

Summary of Major Revisions to Regulation 61-15, Certification of Need for Health Facilities and Services

Note: Asterisks denote revisions that were implemented in accordance with Act 278 which was effective July 1, 2010.

***Section 102.1.e**

In accordance with Act 278, deleted requirement for CON review of a component for health services with an annual operating cost in excess of \$1,000,000 if a capital expenditure is not made.

***Section 102.1.g, h, i**

In accordance with Act 278, deleted requirement for CON review of certain identified acquisitions and expenditures, most notably, change of ownership.

***Section 102.4**

In accordance with Act 278, added the following new verbiage to clarify deletion of change of ownership from CON review:

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 103.1**

In accordance with Act 278, amended the definition of “affected person” to reflect written notice by affected persons to specifically state their opposition to the application under review.

***Section 103.16**

In accordance with Act 278, revised definition of ‘Like equipment with similar capabilities’ which distinguishes it from ‘Like equipment’ as follows:

16. Like equipment with similar capabilities means medical equipment in which functional and technological capabilities are identical to the equipment to be replaced; and the replacement equipment 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.

a. The replacement of like equipment for which a Certificate of Need has been issued and the replacement does not result in a material change in service or a new service.

Sections 104 and Section 105

Revised Exemption and Non-applicability Determination sections to be consistent with changes in Act 278, which relaxed requirements for replacement of like equipment. Non-applicability determinations were specifically added to the regulations. The length of time determinations are valid was relaxed from 6 to 12 months as suggested by the regulated community.

The previous requirement for written exemptions for non-medical projects and certain upgrades to medical facilities was deleted as suggested by the regulated community, and instead requires written notification to the Division of Health Facilities Construction. The following will be removed from CON review, in addition to refinancing of existing debt: An expenditure by or on behalf of a health care facility for non-medical projects, such as parking garages, laundries, roof replacement, computer systems, telephone systems, and heating and air conditioning systems.

Section 202.2.b(27)

Adds requirement for submission quality of patient care information, in accordance with the prior DHEC Board directive to further focus on quality assurance. Note this information has always been requested by staff, but it was not in regulation.

***Section 202.2.d(9)**

Revised to be consistent with Act 278 and to clarify provisions for an unfulfilled Certificate of Need relative to changes in controlling interest:

(9) That the controlling interest in any health care facility shall not be sold or leased or otherwise disposed of unless the Certificate of Need has been fulfilled.

***Section 305**

In accordance with Act 278, changed decision deadlines to no later than 120 calendar days, and 150 days if a public hearing is held.

***Section 312.1**

In accordance with Act 278, revised to add prohibited contact by state and federal elected officials to the Department after a CON application has been filed:

After a Certificate of Need application has been filed with 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 401**

Revised to reference changes in appeals process implemented by Act 278.

***Section 601.1**

In accordance with Act 278, revised to relax CON issuance period to 12 months for all projects.

***Section 601.2**

Revised to relax the submission of progress reports from monthly to quarterly as suggested by the regulated community.

***Section 601.3**

In accordance with Act 278, revised to reflect the relaxation of the staff CON extension period from 6 to 9 months.

***Section 601.4**

In accordance with Act 278, revised to reflect the relaxation of the DHEC Board CON extension period from 6 to 9 months.

***Section 607.1**

Revised to relax the submission of progress reports from monthly to quarterly as suggested by the regulated community.

***Section 701 – renumbered as Section 702**

In accordance with Act 278, deleted Section which required a CON for expenditures for preparation or offering to prepare a health service