receipt of the department staff decision, may file a request with 18 the Administrative Law Court for a contested case hearing."

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20 SECTION 6. Section 44-7-120 of the 1976 Code is amended to read:

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- "Section 44-7-120. The purpose of this article is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities 26 and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State. To achieve these purposes, this article requires:
- 29 (1) the issuance of a Certificate of Need before undertaking a 30 project prescribed by this article;
 - (2) adoption of procedures and criteria for submittal of an application and appropriate review before issuance of a Certificate
 - (3) preparation and publication of a State Health Plan;
 - (4) the licensure of facilities rendering medical, nursing, and other health care."

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SECTION 7. Section 44-7-130(1), (11), (20), and (21) of the 1976 Code, as last amended by Act 278 of 2010, is further amended to

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"(1) 'Affected person' means the applicant, a person residing within the geographic area served or to be served by the applicant,

persons located in the health service area in which the project is to be located and who provide similar services to the proposed project in the health service area in which the project is to be located persons 4 who before receipt by the department of the proposal being reviewed have formally indicated an intention to provide in the 5 future similar services in the future to the proposed project in the health service area in which the project is to be located, persons who pay for health services in the health service area in which the project is to be located and who have notified the department of their interest in Certificate of Need applications, the State Consumer Advocate, and the State Ombudsman. Persons from another state who would otherwise be considered 'affected persons' are not included unless that state provides for similar involvement of 13 persons from South-Carolina in its certificate of need process. A person operating a health care facility or providing a health service in a state other than South Carolina who does not operate a health care facility in the proposed service area which provides similar 17 services or provides a health service similar to that being sought by the applicant is not considered an affected person. 19

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(11) 'Health service' means clinically related, diagnostic, treatment, or rehabilitative services and includes alcohol, drug abuse, and mental health services for which specific standards or criteria are prescribed in the State Health Plan by the department in regulation.

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(20) 'Freestanding or mobile technology' means medical equipment owned or operated by a person other than a health care facility for which the total cost is in excess of that prescribed by regulation and for which specific standards or criteria are prescribed in the State Health Plan.

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(21) 'Like equipment new and emerging technology with similar capabilities' means medical equipment new and emerging technology in which functional and technological capabilities are identical to the equipment to be replaced; and the replacement equipment technology is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and does not constitute a material change in service or a new service."

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SECTION 8. Section 44-7-150(5) of the 1976 Code, as last amended by Act 278 of 2010, is further amended to read:

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1 "(5) The department may as it determines necessary charge and 2 collect fees to cover the cost of operating the Certificate of Need program, including application fees, filing fees, issuance fees, and nonapplicability/exemption determination fees. The department 5 shall develop regulations which set fees as authorized by this article. The level of these fees must be determined after careful consideration of the direct and indirect costs incurred by the 7 department in performing its various functions and services in the Certificate of Need program. All fees and procedures for collecting fees must be adopted pursuant to procedures set forth in the Administrative Procedures Act. Any fee collected pursuant to this section in excess of seven hundred fifty thousand dollars must be retained by the department and designated for the administrative 13 14 costs of the Certificate of Need program. The first seven hundred 15 fifty thousand dollars collected pursuant to this section must be 16 deposited into the general fund of the State. Until fees are 17 promulgated through regulation, all fees established as of January 1, 18 2009, remain in effect."

