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Statutory Authority: 44-7-110 et seq.
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Status: Pending
Subject: Certification of Need for Health Facilities and Services

History: 4181

By	Date	Action Description	Jt. Res. No.	Expiration Date
-	01/28/2011	Proposed Reg Published in SR		
-	06/01/2011	Received by Lt. Gov & Speaker		05/07/2012
H	06/01/2011	Referred to Committee		
S	06/01/2011	Referred to Committee		
S	03/23/2012	Committee Requested Withdrawal 120 Day Period Tolled		
-	03/27/2012	Withdrawn and Resubmitted		05/11/2012

Resubmitted: March 27, 2012

Document No. 4181
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 et seq.

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

Synopsis:

The Department has revised R.61-15, Certification of Need for Health Facilities and Services, to incorporate applicable amendments from Act 278 of 2010 which amended Section 44-7-110 et seq., S.C. Code of Laws, 1976, effective July 1, 2010, and to make other revisions. The amendments include the following, in addition to incorporating provisions from Act 278: clarify Section 604 regarding non-transferability and voidance of a Certificate of Need; add provisions to submit information related to quality of patient care as part of Section 202.2.b; streamline the program by relaxing reporting requirements and extending the period for an exemption or non-applicability determination to be valid; revise the Part A- Questionnaire; and, make other changes to R.61-15 to improve the overall quality of the regulation; such as deleting references to federal acts that are obsolete, revisions for clarity, language style, consistency, grammar, punctuation, codification and other stylistic changes. Numerous changes were made as a result of comments received from the regulated community.

A Notice of Drafting for the proposed revision was published in the *State Register* on September 24, 2010.

Revisions to the Regulation as Requested by the Senate Medical Affairs Committee by Letter Dated March 23, 2012:

Section 103.~~(10)~~9.a, b, and c: The proposed fee increases were removed and returned to the fee amounts in the current regulation.

Section 301. The proposed fee increase was removed and returned to the fee amount in the current regulation.

Section 302.1: The proposed fee increase was removed and returned to the fee amount in the current regulation.

Section 309. The proposed fee increases were removed and returned to the fee amounts in the current regulation.

Discussion of Revisions as Submitted by DHEC to the S.C. General Assembly June 1, 2011:

Revised Statutory authority under title

Table of Contents. The table was revised to reflect changes in the regulation

Section 102.1.c
Revised to write out monetary figure for consistency in regulation

Section 102.1.d
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 102.1.e
Revised to delete cost component in accordance with Act 278. Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 102.1.f
Revised to write out monetary figure for consistency in regulation

Section 102.1.g, h, i
Subitems were deleted in entirety in accordance with Act 278.

Section 102.2
Text is clarified regarding how an applicant must submit expenditures for review by the Department

Section 102.3
Clarified text by adding "Certificate of Need" and "(60) calendar" in conjunction with "sixty days"

Section 102.4
New verbiage is added as Section 102.4 to clarify change of ownership from CON review in accordance with Act 278 and to clarify that no written determination is required. No new requirement has been added.

Section 103.1
Revised to amend the definition of "affected person" to include provisions from Act 278

Section 103.2
Revised to be consistent with the South Carolina Health Plan and Regulation 61-91, Standards for Licensing Ambulatory Surgical Facilities

Section 103.6
Clarifies text to add "calendar" preceding "days"

Section 103.9
Subsection item is deleted to removed obsolete text

Section 103.10 is renumbered to 103.9
Revised to reflect increase of the initial filing fee, application fee and issuance fee. Revised to add collection of a fee for the review of exemption and non-applicability determinations

Section 103.11 is renumbered to 103.10
Revised to adjust wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 103.12 is renumbered to 103.11
Revised to renumber and revised definition in accordance with changes in Act 278

Section 103.13 is renumbered to 103.12
Revised to adjust wording to be consistent with Act 278

Section 103.14 is renumbered to 103.13
Revised to adjust wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 103.15 is renumbered to 103.14 - no text changes

