

CON REVIEW PANEL RECOMMENDATIONS

- I. RECOMMENDATIONS APPROVED BY THE BOARD**
- II. REGULATORY REVISIONS**
- III. CON REVIEW PANEL RECOMMENDATIONS THAT CAN BE ADMINISTRATIVELY IMPLEMENTED**

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 RECOMMENDATIONS¹

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.

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 (\$~~25,000,000~~) 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.

¹ 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 IMPLEMENTED¹

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.

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