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SECTION 9. A. Section 44-7-160 of the 1976 Code, as last amended by Act 278 of 2010, is further amended to read:

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40 41 "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 five million dollars which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure, except for those expenditures otherwise exempted in Section 44-7-170(B)(1). 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. The department shall make an annual adjustment to this capital expenditure amount to reflect changes in the Consumer Price Index for All Urban Consumers,

Medical Care Services as published by the United States Department of Labor, Bureau of Labor Statistics; 2

- (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)(3) 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)(4) 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."
- This SECTION takes effect upon approval by the Governor, 15 and the expenditure threshold set forth in Section 44-7-160(3) first applies to Certificate of Need applications submitted thereafter.
- SECTION 10. Section 44-7-170(A) of the 1976 Code, as last 19 amended by Act 278 of 2010, is further amended to read:
 - "(A) The following are exempt from Certificate of Need review:
 - (1) the acquisition by a person of medical equipment new and emerging technology to be used solely for research, the offering of an institutional health service by a person solely for research, or the obligation of a capital expenditure by a person to be made solely for research if it does not:
 - (a) affect the charges imposed by the person for the provision of medical or other patient care services other than the services that are included in the research; or
 - (b) change the bed capacity of a health care facility; or
 - (e) substantially change the medical or other patient care services provided by the person.

A written description of the proposed research project must be submitted to the department in order for the department to determine 36 if these conditions are met. A Certificate of Need is required in order to continue use of the equipment new and emerging technology or service after the equipment new and emerging technology or service is no longer being used solely for research;

(2) the offices of a licensed private practitioner whether for individual or group practice except as provided for in Section 42 44-7-160(1) and (5);

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- (3) the replacement of like equipment new and emerging technology for which a Certificate of Need has been issued which does not constitute a material change in service or a new service;
- (4) the addition of one or more beds or change in the bed capacity of an existing licensed acute care hospital, rehabilitation facility, or psychiatric hospital;
- (5) a change in the classification of licensure of one or more beds for the purpose of converting between acute care beds and psychiatric beds;
- (6) a capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of an existing health service or for which a Certificate of Need previously has been awarded."

15 SECTION 11. Section 44-7-200 of the 1976 Code, as last 16 amended by Act 278 of 2010, is further amended to read:

"Section 44-7-200. (A) An application for a Certificate of Need must be submitted to the department in a form established by regulation. The application must address all applicable standards and requirements set forth in departmental regulations, and project review criteria of the department, and the South Carolina Health Plan.

(B) Within twenty days before submission of an application, the applicant shall publish notification that an application is to be submitted to the department in a newspaper serving the area where the project is to be located for three consecutive days. The notification must contain a brief description of the scope and nature of the project. No application may be accepted for filing by the department unless accompanied by proof that publication has been made for three consecutive days within the prior twenty day period and payment of the initial application fee has been received.

Within twenty days before submission of an application, the applicant shall file a letter of intent to submit an application with the department. The letter of intent must contain a brief description of the scope and nature of the project. The department must not accept an application for a Certificate of Need unless the application is accompanied by a copy of the letter of intent filed by the applicant with the department within the prior twenty-day period and payment of the initial application fee has been received."

41 (C) Upon publication of this notice and until a contested case 42 hearing is requested pursuant to Section 44-1-60(G):

(1) members of the board and persons appointed by the board to hold a final review conference on staff decisions may not communicate directly or indirectly with any person in connection with the application; and

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(2) no person shall communicate, or cause another to communicate, as to the merits of the application with members of the board and persons appointed by the board to hold a final review conference on staff decisions.

A person who violates this subsection is subject to the penalties provided in Section 1-23-360.

- (D) After receipt of an application with proof of publication a copy of the letter of intent and payment of the initial application fee, the department shall publish in the State Register a notice that an application has been accepted for filing. Within thirty days of acceptance of the application, the department may request additional 16 information as may be necessary to complete the application. The applicant has thirty days from the date of the request to submit the additional information. If the applicant fails to submit the requested information within the thirty-day period, the application is considered withdrawn.
- (E) After a Certificate of Need application has been filed with 22 the department, state and federal elected officials are prohibited from communicating with the department with regard to the Certificate of Need application at any time. This prohibition does not include written communication of support or opposition to an application. Such Written communication must be included in the administrative record."

