

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
November 13, 2014

- (X) ACTION
() INFORMATION

I. TITLE: Proposed Amendments of Regulation 61-15, *Certificate of Need for Health Facilities and Services*.

Legislative review is required.

II. SUBJECT: Request Initial Approval to Publish Notice of Proposed Regulations in the *State Register* to Provide Opportunity for Public Comment.

III. FACTS:

1. Pursuant to S.C. Code Section 44-7-150(3), the South Carolina Department of Health and Environmental Control (Department) proposes amending S.C. Regulation 61-15, *Certification of Need for Health Facilities and Services*, as described by topic in items 2-17 below:

2. The Department proposes amending R.61-15 to delete Section 101.

3. The Department proposes amending R.61-15 to delete Section 102.

4. The Department proposes amending R.61-15 to revise Section 103 to amend the timeframe for submitting a "competing application," to clarify the procedures for collecting "Fees" used by the Certificate of Need program, to add the term "implemented" to the definitions, and to delete certain definitions that are unnecessarily duplicative of S.C. Code Section 44-7-130 or other statutory authority. This provision will be renumbered as Section 101.

5. The Department proposes amending R.61-15 to add Section 102 to clarify the "Timing" requirement for deadlines that fall on weekends and holidays that was previously addressed in Section 304(4).

6. The Department proposes amending R.61-15 to add Section 103 to modify the monetary thresholds for Certificate of Need review of capital expenditures and acquisitions of equipment referenced in S.C. Code Section 44-7-160(3) and (6) that were previously addressed in Section 102.

7. The Department proposes amending R.61-15 to revise Section 104 to simplify the requirements for obtaining an exemption from Certificate of Need review pursuant to S.C. Code Section 44-7-170.

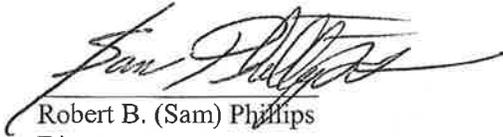
8. The Department proposes amending R.61-15 by deleting Section 105 (Non-Applicability Determination) due to introduction of the web-based Certificate of Need application and the revision to Section 104 of this Regulation.

9. The Department proposes amending R.61-15 to revise Section 106 to simplify the procedures for the South Carolina Health Plan. This provision will be renumbered as Section 105.

10. The Department proposes amending R.61-15 by deleting Chapter 2 (Sections 201 & 202) because these provisions will be supplanted by the implementation of a web-based Certificate of Need application and other revisions to this Regulation.

V. RECOMMENDATION:

Department staff recommends the Board grant initial approval to publish a Notice of Proposed Regulation in the *State Register*, to provide an opportunity for public comment, to receive and consider comments, and to allow staff to proceed with a public hearing before the Board.



Robert B. (Sam) Phillips
Director
Certificate of Need Program



Jamie Shuster
Director of Public Health

Attachments

- A. Statement of Need and Reasonableness
- B. Summary of Proposed Revisions
- C. Text of Proposed Amendments
- D. Draft of *State Register* Notice of Proposed Regulation
- E. *State Register* Notice of Drafting
- F. Summary of Public Comments and Department Responses

7. The Department proposes amending R.61-15 to revise Section 104 to simplify the requirements for obtaining an exemption from Certificate of Need review pursuant to S.C. Code Section 44-7-170.

8. The Department proposes amending R.61-15 by deleting Section 105 (Non-Applicability Determination) due to introduction of the web-based Certificate of Need application and the revision to Section 104 of this Regulation.

9. The Department proposes amending R.61-15 to revise Section 106 to simplify the procedures for the South Carolina Health Plan. This provision will be renumbered as Section 105.

10. The Department proposes amending R.61-15 by deleting Chapter 2 (Sections 201 & 202) because these provisions will be supplanted by the implementation of a web-based Certificate of Need application and other revisions to this Regulation.

11. The Department proposes amending R.61-15 to revise Section 301 to conform the application procedures set forth therein to the requirements of the new web-based Certificate of Need application. This provision will be renumbered as Section 201.

12. The Department proposes amending R.61-15 to add Section 202 that sets forth the requirement to post notice that the Department has accepted a Certificate of Need application for filing.

13. The Department proposes amending R.61-15 to delete Section 302 (Additional Information).

14. The Department proposes amending R.61-15 to add Section 203 that sets forth the requirement to post notice that the Department has deemed a Certificate of Need application to be complete.

15. The Department proposes amending R.61-15 by deleting Sections 303 thru 312, which are unnecessarily duplicative of statutory provisions or which have been supplanted by the implementation of a web-based Certificate of Need application and other revisions to this Regulation, and replacing them with the following Sections: 301 (Project Changes During Review Period), 302 (Project Changes After Receipt of Certificate of Need), 303 (Implementation and Extension Procedures), 304 (Reporting of Certificate of Need Implementation), and 305 (Joint Annual Reports).

16. The Department proposes amending R.61-15 to delete Chapters 4, 5, 6, 7, 8 and the existing Appendix A to simplify the Certificate of Need application and implementation processes, and conform the existing Regulation to the new web-based Certificate of Need application. Additionally, some of the deleted provisions were unnecessarily duplicative of the requirements set forth in S.C. Code Sections 44-1-60, 44-7-190, 44-7-210, 44-7-230, 44-7-320, 44-7-340 and related authority.

17. The Department proposes amending R.61-15 to add Section 401 to simplify and focus the Certificate of Need project review criteria in compliance with S.C. Code Section 44-7-190.

The intent of these amendments is to simplify the Certificate of Need process and facilitate the introduction of a web-based Certificate of Need application. These changes support the Department's goal of promoting and protecting the health of the public in a more efficient and effective manner. There would be no detrimental effect on the environment and public health if the proposed amendments to R. 61-15 are adopted.

ATTACHMENT B
Summary of Proposed Revisions to
Regulation 61-15, Certification of Need for Health Facilities and Services
November 13, 2014

SECTION CITATION/EXPLANATION OF CHANGE:

1. The Department proposes amending R.61-15 to delete and/or rename several provisions that have been supplanted by the adoption of the web-based Certificate of Need application or that are unnecessarily duplicative of statutory requirements:

R.61-15, delete Section 101 (Purpose). Deleted provision is unnecessarily duplicative of statutory language.

