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**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

61-15. Certification of Need for Health Facilities and Services

**Preamble:**

Regulation 61-15 prescribes the process by which healthcare providers obtain authorization from the state before making major capital expenditures, acquiring high cost medical equipment or expanding medical services. The purpose of this regulation is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this state. The Department is proposing to amend Sections 102 and 601 of R.61-15, Certification of Need for Health Facilities and Services (CON).

A Notice of Drafting for this amendment was published in the *State Register* on April 26, 2013. See the section-by-section discussion of the proposed revisions below and also a fiscal impact statement, a statement of need and reasonableness, and a statement of rationale provided herein.

Section-by-Section Discussion of Proposed Revisions:

SECTION CITATION AND EXPLANATION OF CHANGE

61-15.102.1.c.

Applicability: Increase capital threshold from $2 million to $5 million.

61-15.102.1.f.

Applicability: Increase threshold for equipment from $600,000 to $1.5 million, to be adjusted annually.

61-15.601.4.

Voidance and Extension Procedures: Allow more flexibility within the required 90 day submission period for CON extensions.

**Notice of Public Hearing and Opportunity for Public Comment:**

A public hearing on the proposed regulation is scheduled pursuant to S.C. Code Section 1-23-110(A)(3) to be held before the Board of Health and Environmental Control at its regularly-scheduled meeting at 10:00 a.m. on August 8, 2013, if requested in writing by twenty-five persons, by a governmental subdivision or agency, or by an association having not less than twenty-five members. Interested persons may also submit written comments on the proposed regulation. To be considered, requests for public hearing and written comments must be submitted to Melinda Bradshaw at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina 29201 no later than 5:00 p.m. on July 29, 2013, the close of the public comment period. If a qualifying request for a public hearing is not received in a timely manner, the hearing may, at the Board's discretion, be canceled. Notice of cancellation, or any change in meeting times, will be published in the Board meeting agenda at least 24 hours in advance of the meeting. The Board agenda at the Department of Health and Environmental Control can be accessed on the internet at <http://www.scdhec.gov/administration/board.htm>, or information on the public hearing can be obtained by calling the Clerk of the Board at (803) 898-3350.

If timely requested, the public hearing, as noticed above for August 8, 2013, will be held in Room 3420 (Board Room), Third Floor, Aycock Building of the Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. Please use the front entrance to the building facing Bull Street. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less and are asked to provide written copies of their presentation for the record.

Copies of the proposed regulation for comment may be obtained by contacting Melinda Bradshaw at the above address, or by phone at (803) 545-5200, or by email at bradshmw@dhec.sc.gov. Also, an electronic copy of the proposed regulation may be obtained on the Department’s Regulatory Information Internet Site in the *DHEC Regulation Development Update* at <http://www.scdhec.gov/regulatory.htm>. (Click on the *Update*, the Certification of Need for Health Facilities and Services category, and scan down for this proposed amendment).

**Preliminary Fiscal Impact Statement:**

No additional cost will be incurred by the State or its political subdivisions by the implementation of this amendment. Existing staff and resources will be utilized to implement this amendment to the regulation.

**Statement of Need and Reasonableness:**

This statement was determined by staff analysis pursuant to S.C. Code Section 1-23-115(c)(1)-(3) and (9)-(11), S.C. Code of Laws, 1976, as amended.

DESCRIPTION OF REGULATION: R.61-15, Certification of Need for Health Facilities and Services.

Purpose: The Department is proposing amendment of R.61-15, Certification of Need for Health Facilities and Services, to incorporate recommendations made by the SC DHEC Board at its February 14, 2013 meeting. These recommendations arise from the compilation of suggestions created by the CON Review Panel. Appointed by the DHEC Board in January 2012, the CON Review Panel included 24 members representing a broad range of stakeholder interests. The panel was charged to improve the agency's internal process regarding its CON program through user/provider input.

Legal Authority: S.C. Code Sections 44-7-110 through 44-7-394, 1976, as amended.