Section 103.16 is renumbered to 103.15 - no text changes

Section 103.17 is renumbered to 103.16
Revised to be consistent with the definition of 'Like equipment with similar capabilities' in Act 278

Section 103.18 is renumbered to 103.17 - no text changes

Section 103.19 is renumbered to 103.18
Revised to be consistent with the definition of 'person' in Act 278

Section 103.20 is renumbered to 103.19 - no text changes

Section 103.21 is renumbered to 103.20
Revised to be consistent with the definition of 'Residential treatment facility for children and adolescents' in Act 278

Sections 22 through 25 are revised to 21-24 - no text changes

Sections 104 and Section 105
Titles amended and revised in entirety to delete all text and replace it with text consistent with changes in Act 278 in order to clarify what projects are exempt from Certificate of Need review, for which projects Certificate of Need review is not applicable, and to clarify and organize text. Revised text to reflect accurate names for the South Carolina Department of Mental Health and the South Carolina Department of Disabilities and Special Needs

Revised and renumbered text to eliminate written requirement for non-applicability determinations for certain non-medical projects, and to add a provision to provide written notification to the DHEC Division of Health Facilities Construction for these projects.

Section 106
Title amended and revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan. Corrects typographical error

Section 202.1
Corrects typographical error - corrected to add the word "inch" for clarity

Section 202.2.a.
Revised wording to include the proposal page and corrects typographical error by removing page numbers and inserting "Appendix"

Section 202.2.b(3)
Revised to clarify what type of estimate from a vendor is acceptable

Section 202.2.b(8)(l)
Revised to write out number 5 to "five"

Section 202.2.b(14)
Corrects typographical error - corrects the spelling of "effects" to "affects"

Section 202.2.b(15)
Revised to clarify that financing information must be identified

Section 202.2.b(16)
Clarifies by deletion of obsolete text and revised verbiage

Section 202.2.b(17)
Revised to clarify text regarding charges

Section 202.2.b(18)
Revised to clarify text

Section 202.2.b(21)
Revised to delete obsolete text

Section 202.2.b(22)
Revised to delete obsolete text

Section 202.2.b(27)
Adds subitem providing for submitted quality of patient care information

Section 202.2.b(27) is renumbered to 202.2.b(28)

Section 202.2.c(6)
Revised to clarify zoning for a proposed project.

Section 202.2.c(8)
Revised to correct grammatical error. Revised to add "governmental elected officials" to this subitem

Section 202.2.d(9)
Revised to be consistent with Act 278 and to clarify provisions for an unfulfilled Certificate of Need

Section 202.2.d(10)
Revised by changing "should" to "must" to ensure consistency with existing provisions in this subpart

Section 202.2.d(11)
Corrects typographical error

Section 301
Corrects typographical error and revised to reflect the increase of the filing fee.

Section 302.1
Revised to add current policy of the Department to notify the applicant in writing when the application is not acceptable for filing. Revised to write out monetary figure for consistency in regulation

Section 302.2
Revised to add "thirty (30) calendar days" through out this subitem

Section 302.3
Revised to add "thirty (30) calendar days" through out this subitem

Section 302.4
Adds subitem for extension of deadline if it falls on a weekend or state holiday in accordance with Act 278

Section 303.1
Revised to add provision for payment of fees by credit card and to reflect the clarification of the phrase "fifteen (15) calendar days"

Section 303.2
Adds subitem for extension of deadline if it falls on a weekend or state holiday in accordance with Act 278

Section 304
Revised to reflect the clarification of the phrase "thirty (30) calendar days."
Subitems added to reflect changes from Act 278 regarding reordering and changing of the project review criteria

Section 305
Revised to add changes from Act 278 regarding decision deadlines and project review criteria and to delete old text. Revised to clarify text

Section 306
Clarified text by adding "(30) calendar" in conjunction with "thirty days"

Section 307
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 308.1
Revised to delete outdated references to appeals/reconsideration process

Section 308.2
Revised to delete text

Section 309
Revised to include the increase in the issuance fee and to clarify text

Section 310
Corrects typographical error

Section 312 title amended

Section 312.1
Revised to add prohibited contact provision from Act 278

Section 312.2
Revised to reflect accurate verbiage from 2006 revision of the appeals process. Revised to clarify text

Section 401 title amended

Section 401
Revised to add text to reference law regarding appeals process and for clarification and to delete unnecessary text

Section 402
Deleted obsolete text of Section 402 and reserved section.