R.61-15, delete Section 102 (Applicability). Monetary threshold provisions now addressed in Section 104; other provisions are unnecessarily duplicative of statutory language.

R.61-15, rename Section 103 as 101 (Definitions). Delete certain definitions that are unnecessarily duplicative of statutory authority; update procedures for collecting Certificate of Need-related fees; modify timeframe for competing applications; and add clarifying language to define “implementation” of a Certificate of Need.

R.61-15, Section 102 (Timing). Add section to clarify the procedure for extending deadlines that fall on weekends and State holidays.

R.61-15, Section 103 (Monetary Thresholds). Add section to increase monetary thresholds for Certificate of Need reviews for capital expenditures and acquisition of new equipment, formerly addressed in Section 102.

R.61-15, Section 104 (Exemption Determinations). Revise and simplify the procedures for obtaining an exemption; delete language unnecessarily duplicative of statutory language.

R.61-15, Section 105 (Determinations of Non-Applicability). Delete section that is unnecessarily duplicative of statutory language or otherwise addressed in Section 104.

R.61-15, rename Section 106 as 105 (Procedure for South Carolina Health Plan). Revise and clarify the procedures for obtaining public comments to a proposed change to the South Carolina Health Plan, and delete language that is unnecessarily duplicative of statutory provisions.

R.61.15, delete Chapter 2 (Application Procedures). Delete provision supplanted by adoption of web-based Certificate of Need application.

R.61.15, revise Chapter 3 and rename it as Chapter 2 (Application, Review and Decision). Conforms regulation to requirements and capabilities of a web-based Certificate of Need application.

R.61-15, rename Section 301 as 201 (Submission of Application). Delete provisions that will be supplanted by the adoption of the web-based Certificate of Need application.

R.61-15, Section 202 (Acceptance of Application for Filing). Simplify and conform existing procedures to the requirements and capabilities of a web-based Certificate of Need application.

R.61-15, rename Sections 801 & 802 as Section 401 (Criteria for Project Review). Delete provisions that have been replaced by other criteria promulgated by the Department and provide simplified criteria to allow for the efficient review of applications for a Certificate of Need.

R.61-15, Appendix (Application). Delete paper-based application supplanted by adoption of the web-based Certificate of Need application.

Section 304. Reporting of Certificate of Need Implementation

Section 305. Joint Annual Reports

CHAPTER 4 -- PROJECT REVIEW CRITERIA

Section 401. Criteria for Project Review

~~CHAPTER 4 -- APPEALS~~

~~Section 401. Notification of Decision~~

~~Section 402. [Reserved]~~

~~CHAPTER 5 -- GENERAL PROVISIONS~~

~~Section 501. Findings of the Department~~

~~Section 502. Periodic Reports~~

~~Section 503. Distribution of Procedures Criteria~~

~~Section 504. Review Under Applicable Plan~~

~~CHAPTER 6 -- VOIDANCE AND EXTENSION OF CERTIFICATES OF NEED~~

~~Section 601. Voidance and Extension procedures~~

~~Section 602. Extension Request~~

~~Section 603. Criteria for Extension~~

~~Section 604. Non-Transferability of Certificate of Need~~

~~Section 605. Project Changes After Receipt of Certificate of Need~~

~~Section 606. Total Project Cost~~

~~Section 607. Periodic Reporting of Certificate of need Implementation~~

~~CHAPTER 7 -- PENALTIES FOR NON-COMPLIANCE~~

~~Section 701. Penalties~~

~~Section 702. [Reserved]~~

~~CHAPTER 8 -- PROJECT REVIEW CRITERIA~~

~~Section 801. Applicability and Weighting~~

~~Section 802. Criteria for Project Review~~

~~APPENDIX: APPLICATION FOR CERTIFICATION OF NEED FOR A HEALTH FACILITY OR SERVICE~~

~~QUESTIONNAIRE -- PART A
APPLICATION~~

*CHAPTER 1
PURPOSE, APPLICABILITY AND DEFINITIONS*

CHAPTER 1 - PURPOSE, APPLICABILITY AND DEFINITIONS AND APPLICABILITY

SECTION 101. Purpose

~~The purpose of these Regulations 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.~~

SECTION 102. Applicability

~~—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, persons who before receipt by the Department of the proposal being reviewed have formally indicated an intention to provide similar services in the future, 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 in writing 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 persons from South Carolina in its Certificate of Need process. A person may not file a request for final review in 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. Affected persons may request in writing to be notified of a Department decision by regular mail or electronic mail in lieu of certified mail.~~

~~—2. Ambulatory surgical facility means a distinct, free standing, self-contained entity that is organized, administered, equipped and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures and/or services for which patients are scheduled to arrive, receive surgery, or related care, treatment, procedures and/or services and be discharged on the same day. The owner or operator makes the facility available to other providers who comprise an organized professional staff.~~

~~—3. Arrangement for financing means a financial commitment, i.e. enforceable contract.~~

~~—4. Board means the State Board of Health and Environmental Control.~~

~~—5. Children and adolescents in need of mental health treatment in a residential treatment facility means a child or adolescent under age eighteen who manifests a substantial disorder of cognitive or emotional process, which lessens or impairs to a marked degree that child's capacity either to develop or to exercise age appropriate or age adequate behavior. The behavior includes, but is not limited to, marked disorders of mood or thought processes, severe difficulties with self-control and judgment including behavior dangerous to self or other, and serious disturbance in the ability to care for and relate to others.~~

16. "Competing applicants" means two or more persons and/or health care facilities as defined in this regulation Section 44-7-130 of the South Carolina Code of Laws who apply for Certificates of Need to provide similar services and/or facilities in the same service area within the time frame established in this section and whose applications, if approved, would exceed the need for this facility or service the services or facilities. An application shall be considered competing if it is received by the Department no later than fifteen thirty (1530) calendar days after a Notice of Affected Persons is published in the State Register notice is posted on the Department's website, pursuant to Section 202 of this Regulation, that an application has been accepted for filing for one or more applications for similar services and/or facilities in the same service area. All Only applications received by the Department within fifteen thirty (1530) calendar days of publication of the Notice of Affected Persons in the State Register for the posting on the Department's website that the first application(s) has been accepted for filing will be considered to be competing. Any applications received by the Department later than the fifteenth day following publication of the Notice of Affected Persons in the State Register for the first application(s) will not be considered to be competing with the(se) application(s).