SECTION 12. Section 44-7-210 of the 1976 Code, as last 29 amended by Act 278 of 2010, is further amended to read:

"Section 44-7-210. (A) After the department has determined that an application is complete, affected persons must be notified in accordance with departmental regulations. The notification to affected persons that the application is complete begins the review period; however, in the case of competing applications, the review period begins on the date of notice to affected persons that the last of the competing applications is complete and notice is published in the State Register. The staff shall issue its decision to approve or deny the application no earlier than thirty calendar days, but no later than one hundred twenty calendar days, from the date affected persons are notified that the application is complete, unless a public hearing is timely requested as may be provided for by department

- regulation. If a public hearing is properly requested, the staff's decision must not be made until after the public hearing, but in no event shall the decision be issued more than one hundred fifty 4 calendar days from the date affected persons are notified that the application is complete. The staff may reorder the relative importance of the project review criteria no more than one time during the review period. The staff's reordering of the relative importance of the project review criteria does not extend the review period provided for in this section.
- (B) The department may not issue a Certificate of Need unless an application complies with the South Carolina Health Plan, project review criteria, and other regulations. Based on project review criteria and other regulations, which must be identified by the department, the department may refuse to issue a Certificate of Need even if an application complies with the South Carolina Health Plan. 16 In the case of competing applications, the department shall award a Certificate of Need, if appropriate, on the basis of which, if any, most fully complies with the requirements, goals, and purposes of this article and the State Health Plan, project review criteria, and the regulations adopted promulgated by the department.
 - (C) On the basis of staff review of the application, the staff shall make a staff decision to grant or deny the Certificate of Need and the staff shall issue a decision in accordance with Section 44-1-60(D). Notice of the decision must be sent to the applicant and affected persons who have asked to be notified. The decision becomes is the final agency decision unless a timely written request for a final review is filed with the department as provided for in Section 44-1-60(E).

However, a person may not file a request for final review in 30 opposition to the staff decision on a Certificate of Need unless the person provided written notice to the department during the staff review-that he is an affected person and specifically states-his opposition to the application under review.

- (D) The staff's decision is not the final agency decision until the completion of the final review process provided for in Section 44-1-60(F).
- 37 (E) A contested case hearing of the final agency decision must 38 be requested in accordance with Section 44-1-60(G). The issues considered at the contested case hearing considering a Certificate of Need are limited to those presented or considered during the staff 41 review.
- 42 (F)(E) Notwithstanding any other provision of law, including Section 1-23-650(C) in a contested case arising from the

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department's decision to grant or deny a Certificate of Need application, to grant or deny a request for exemption under Section 44-7-170, or the issuance of a determination regarding to determine 4 the applicability of Section 44-7-160, the following apply each party:

- (1) each party may name no more than ten witnesses who may 6 testify at the contested case hearing; 7
 - (2) each party is permitted to take only the deposition of a person listed as a witness who may testify at the contested case hearing, unless otherwise provided for by the Administrative Law Court:
 - (3) each party is permitted to serve only ten interrogatories pursuant to Rule 33 of the South Carolina Rules of Civil Procedure;
 - (4) each party is permitted to serve only ten requests for admission, including subparts; and
- 16 (5) each party is permitted to serve only thirty requests for production, including subparts. 17

The limitations provided for in this subsection are intended to make the contested case process more efficient, less burdensome, and less costly to the parties in Certificate of Need cases. Therefore, the Administrative Law Court may, by court order, lift these limitations beyond the parameters set forth in this subsection only in exceptional circumstances when failure to do so would cause substantial prejudice to the party seeking additional discovery.

(G) Notwithstanding any other provision of law, in a contested case arising from the department's decision to grant or deny a Certificate of Need application, grant or deny a request for exemption under Section 44-7-170, or the issuance of a determination regarding the applicability of Section 44-7-160, the Administrative Law Court shall file a final decision no later than eighteen months after the contested case is filed with the Clerk of the Administrative Law Court, unless all parties to the contested case consent to an extension or the court finds substantial cause otherwise."