Section 403
Deleted Section 403 to remove obsolete text

Section 404
Deleted Section 404 to remove obsolete text

Section 501
Typographical errors are corrected in the introductory paragraph and in 501.4

Section 504
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan
Revised to add "calendar" after "days" for clarification

Section 601.1
Revised for further clarification and to reflect change of issuance period to twelve months in accordance with Act 278

Section 601.2
Revised verbiage for further clarification and to clarify the submission of quarterly progress reports.

Section 601.3
Revised to reflect change of extension period to nine months in accordance with Act 278. Revised to delete verbiage for further clarification

Section 601.4
Revised for further clarification and to reflect change of extension period to nine months in accordance with Act 278

Section 602.1
Revised for further clarification

Section 604
Revised to add and to delete text in accordance with Act 278 and to provide clarification regarding non-transferability

Section 605
Revised to correct typographical error

Section 606
Revised to clarify text and to correct typographical error

Section 607.1
Revised to clarify text and to clarify the submission of quarterly progress reports and when the first quarterly report is due.

Section 701 – renumbered as Section 702
Section is deleted to remove text in accordance with Act 278. Section renumbered and reserved.

Section 702 – renumbered as Section 701
Title is struck and removed. Text of section was revised to correct and clarify text.

Section 801.3
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 802.1
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 802.2.c
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 802.31.a
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Section 802.33
Revised wording to be consistent with Act 278 which deleted "State" and added "South Carolina" for the title of the South Carolina Health Plan

Application for Certification of Need for a Health Facility or Service
Revised format, changed title, naming it the appendix to the regulation, and revised the text of Part A – Questionnaire for further clarification

Instructions: Amend R.61-15 pursuant to each individual instruction below in the text of the regulations.

~~Indicates Matter Stricken~~
Indicates New Matter

Text:

Revise Table of Contents to read:

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

Statutory Authority: 1976 Code ~~44-4-110 through 44-7-340~~ Sections 44-7-110 et seq.

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Section 701. Penalties
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Section 802. Criteria for Project Review

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

Revise Section 102 to read:

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 million dollars ($2,000,000) 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 ~~State~~ 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 which has an annual operating cost in excess of $1,000,000~~ and for which specific standards or criteria are prescribed in the ~~State~~ 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);

~~g. The acquisition or change in ownership or in controlling interest of a health care facility or entity owning a health care facility directly or indirectly by purchase, lease, gift, donation, sale of stock, or comparable arrangement if the acquisition or change in ownership or controlling interest may result in an increase in depreciation or interest cost to the facility, or lease cost greater than depreciation and interest cost added together, or increase in government-sponsored reimbursement. If the acquisition does not~~

~~result in increased depreciation or interest cost or government-sponsored reimbursement, the facility must request an exemption in writing from the department; the facility must provide a current and projected budget which shows the impact of this transaction. The South Carolina Health and Human Services Finance Commission will be notified of any exemption or Certificate of Need issued for the change of controlling interest of a nursing home;~~

~~h. The acquisition of an existing health care facility by a person who has failed to notify the Department and seeks an exemption prior to entering into a contractual arrangement to acquire an existing facility;~~

~~i. An expenditure or financial obligation made in preparation for the offering or developing of a project which requires certification of need pursuant to this section if the expenditure or financial obligation is in excess of $4,000,000.~~

2. ~~Common practice and common sense must govern in determining what is considered to be a single expenditure.~~ An applicant ~~should~~ may not ~~be allowed to~~ split or combine ~~what is really~~ one expenditure into two or more expenditures for the purpose of avoiding Certificate of Need review~~. The~~, nor may the Department ~~should not~~ 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 Ceertificate of Nneed 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.