~~—7. Department means the Department of Health and Environmental Control.~~

~~8. Facility for chemically dependent or addicted persons means a facility organized to provide outpatient or residential services to chemically dependent or addicted persons and their families based on~~

~~—12. Health care facility for the purposes of Certificate of Need means acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care for the mentally retarded, inpatient hospice facilities, radiation therapy facilities and any other facility for which Certificate of Need review is required by state law.~~

~~—13. 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 South Carolina Health Plan.~~

~~—14. Hospital means a facility organized and administered to provide services to accommodate two or more non-related persons for the diagnosis, treatment and care of such persons over a period exceeding 24 hours and provides medical or surgical care or nursing care of illness, injury, or infirmity and may provide obstetrical care, and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.~~

~~—15. Institutional health services means health services provided in or through health care facilities and includes the entities in or through which such services are provided.~~

~~—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.~~

~~17. Nursing home means a facility with an organized nursing staff to maintain and operate organized facilities and services to accommodate two or more unrelated persons over a period exceeding twenty-four hours which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing nursing care for persons who are not in need of hospital care.~~

~~—18. Person means an individual, a trust or estate, a partnership, a corporation including an association, joint stock company, insurance company, and a health maintenance organization, health care facility, a state, a political subdivision or an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.~~

~~—19. Psychiatric Hospital means an institution which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.~~

~~—20. Residential treatment facility for children and adolescents means a facility operated for the assessment, diagnosis, treatment, and care of two or more 'children and adolescents in need of mental health treatment' which provides:~~

~~— a. a special education program with a minimum program defined by the South Carolina Department of Education.~~

~~— b. recreational facilities with an organized youth development program; and~~

~~— c. residential treatment for a child or adolescent in need of mental health treatment.~~

~~—21. Solely for research means a service, procedure, or equipment which has not been approved by the Food and Drug Administration (FDA) but which is currently undergoing review by the FDA as an~~

~~— 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.~~

~~— b. The acquisition by a health care facility of medical equipment to be used solely for research, the offering of an institutional health service by a health care facility solely for research, or the obligation of a capital expenditure by a health care facility to be made solely for research if it does not: (a) affect the charges of the facility for the provision of medical or other patient care services other than the services which are included in the research; (b) change the bed capacity of the; or (c) substantially change the medical or other patient care service of the facility. FDA research protocol and any applicable Investigational Device Exemption (IDE) policies and regulations must be followed by the facility. A written description of the proposed research project must be submitted to the department in order for the department to determine if the above conditions are met. A Certificate of Need is required to continue use of the equipment or service after the equipment or service is no longer being used solely for research;~~

~~— c. The permanent reduction in bed capacity, including the permanent closure of a health care facility.~~

~~— 2. In order to request an exemption the following information must be provided to the Department in writing at a minimum:~~

~~a. A complete description of the proposed project, including, but not limited to, location of the project, and total project costs;~~

~~— b. Other documentation requested by the Department in order to determine compliance with these regulations;~~

~~— c. Additional information as may be reasonably necessary for the Department to make a determination.~~

~~— 3. If an exemption is granted, it is valid for a period of twelve (12) months from the date of issuance. If the proposal is not implemented within this twelve month period, the exemption becomes void and another exemption must be requested in order for the applicant to undertake the proposal.~~

~~— 4. The following projects are exempt from Certificate of Need review but and do not require a written determination from the Department: the offices of a licensed private practitioner whether for individual or group practice. This exemption shall not apply to: (1) the construction or other establishment of a new health care facility, as in Section 102.1.a; or (2) 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), as in Section 102.1.f.~~

SECTION 105. Determinations of Non-Applicability

~~— 1. Certificate of Need review is not applicable to the following, but prior to undertaking the proposed project, a written determination of non-applicability from the Department is required:~~

~~— a. Replacement of like equipment with similar capabilities as defined by the Department in Section 103.16.~~

~~— b. Acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is not in excess of six hundred thousand dollars (\$600,000). A written determination of non-applicability is only required when any question exists as to whether or not the total project cost is below the six hundred thousand dollars (\$600,000) threshold.~~

- ~~— a. an inventory of existing health care facilities, beds, specified health, services, and equipment.~~
 - ~~— b. projections of need for additional health care facilities, beds, health services, and equipment;~~
 - ~~— c. standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of service, and proper planning of health care facilities; and~~
 - ~~— d. a general statement as to the project review criteria considered most important in evaluating Certificate of Need applications for each type of facility, service and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service and equipment, may outweigh the adverse affects caused by the duplication of any existing facility, service or equipment.~~
- ~~— 2. The South Carolina Health Plan must address and include projections and standards for specified health services and equipment which have a potential to substantially impact health care cost and accessibility. Nothing in this provision shall be construed as requiring the Department to approve any project which is inconsistent with the South Carolina Health Plan.~~
- ~~— 3. Upon approval by the health planning committee, the South Carolina Health Plan must be submitted at least once every two years to the Board for final revision and adoption. Once adopted by the Board, the Plan may later be revised through the same planning and approval process, public review and comment, including four regional public hearings before adoption or revision of the Plan. Prior to revising the plan, the Department will publish a notice in the State Register, announcing a period for public comments and scheduling public hearings to receive public comments.~~

CHAPTER 2
APPLICATION PROCEDURES

SECTION 201. Public Notification.

