



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 Administration (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 Health. 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.

Recommendation: *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.

Recommendation: *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.”

Recommendation: 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.

Recommendation: 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.

Recommendation: 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.