Revise Section 103 to read:

SECTION 103. Definitions

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~~facility organized and administered~~ 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.

6. Competing applicants means two or more persons and/or health care facilities as defined in this regulation who apply for Certificates of Need to provide similar services and/or facilities in the same service area and whose applications if approved would exceed the need for this facility or service. An application shall be considered competing if it is received by the Department no later than fifteen (15) calendar days after a Notice of Affected Persons is published in the State Register for one or more applications for similar services and/or facilities in the same service area. All applications received by the Department within fifteen (15) days of publication of the Notice of Affected Persons in the State Register for the first application(s) 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 an individual treatment plan including diagnostic treatment, individual and group counseling, family therapy, vocational and educational development counseling, and referral services.

~~9. The federal act means Title VI of the United States Public Health Service Act (the Hill-Burton Construction Program); Title XVI of the United States Public Health Service Act (National Health Planning and Resources Development Act of 1974 Public Law 93-641); grants for all center and facility construction under Public Law 91-211 (community mental health centers' amendments to Title II, Public Law 88-164, Community Mental Health Centers Act); grants for all facility construction under Public Law 91-517 (developmental disabilities services and facilities construction amendments of 1970 to Part C, Title I, grants for construction of facilities for the mentally retarded Public Law 88-164); and other federal programs as may exist or be enacted which provide for the construction of hospitals or related health facilities.~~

~~10.~~9. Fees mean the Department may charge and collect fees to cover the cost of operating the program. The fees for review of certificate of need projects include: (a) initial filing fee; (b) application fee; and (c) issuance fee.

a. Initial filing fee is five hundred dollars ($500), which must be submitted as a non-refundable initial payment at the time the application is submitted.

b. Application fee is one half of one percent (.5%, .005) of the total project cost (as defined in Section 103.25) which is payable when the application is deemed complete under Section 303. The application fee shall not exceed seven thousand dollars ($7,000).

c. Issuance fee is seven thousand five hundred dollars ($7,500) payable upon the granting of a Ceertificate of Nneed to any project whose total project cost (as defined in Section 103.25) is greater than one million four hundred thousand dollars ($1,400,000). Should the project not be approved, the issuance fee will not be assessed.

~~11.~~10. Freestanding or Mobile technology means medical equipment owned or operated by a person other than a health care facility for which the total cost is in excess of that prescribed in these regulations and for which specific standards or criteria are prescribed in the ~~State~~ South Carolina Health Plan.

~~12.~~11. Good cause is defined as:

a. presentation of significant and relevant information not previously considered by the Department;

b. demonstration that there have been significant changes in factors or circumstances relied upon by the Department in reaching its decision;

c. demonstration that the Department has materially failed to follow its adopted procedures in reaching its decision; or

d. such other basis for a public hearing as the Department determines constitutes good cause.

~~13.~~12. Health care facility for the purposes of Certificate of Need means acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, ~~tuberculosis hospitals,~~ nursing homes, ~~kidney disease treatment centers (including freestanding hemodialysis centers),~~ ambulatory surgical facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care for the mentally retarded, ~~habilitation centers for mentally retarded persons or persons with related conditions~~ inpatient hospice facilities, radiation therapy facilities and any other facility for which Certificate of Need review is required by ~~federal or~~ state law.

~~14.~~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 ~~State~~ South Carolina Health Plan.

~~15.~~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.

~~16.~~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.

~~17.~~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 ~~increase the potential volume or type of procedures possible~~ constitute a material change in service or a new service.

~~18.~~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.

~~19.~~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.

~~20.~~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.

~~21.~~20. Residential treatment facility for children and adolescents means a facility operated for the assessment, diagnosis, treatment, and care ~~by~~ of two or more ~~persons of~~ "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.