Within twenty days prior to submission of an application, the applicant shall publish notification that an application is to be submitted to the Department in the legal section of a daily newspaper serving the area where the project is to be located for three consecutive days. The notification must contain at least the following information: 1) that a Certificate of Need is being applied for; 2) a description of the scope and nature of the project; and 3) the estimated project capital cost. No application may be accepted for filing by the department unless accompanied by documentation from the newspaper that publication has been made for three consecutive days within the prior twenty day period.

SECTION 202. Application.

—1. Two copies of the application shall be forwarded to the Department in the following format and shall contain the following information as applicable. The application will be on 8 1/2 X 11 inch paper, one side only, and 3 hole punched on the left side.

—2. Application

— a. Proposal Page and Part A. Questionnaire (See Appendix)

— b. Part B. Additional Information

~~_____ (f) Name and mailing address of all persons and/or legal entities claiming liabilities of the licensee or of the facility or service for which this Certificate of Need is requested to include a schedule of percent and type of claim of each.~~

~~_____ (g) Provide a listing which identifies all officers of the licensee.~~

~~_____ (h) Is the land and/or building on/in which the proposed facility or service is to be conducted owned by the applicant. _____ YES _____ NO. If no, provide information on the land and building similar to that required in (b) through (g) above.~~

~~_____ (i) Has the licensee engaged an entity other than an employee of the licensee to manage or operate the facility or service? _____ YES _____ NO. If yes, provide information similar to that required in (b) through (g) above.~~

~~_____ (j) Is there any agreement, contract, option, understanding, intent or other arrangement that will effect a change in any of the information requested and/or provided in (b) through (g) above. _____ YES _____ NO. If yes, provide information similar to that required in (b) through (g) above.~~

~~_____ (k) Provide a complete listing of all existing licensed health care facilities and/or services and Certificates of Need in which the proposed licensee currently has an ownership interest, to include names and addresses of each facility or service. In the cases of Certificates of Need for undeveloped facilities and services, provide the name, address, and telephone number of a contact person representing the authority which issued the Certificate of Need.~~

~~_____ (l) Should the licensee be a subsidiary corporation, provide a diagram of the licensee's relationship to the parent corporation and list the name and address of the parent corporation as well as the corporation which has ultimate control. In addition, please provide the name and mailing address of all persons and/or legal entities having ownership interest of five percent or more or any person with any agreement, contract, option, arrangement, or intent to acquire ownership interest of five percent or more, of all corporations in the corporate organizational structure which have ultimate control of the licensee.~~

~~_____ (9) Provide documentation that the applicant has sought cooperative agreements such as transfer agreements with other facilities, as applicable.~~

~~_____ (10) Indicate the means by which a person will have access to the facility's services (i.e. physician referral, self admission, etc). Identify the specific facilities or agencies the applicant expects to receive referrals from (i.e. hospitals, home health agencies, etc). Describe any limitations placed on admissions.~~

~~_____ (11) Demonstrate that the proposed project is needed or projected as necessary to meet an identified need of the public. This shall address at a minimum: identification of the target population; the degree of unmet need; projected utilization of the proposed facility or service; utilization of existing facilities and services; past utilization of existing similar services within the facility; and justification that the proposed project will not unnecessarily duplicate existing entities. The applicant must show all assumptions, data sources, and methodologies used. The applicant must use population statistics consistent with those generated by the State Demographer, State Budget and Control Board.~~

~~_____ (12) Discuss alternative facilities and/or services considered including the advantages and disadvantages of each alternative. Include a statement as to why this project alternative was adopted.~~

~~—— (26) Discuss the impact of the project on the clinical training programs of health professional schools, particularly the extent to which these schools will have access to the services for training.~~

~~—— (27) Provide documentation of policies and procedures to assure the quality of healthcare services by addressing patient safety and quality indicators, as applicable. Documents may include, but are not limited to, measures of patient care, patient safety, healthcare acquired infections and the following of best practices established by recognized organizations. Applicable quality standards in the South Carolina Health Plan must be addressed.~~

~~—— (28) Provide any additional information that would assist the department in evaluating this project.~~

~~—— c. Part C. Programmatic Documents~~

~~Provide adequate programmatic documents in support of the various elements of the proposed project. These documents will include as appropriate:~~

~~—— (1) An Indigent Care Plan as required by the Board of Health and Environmental Control. It shall address at a minimum, the following:~~

~~—— (a) The existing and proposed admission and treatment policies of the facility or agency with regard to race, sex, creed, national origin, and ability to pay.~~

~~—— (b) The proposed admission and treatment policies of the facility or agency with respect to admission and care of indigent patients including those patients unable to pay at the time of admission and those whose benefits expire while in the care of the facility or agency.~~

~~—— (c) In existing facilities or agencies, provide the amount, in dollars and percent of gross revenues, that the facility or agency provided in indigent care during the past three fiscal years. NOTE: Indigent care does not include bad debt; contractual adjustments; or care which is reimbursed by a governmental program (Medicare, Medicaid, county indigent program), church, or philanthropic organization.~~

~~—— (d) Provide the proposed amount of indigent care the facility or agency projects to provide during the existing fiscal year and next fiscal year. This projection should be expressed in both dollars and a percent of gross revenues.~~

~~—— (e) A discussion of why the above figures are adequate or inadequate for the needs of the community; the need of indigent care within the proposed service area; and any solutions, remedial plans or proposals by the facility or agency to better address the indigent care problem in the service area. Include any initiatives or undertakings the facility or agency has begun to address the indigent care problem in the proposed service area.~~

~~—— (f) Describe any Board or Advisory Board established to implement or control the indigent problem at the facility or agency. Include the Board's functions, responsibilities, and limitations.~~

~~—— (2) A map of sufficiently large scale to be meaningful, indicating the location of the project site and its geographical area.~~

~~————(6) That the facility will be operated and maintained in accordance with the standards prescribed by law and regulations for the maintenance and operation of such facilities.~~

~~————(7) That the applicant understands that the Certificate of Need shall become void at the end of the specified time period from the date of issuance unless otherwise extended under Chapter 6 of these regulations.~~