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SECTION 13. Section 44-7-220 of the 1976 Code, as last amended by Act 278 of 2010, is further amended to read:

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"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.

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(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, when claiming an exemption under Section 44-7-170, or when claiming that the article is not applicable pursuant to Section 44-7-160, 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, when claiming an exemption under Section 44-7-170, or when claiming that the article is not applicable pursuant to Section 44-7-160, 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 16 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 22 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 27 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, the denial of an exemption request under Section 44-7-170, or 32 appeals the a determination that the article applies under 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.
 - (C)(D)(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.

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- (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 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.

- (E) The court must not assess attorney's fees or costs awarded against or 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 14. Section 44-7-230(A) and (D) of the 1976 Code, as last amended by Act 278 of 2010, is further amended to read:
- "(A) The Certificate of Need, if issued, is valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with regulations. The department shall require periodic reports and make inspections to determine compliance with the Certificate of Need. Implementation of the project or operation of the facility or medical equipment new and emerging technology that is not in accordance with the Certificate of Need application or conditions subsequently agreed to by the applicant and the department may be considered a violation of this article.
- (D) A Certificate of Need is valid for one year from the date of issuance. A Certificate of Need must be issued with a timetable submitted by the applicant and approved by the department to be followed for completion of the project. The holder of the Certificate

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1 of Need shall submit periodic progress reports on meeting the 2 timetable as may be required by the department. Failure to meet the 3 timetable results in the revocation of the Certificate of Need by the 4 department unless the department determines that extenuating 5 circumstances beyond the control of the holder of the Certificate of 6 Need are the cause of the delay. The department may grant two extensions of up to nine months each upon evidence that substantial 8 progress has been made in accordance with procedures set forth in regulations. The board department may grant further extensions of 10 up to nine months each only if it determines that substantial progress has been made in accordance with the procedures set forth in regulations." 12

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SECTION 15. Section 44-7-240 of the 1976 Code is amended to 14 15 read:

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"Section 44-7-240. The department may establish a construction program providing for adequate facilities in this State and, insofar as possible, shall provide for the distribution of facilities and 20 services throughout this State in such a manner as to make all types 21 of health services reasonably accessible to all persons in this State. 22 The State Health-Plan as required by this article may be used for purposes of establishing department shall establish the relative need of projects for which applications are submitted under this 25 construction program. Submittal of applications and review and approval of projects for which federal funds are requested must be in accordance with regulations adopted by the department and applicable federal act."

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SECTION 16. Section 44-7-1590(C) of the 1976 Code is 30 amended to read:

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"(C) Any interested party, within twenty days after the date of the publication of the notice, but not afterwards; may challenge the action so taken by the state board, or the county board, or the 36 Department of Health and Environmental Control, by action de novo in the court of common pleas in any county where the hospital facilities are to be located."

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40 SECTION 17. Section 44-7-180 and Section 44-7-225 of the 1976 Code are repealed.

SECTION 18. (A) The South Carolina Board of Health and 2 Environmental Control shall review the projects of persons and 3 health care facilities that were initiated between July 1, 2013, and 4 April 14, 2014, for which a Certificate of Need is required pursuant 5 to Article 3, Chapter 7, Title 44 of the Code of Laws of South 6 Carolina, 1976. In its review, the board shall determine if the 7 projects merit a Certificate of Need. If the board determines a project merits a Certificate of Need, the board shall stand in the place of the Department of Health and Environmental Control and 10 may issue the Certificate of Need nunc pro tunc. Any certificate issued by the board is deemed to have been issued by the 12 Department of Health and Environmental Control. All requirements governing Certificates of Need apply to those persons or health care facilities issued a Certificate of Need pursuant to this section. 14

(B) The board shall establish an application, notice, and appeals 16 process, similar to that set forth in Article 3, Chapter 7, Title 44, mutatis mutandis.

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SECTION 19. Except as otherwise provided herein, this act takes effect upon approval by the Governor.

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