Plan for Implementation: The proposed amendments would be incorporated within R.61-15 upon approval of the Board of Health and Environmental Control, the General Assembly, and publication in the State Register. The proposed amendments will be implemented in the same manner in which the existing regulation was implemented. The Department will also provide notice of this amendment in its Regulatory Information website.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Appointed by the DHEC Board in January 2012, the CON Review Panel included 24 members who represented a broad range of stakeholder interests. The panel was charged with improving the agency's internal process regarding its CON program through user/provider input. These amendments would implement some of the streamlining initiatives as directed by the DHEC Board.

DETERMINATION OF COSTS AND BENEFITS:

See Preliminary Fiscal Impact Statement above for cost to the state and its political subdivisions.

The regulated community will be impacted by these amendments in the following manner: Streamline the CON process, making it less onerous.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties associated with the proposed amendments to R.61-15.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There is no effect on the environment or public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There will be no detrimental effect on the environment and public health if the amendments are not implemented.

**Statement of Rationale**:

The proposed amendments will lessen the regulatory burden on the regulated community by increasing the monetary threshold for capital expenditures by or on behalf of a health care facility from $2 million to $5 million, and by raising the existing monetary threshold on equipment used for diagnosis or treatment from $600,000 to $1.5 million. Finally, the amendments will allow more flexibility within the required 90 day submission period for requests for CON extensions. These proposed amendments are in keeping with the directive issued by the SC DHEC Board to evaluate and streamline the CON process.

~~Indicates Matter Stricken~~

Indicates New Matter

**Text:**

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:

 a. The construction or other establishment of a new health care facility;

 b. 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;

 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 except those expenditures 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;

 d. 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;

 e. If no capital expenditure is made, the offering of any 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. For purposes of this section, operating costs include expenditures incurred by the health care facility and any person or other entity on behalf of the health care facility to establish a new service. A person or other entity shall not be allowed to incur costs thereby attempting to enable a health care facility to avoid Certificate of Need review and establish a new service as described above;

 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 annually, on July 1 or, if July 1 is a Saturday, Sunday, or holiday, on the next non-holiday business day following July 1, by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the medical equipment and supplies index of the Consumer Price Index published by the United States Department of Labor, Bureau of Labor Statistics.

 2. An applicant may not split or combine one expenditure into two or more expenditures for the purpose of avoiding Certificate of Need review, nor may the Department be allowed to lump projects together arbitrarily to bring them under Certificate of Need review.

 3. When any question exists, a potential applicant shall forward a letter requesting a formal determination by the Department as to the applicability of the Certificate of Need requirements to a particular project. Such a letter shall contain a detailed description of the project including the extent of modifications, changes in services and total costs. Additional information may be requested as may be reasonably necessary to make such applicability determination. The Department shall respond within sixty (60) calendar days of receipt of the necessary information.

 4. These provisions do not apply to acquisitions or changes of ownership of health care facilities, services, and equipment that are already in existence, operational, and providing services in a particular service area, and which have undergone the review and obtained the approval that was appropriate under the law at the time they first entered the relevant service area, so long as the facility or service is not being relocated. For facilities, services, and equipment which have previously undergone Certificate of Need review, the Certificate of Need must be fulfilled prior to a change of ownership.

Section 601. Voidance and Extension Procedures.

 1. The Certificate of Need shall become void twelve months (one year) from the date of issuance. The Department may void a Certificate of Need if requested by the applicant, or if the Department determines that the Certificate of Need has not fully implemented within one year from the date issued. Implementation may be evidenced by, but not limited to, a properly negotiated valid construction contract or appropriate purchase order for service projects.

 2. 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 of Need must submit quarterly progress reports documenting compliance with the aforementioned timetable. Failure to meet the timetable results in the revocation of the Certificate of Need by the Department unless the Department determines that extenuating circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay. If the applicant has not met the approved timetable, documented evidence that extenuating circumstances beyond the control of the holder of the Certificate of Need should be provided to the Department. This information can also be included in a request for an extension as provided in Section 602.

 3. The Department may grant up to two extensions of up to nine months each. In order to obtain an extension, the applicant must have demonstrated substantial progress and must either be complying with the approved timetable or have submitted documentation satisfactory to the Department that extenuating circumstances beyond the control of the applicant have prevented compliance with the timetable. After the nine month extension period, the Certificate of Need will expire and become void.

 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.