~~————(8) That the Department or its authorized representatives may at any time during the course of construction and upon the completion of the project make an on site inspection of the construction and equipment to check for compliance of the construction in accordance with the application for which the Certificate of Need was issued.~~

~~————(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.~~

~~————(10) That the applicant will notify the Department in writing that the contractual agreement has been completed. For a construction project, the letter shall indicate that a construction contract specifying the beginning and completion dates of the project, has been signed by both parties. For services projects, the letter must indicate that equipment purchase orders with estimated delivery dates have been properly negotiated.~~

~~————(11) That the applicant will notify the Department in writing of the date that a new or expanded service has been implemented, completed or terminated.~~

~~————(12) That the applicant will provide monthly progress reports and a final completion report which contain the information required by Section 607 of these regulations.~~

CHAPTER 3 DISPOSITION OF APPLICATION

CHAPTER 2 - APPLICATION, REVIEW AND DECISION

SECTION ~~301~~201. Submission of Application

The application shall be submitted utilizing the web-based application available on the Department's web site or by such other means the Department may provide.

Section 202. Acceptance of Application for Filing

1. Upon submission of an application and receipt of the filing fee, the Department shall post notice on its website that an application has been accepted for filing. The posting shall indicate the date the application was accepted for filing. The Department shall comply with any additional notice requirements set forth in Section 44-7-200(D) of the South Carolina Code of Laws.

2. If the Department determines that the application is not acceptable for filing, the Department shall notify the applicant in writing.

Two copies of the application along with a non-refundable filing fee of five hundred dollars (\$500) shall be forwarded to the Bureau of Health Facilities and Services Development, S.C. Department of Health

by certified mail. The applicant will have thirty (30) calendar days from receipt of the revised notice to submit any additional information.

— 2. 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.

— 3. When an application has been appealed, the Department may not change the weight of the importance of the project review criteria.

SECTION 305. Review Time Frames

— 1. Upon determination by the Department that the application is complete, and receipt of the application fee, the Department shall publish in the State Register a notice that the review cycle for the project has begun. Any affected person who has notified the Department in writing that they desire to be notified of the beginning of the review period be sent a copy of the notification.

— 2. The Department will make a decision on the complete application no earlier than thirty (30) calendar days but no later than 120 calendar days of the date of publication in the State Register unless a public hearing is held. Notice of a Department decision must be sent by certified mail, return receipt requested to the applicant and affected persons who have requested in writing to be notified.

— a. If a public hearing is held pursuant to Section 306, the Department will render its decision no later than 150 calendar days from the date the affected persons are notified that the application is complete.

— b. [Reserved]

SECTION 306. Public Hearing

A public hearing must be requested in writing by an "affected person" as defined in these regulations within thirty (30) calendar days of the notification of the beginning of a review. Where such a hearing is requested, prior notice of the hearing will be provided to "affected persons" The written notification of the hearing shall include the proposed schedule for the review, time, date, and place of such hearing. The public hearing shall provide an opportunity for any person to present information relevant to the application.

SECTION 307. Department Review

— 1. The Department may not issue a Certificate of Need unless an application is in compliance with the South Carolina Health Plan as described in this regulation, 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 is in compliance with the South Carolina Health Plan but is inconsistent with project review criteria or departmental regulations. The Department must identify any regulation that is used as a basis for denying an application that is in compliance with the South Carolina Plan.

— 2. 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 the Certificate of Need program, South Carolina Health Plan, project review criteria, and any regulations developed by the Department.

SECTION 308. Department Decision

SECTION 301. Project Changes During Review Period

If an applicant amends his application during the review process, the Department shall determine whether or not the amendment is substantial and constitutes a new application. If the change results in an increase in cost, the fees shall be adjusted accordingly.

SECTION 302. Project Changes After Receipt of Certificate of Need

If an applicant amends or alters his project after receipt of a Certificate of Need, the Department shall decide whether or not the amendment is substantial and thereby constitutes a new project.

SECTION 303. Implementation and Extension Procedures

1. The Certificate of Need must be implemented within twelve months (one year) from the date of issuance or within such additional time as may be granted by an extension of the Certificate of Need pursuant to this section.

2. Requests for extensions of Certificates of Need shall be submitted to the Department to the attention of the Director of the Certificate of Need Program and shall contain the following information: (a) a statement as to the amount of time for which the extension is requested; (b) a description of any changes to the cost, location, services, or scope of the project; (c) a description of any progress on the project; and (d) an estimated timetable for commencement and completion of all remaining components of the project. The Department will determine whether the extension request requires review by the Board pursuant to Section 44-7-230(D) of the South Carolina Code of Laws. If the extension request requires review by the Board, the Department will forward the information provided by the applicant to the Board for consideration.

3. Requests for extensions may be granted by the Department or the Board, as appropriate pursuant to Section 44-7-230(D), upon evidence that substantial progress has been made on the project. Consideration may be given to any evidence presented by the requestor indicating that extenuating circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay.

SECTION 304. Reporting of Certificate of Need Implementation

Should circumstances indicate to the holder of a Certificate of Need that it may not be possible to meet the timetable contained in the Certificate of Need application and approved by the Department for implementing the Certificate of Need, the holder shall submit a report to the Department explaining the circumstances.

SECTION 305. Joint Annual Reports

For the purpose of health planning, health care facilities and others who provide services that require a Certificate of Need or who have received an exemption from Certificate of Need, shall on an annual basis submit information requested on the applicable Joint Annual Report.

CHAPTER 4 – PROJECT REVIEW CRITERIA

SECTION 401. Criteria for Project Review

The following project review criteria shall be used in reviewing Certificate of Need applications:

SECTION 502. Periodic Reports:

For the purpose of health planning, health care facilities and others who provide services that requires a Certificate of Need or who have been exempted, shall on an annual basis submit information requested on the applicable Joint Annual Report.

SECTION 503. Distribution of Procedures Criteria

The Department shall distribute copies of its proposed and adopted review procedures and criteria, and proposed revisions to statewide health agencies and organizations, any agency which establishes rates for health care facilities in the state, and other persons upon request.

SECTION 504. Review Under Applicable Plan

All decisions on Certificate of Need applications shall be made based on the currently approved South Carolina Health Plan in effect at the time such application is accepted. Should a new plan be adopted during any phase of the review or appeals process, the applicant shall have the option of withdrawing the application and resubmitting under the newly adopted plan or continuing the review or appeal process under the plan in use when the application was submitted. In cases where applications are withdrawn and resubmitted under the newly adopted South Carolina Health Plan within forty five (45) calendar days of the date of withdrawal, no additional filing fee shall be required.

CHAPTER 6

VOIDANCE AND EXTENSION OF CERTIFICATES OF NEED

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 nine month extension period, the Certificate of Need will expire and become void.

Need voided shall not be eligible to apply for a new Certificate for a period of one (1) year without Board approval.

SECTION 605. Project Changes After Receipt of Certificate of Need

If an applicant amends or alters his project after receipt of a Certificate of Need, the Department will decide whether or not the amendment is substantial and thereby constitutes a new project.

SECTION 606. Total Project Cost

In issuing a Certificate of Need, the Department shall specify the approved total project cost. A project is only approved for the amount specified in the Certificate of Need. The Department will review overruns on an individual basis.

SECTION 607. Periodic Reporting of Certificate of Need Implementation

— 1. The applicant is required to submit a quarterly progress report that corresponds with the timetable included in the Certificate of Need application beginning ninety (90) calendar days after receipt of the Certificate of Need. Failure to meet the timetable results in the revocation of the Certificate of Need by the Department unless a determination is made by the Department that circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay.

— 2. The applicant shall report on, if applicable: (1) costs incurred on the project; (2) construction activity; (3) program or service activity; and (4) any deviations from the submitted application with supporting documentation.

— 3. After the project has been fully implemented, the applicant shall provide the Department with a final completion report that contains, at a minimum:

- a. An audited cost report that shows all expenditures on the approved project;
- b. A list of average charges and costs for the services approved in the application and documented by affidavit, certification or other proof;
- c. A registered architect's or engineer's signed statement of final construction costs;
- d. An equipment listing and inventory for the project;
- e. A program and/or service narrative describing the final project configuration; and
- f. An explanation of any deviation from the approved application with justification, or a signed statement from the applicant that the project was implemented as outlined in the application.

— 4. Records relating to the project shall be maintained by the applicant for seven (7) years following the completion of the project and these records shall be made available to the Department's auditors for inspection as needed.

— 5. The Department may audit any project for consistency with the information provided in the Certificate of Need application. Undertaking a project that is not in accordance with the approved application or conditions or amendments subsequently agreed to by the applicant and the Department may be considered a violation of this article.

~~application. The applicant must use population statistics consistent with those generated by the State Demographer, State Budget and Control Board.~~

~~— c. The proposed project should provide services that meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and based on a reasonable approach as judged by the reviewing body. Any deviation from the population projection used in the South Carolina Health Plan should be explained.~~

~~— d. In the case of a reduction, relocation, or elimination of a facility or service, the applicant should address the need that the population presently has for the service, the extent to which that need will be met by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination, or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other underserved groups, to obtain needed health care.~~

~~— e. Current and/or projected utilization should be sufficient to justify the expansion or implementation of the proposed service.~~

~~— 3. Distribution (Accessibility):~~

~~— a. Duplication and modernization of services must be justified. Unnecessary duplication of services and unnecessary modernization of services will not be approved.~~

~~— b. The proposed service should be located so that it may serve medically underserved areas (or an underserved population segment) and should not unnecessarily duplicate existing services or facilities in the proposed service area.~~

~~— c. The location of the proposed service should allow for the delivery of necessary support services in an acceptable period of time and at a reasonable cost.~~

~~— d. The proposed facility should not restrict admissions. If any restrictions are applied, their nature should be clearly explained.~~

~~— e. The applicant must document the means by which a person will have access to its services (e.g. outpatient services, admission by house staff, admission by personal physician)~~

~~— f. The applicant should address the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other medically underserved groups, are likely to have access to those services being proposed.~~

~~— g. The facility providing the proposed services should establish provisions to insure that individuals in need of treatment as determined by a physician have access to the appropriate service, regardless of ability to pay.~~

~~— h. Potential negative impact of the proposed project upon the ability and/or resources of existing providers to serve medically underserved groups must be considered.~~

~~— 4. Acceptability:~~

~~— a. The proposal and applicant should have the support of “affected persons” (including local providers and the target population). The lack of opposition should not be considered support for the purposes of these criteria.~~

~~— a. Debt service (interest cost plus payment toward principal) should not be so large as to cause a negative net income.~~

~~— b. Characteristics of the debt (interest, prepayment arrangements, etc.) should be consistent with those arrangements used by other health service entities in the State and consistent with accepted good business practices in terms of assumption and retirement of debt.~~

~~— c. The applicant must document the impact the project will have on the facility's proposed level of patient charges.~~

~~— 11. Methods of Financing:~~

~~— a. Possible alternatives should be identified.~~

~~— b. Reasons for the selection of the proposed funding method should be stated and reasonable.~~

~~— 12. The applicant should demonstrate an ability to obtain the desired capital. The applicant must provide at least conditional commitment from an appropriate institution.~~

~~— 13. Record of the Applicant (Owner and/or Administrator):~~

~~— a. The applicant's record should be one of successful operation with adequate management experience.~~

~~— b. The applicant should have a demonstrated ability to obtain necessary capital financing.~~

~~— c. If the applicant has no prior experience, sources of assistance should be specified (i.e. technical assistance from specific individuals or organizations).~~

~~— d. The applicant's record or his representative's record of cooperation and compliance with State and Federal regulatory programs will be considered.~~

~~— 14. Ability to Complete the Project:~~

~~— a. The applicant should have demonstrated that the project can be initiated and completed within the proposed time frame specified in the application.~~

~~— b. The financial schedules and time frames contained in the application should be consistent with those usually experienced in the development of similar facilities or services.~~

~~— 15. Financial Feasibility:~~

~~The applicant must have projected both the immediate and long term financial feasibility of the proposal. Such projection should be reasonable and based upon accepted accounting procedures.~~

~~— 16. Cost Containment (Minimizing Costs):~~

~~— a. The applicant should have identified and sought alternative sources and/or methods of funding and demonstrated that the method chosen was the most feasible option.~~

~~The existing distribution of the health service(s) should be identified and the effect of the proposed project upon that distribution should be carefully considered to functionally balance the distribution to the target population.~~

~~—23. Adverse Effects on Other Facilities:~~

~~— a. The impact on the current and projected occupancy rates or use rates of existing facilities and services should be weighed against the increased accessibility offered by the proposed services.~~

~~— b. The staffing of the proposed service should be provided without unnecessarily depleting the staff of existing facilities or services or causing an excessive rise in staffing costs due to increased competition.~~

~~—24. Adverse Effects on Training Programs:~~

~~The proposed delivery of health services should not adversely affect the ability of local health professional training programs to meet their clinical needs.~~

~~—25. Access:~~

~~If the proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools in the area will have access to the services for training purposes should be clearly delineated in the proposal.~~

~~—26. Zoning:~~

~~The proposed site must comply with local zoning regulations. Documentation should be provided from the appropriate zoning authorities that the proposed site is or can be zoned for the intended use.~~

~~—27. Utilities:~~

~~The utilities necessary for the facility to operate should be available on site or the application should state provisions made for bringing these utilities on site or providing alternatives such as wells or sewage treatment plants. Applicants should document the availability of needed utilities. The cost of such provisions should be detailed in the financial section of the application.~~

~~—28. Site Size:~~

~~Documentation should be provided that all of the property intended for use is available to the applicant. Consideration may also be given to the suitability of the proposed site for any expansion of services included in the applicant's long range plans.~~

~~—29. Environmental Hazard:~~

~~The proposed facility should not be located on a site where environmental conditions would either create a health hazard or aggravate an existing health condition in individuals served by the facility.~~

~~—30. Square Footage:~~

~~Space allocations should conform to applicable local, state, and federal regulations or minimum standards. For all projects, state or other applicable licensing standards must be met by the proposal.~~

APPENDIX

APPLICATION FOR CERTIFICATION OF NEED
FOR A HEALTH FACILITY OR SERVICE

Proposal Prepared By:

Name: _____ Title _____
 Organization: _____
 Address: _____
 City: _____ State: _____ Zip Code: _____
 Telephone Number _____
 Email: _____ Fax Number: _____

The Applicant hereby certifies that the information contained in this Application, including all assurances and attachments, are correct to the best of his knowledge and belief.

Applicant's Signature: _____
 Date: _____

Forward to:
 Bureau of Health Facilities and Services Development
 S.C. Department of Health and Environmental Control
 2600 Bull Street
 Columbia, S.C. 29201

NOTE: A "complete" application shall include a written narrative report by the applicant (Regulation 61-15, Section 202).

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| PART A - QUESTIONNAIRE |
| 1. Name of Facility |
| 2. Address, City, County, State, Zip Code |

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|-------------------------------------|-----------------------------|--------------------------------|
| 3. Type of Facility (Circle) | | |
| A. Hospital | B. Nursing Home | C. Psychiatric Facility |
| D. Rehabilitation Facility | E. Substance Abuse Facility | F. Ambulatory Surgery Facility |
| G. Other (Specify) | | |

| | | |
|--------------------------------------|------------------------|----------------------------------|
| 4. Purpose of Review (Circle) | | |
| A. New Facility | B. Change of Licensure | C. Addition to Existing Facility |
| D. Renovation of Existing Facility | | E. Change of Services |
| F. Other (Specify) | | |

| | | |
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| 5. Management | | |
| A. Name of Administrator | B. Address, City, State, Zip Code | |
| C. Telephone: | D. Fax Number | E. Email |

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| 6. Licensee |
| A. Name of Licensee |
| B. Address, City, State, Zip Code |

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| 12. Costs (Provide Estimated Signed Cost Statement from Either the Architect or Engineer) | |
| A. Land Cost | B. Construction Cost |
| C. Architect's/Engineer's Fee | D. Equipment Costs (to include taxes) 1) Fixed Equipment 2) Movable Equipment |
| E. Financing Cost During Construction | F. Other Costs (Specify) |
| G. Total Project Cost | H. Construction and Equipment Cost 1) Per Square Foot 2) Per Bed |

comment period. Comments received shall be submitted in a Summary of Public Comments and Department Responses for the Board of Health and Environmental Control's consideration at the public hearing.

Copies of the proposed amendments for public comment as published in the *State Register* on November 28, 2014 may be obtained online in the DHEC Regulation Development Update at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>. Click on the Certification of Need for Health Facilities and Services topic and scan down to the proposed amendments of R. 61-15. A copy can also be obtained by contacting Sam Phillips at the above address or by facsimile at (803)545-4412, or by email at phillipb@dhec.sc.gov.

Preliminary Fiscal Impact Statement:

The Department estimates the net cost to the Department resulting from this proposed regulation revision to be approximately \$79,000 annually, which will be associated with the cost of maintaining the web-based application. This cost will be offset by the benefit to the Department and to the regulated community of utilizing an efficient web-based Certificate of Need application that will utilize standardized requests for information that will require less time to prepare and submit, will minimize costs associated with contractors (consultants, attorneys, etc.), and will allow decisions to be made approximately four (4) months faster than with the paper-based system.

Statement of Need and Reasonableness and Rationale:

The text of this statement is submitted in Attachment A and is omitted here to conserve space in the Board Item.

Text:

The text of the proposed amendments is submitted in Attachment C and is omitted here to conserve space in the Board Item.

ATTACHMENT F
SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES
State Register No.
Regulation 61-15, Certificate of Need for Health Facilities and Services
November 13, 2014

| Name | Section Citation | Public Comment | Department Response |
|---|--|--|---|
| <p>Jamie R. Thomas Hospital Corp. of America</p> <p>Shelley Pifer Dir. of Planning Lexington Medical Center</p> | <p>102(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] 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."</p> | <p>Eliminate the CON requirement for the expansion of beds and services on existing campus for licensed hospitals.</p> <p>Eliminate the CON requirement for the conversion of up to 10% of existing beds to psychiatric beds based on demonstrated need.</p> <p>Lexington Medical Center believes that licensed hospitals should be able to add new beds in response to market demand. However, hospitals should not be allowed to add new beds in a service for which they have not already been license.</p> | <p>Partially Adopted.</p> <p>Text: 102 "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] 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." The requirements for CON review are set forth in S.C. Code Section 44-7-160.</p> |
| <p>Jamie R. Thomas Hospital Corp. of America</p> <p>Elizabeth Fletcher VP, Spartanburg Regional Healthcare System.</p> <p>James R. Walker SVP, SC Hospital Association.</p> | <p>102(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) [a]n expenditure by or on behalf of a health care facility in excess of two</p> | <p>Eliminate the \$2 million capital expenditure threshold.</p> <p>SRHS supports either an increase in the capital threshold for which a CON would be required or the elimination of dollar thresholds entirely.</p> <p>[SCHA] believe the capital threshold of two million dollars (\$2,000,000) is too low, given the current cost of construction. Therefore, we recommend the threshold be increased to five million dollars.</p> | <p>Partially Adopted.</p> <p>Text: 102(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) [a]n expenditure by or on behalf of a health care facility in excess of two million dollars (\$2,000,000)" Text: Department is adding the following provision:</p> |

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| Center | undertaking any of the following ... (d) [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.” | service that is prescribed in the SC Health Plan and the service has been approved through the CON process, the facility should be allowed to expand the service without having to obtain an additional Certificate of Need. | 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.” The requirements for CON review are set forth in S.C. Code Section 44-7-160. |
| Shelley Pifer Dir. of Planning Lexington Medical Center | 104 “The following are exempt from Certificate of Need review, but prior to undertaking these projects, a written determination from the Department is required....” 105 “Certificate of Need review is not applicable to the following, but prior to undertaking the proposed project, a written determination of non-applicability from the Department is required....” | Lexington Medical Center recommends eliminating the requirement for a written determination of exemptions and non-applicability. | Partially Adopted. Department proposes deleting the existing Sections 104 and 105 in their entirety, and replacing them with revised Section 104. Text: 104 The following are exempt from Certificate of Need review, but prior to undertaking these projects, a written determination from the Department is required.... Text: 105 Certificate of Need review is not applicable to the following, but prior to undertaking the proposed project, a written determination of non-applicability from the Department is required.... Text: <u>104 Before undertaking a project for which Section 44-7-170 of the South Carolina Code of Laws requires a written exemption from the Department, a person shall submit to the Department a description of the proposed project, including, but not limited to, the location of the</u> |

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| | | <p>to create a more efficient and effective program.</p> <p>This would include the ability to submit CON applications and respond to additional questions asked by the department on-line. The on-line process will also give affected person the ability to submit comments and/or express opposition to projects.</p> <p>DHEC should only be allowed to request additional information from the CON applicant one time. If the additional information is incomplete, the application should be denied.</p> | <p>Department is implementing a web-based CON application, it will not have the capability to submit/receive questions to/from applicants on-line nor will it have the capability to interact with Affected Persons.</p> <p>Adopted. Text: Section 302(3) Should the applicant within such thirty (30) calendar day period submit incomplete additional information, the Department will have thirty (30) calendar days in which to request further information.</p> |
| James R. Walker SVP, SC Hospital Assn. | 202(2)(a) "Proposal Page and Part A. Questionnaire (See Appendix)." | We recommend that DHEC eliminate needless requirements for information that is not useful. | Adopted. Text: 202(2)(a) Proposal Page and Part A. Questionnaire (See Appendix). |
| Shelley Pifer Dir. of Planning Lexington Medical Center | 202(2)(b) "Part B. Additional Information (1) Document that the applicant has published" | Lexington Medical Center supports the removal of the following questions from the Certificate of Need Application [Section 202(b)(1), (5), (6), (8), (9), (10), (12), (13), (14), (16), (17), (18), (21), (23), & (27)] | Partially Adopted. Text: 202(2)(b) Part B. Additional Information (1) Document that the applicant has published |
| Shelley Pifer Dir. of Planning Lexington Medical Center | 302(1) "After receipt of an application with proof of publication in a local newspaper and the five hundred dollars (\$500) non- refundable filing fee, the Department shall publish in the State Register a notice that an | Utilize the DHEC website for providing notices about CON applications filing and review cycles instead of posting a notice in the State Register. The State Register is an antiquated document that is rarely viewed. | Partially Adopted. Text: 302(1) After receipt of an application with proof of publication in a local newspaper and the five hundred dollars (\$500) non refundable filing fee, the Department shall publish in the State Register a notice that an application has been accepted for filing. |

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| <p>Fletcher VP, Spartanburg Regional Healthcare System.</p> | <p>Department may audit any project for consistency with the information provided in the Certificate of Need application. Undertaking a project that is not in accordance with the approved application or conditions or amendments subsequently agreed to by the applicant and the Department may be considered a violation of this article.”</p> | <p>define the methodology and establish clear parameters in the Regulation for circumstances in which fines are issued for cost overruns.</p> | <p>Text: 607(5) The Department may audit any project for consistency with the information provided in the Certificate of Need application. Undertaking a project that is not in accordance with the approved application or conditions or amendments subsequently agreed to by the applicant and the Department may be considered a violation of this article.</p> |
| <p>Elizabeth Fletcher VP, Spartanburg Regional Healthcare System.</p> | <p>No reference, either direct or indirect, to Regulation 61-15.</p> | <p>SRHS requests that DHEC update the regulation to enable inpatient facilities to continue to provide post-acute care to patients discharged from their facility.</p> | <p>No response possible as Department cannot discern a reference to a specific provision of Reg. 61-15. Provision of home health care services pursuant to the requirement of a Certificate of Need are subject to requirements set forth in the South Carolina Health Plan.</p> |