~~22.~~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 investigational device. FDA research protocol and any applicable Investigational Device Exemption (IDE) policies and regulations must be followed by a facility proposing a project 'solely for research.'

~~23.~~22. To develop when used in connection with health services, means to undertake those activities which on their completion will result in the offering of a new institutional health services or the incurring of a financial obligation in relation to the offering of such a service.

~~24.~~23. To offer when used in connection with health services means that the health care facility holds itself out as capable of providing or as having the means for the provision of, specified health services.

~~25.~~24. Total project cost is the estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect's fee, financing cost, and other capital costs properly charged under generally accepted accounting principals as a capital cost. The determination of project costs involving leased equipment of buildings will be calculated based on the total value (purchase price) of the equipment or building being leased.

Revise Section 104, Exemptions, to read:

1. If a person is required to obtain a written exemption from the Department, a letter describing the proposal should be submitted to the Bureau of Health Facilities and Services Development, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201. It should contain, at a minimum, a project description, capital and/or operational cost, location, and any other information deemed necessary in order for the Department to make a determination. If an exemption is granted, it is valid for a period of six months from the date of issuance. If the proposal is not implemented within this six-month period, the exemption becomes void and another exemption must be requested in order to undertake the proposal.

2. The following are exempt from Certificate of Need:

a. Health care facilities owned and operated by the federal government;

b. Any federal health care facility sponsored and operated by this State;

c. Educational and penal institutions maintaining infirmaries for the exclusive use of their respective student bodies and inmate populations;

d. Facilities owned and operated by the State Department of Mental Health and the South Carolina Department of Mental Retardation, except an addition of one or more beds to the total number of beds of the departments' health care facilities existing on July 1, 1988;

e. The offices of a licensed private practitioner whether for individual or group practice except as provided for in Section 102.1.f;

f. An expenditure by or on behalf of a health care facility for nonmedical projects (such as refinancing existing debt, parking garages, laundries, roof replacement, computer systems, telephone systems, and heating and air conditioning systems). Such exemptions must be obtained in writing from the Department.

g. the upgrading of medical facilities which do not involve additional square feet to the facility or additional health services. Such exemptions must be obtained in writing from the Department.

h. The replacement of like equipment with similar capabilities, or similar projects. Such exemptions must be obtained in writing from the Department.

i. Purchases of or agreements to purchase real estate; however, the costs associated with the purchase of real estate must be included in determining the total project cost at the time the real estate is proposed to be developed;

j. 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 facility; 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 research restrictions are removed;

~~k. The permanent reduction in bed capacity. The permanent closure of health care facility shall be considered in this category. A facility must obtain this exemption in writing from the Department in order that it be a valid exemption.~~

~~l. The acquisition or change in ownership which does not result in increased depreciation or interest cost or lease cost greater than depreciation and interest cost added together or government sponsored reimbursement. This exemption must be obtained in writing from the Department.~~

SECTION 104. Exemption Determinations

1. The following are exempt from Certificate of Need review, but prior to undertaking these projects, a written determination from the Department is required:

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 facility; 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 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.

Revise Section 105 to read:

~~**SECTION 105 Exemption Request**~~

~~1. In order to request an exemption, a health care facility should provide the following information in writing to the department:~~

~~a. A complete description of the proposal, including total project costs;~~

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

~~2. Additional information may be requested as may be reasonably necessary to make such exemption determination.~~

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.

2. 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, total project costs, capital and/or operational cost;

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

c. Additional information as may be reasonably necessary to make a determination.

3. If a determination of non-applicability 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 (12) month period, the non-applicability determination becomes void and another determination must be requested in order to undertake the proposal.

4. Certificate of Need review is not applicable to the following projects and a written non-applicability determination from the Department is not required prior to undertaking these projects:

a. Health care facilities owned and operated by the federal government;

b. Any federal health care facility sponsored and operated by this State;

c. Educational and penal institutions maintaining infirmaries for the exclusive use of their respective student bodies and inmate populations;

d. Facilities owned and operated by the South Carolina Department of Mental Health and the South Carolina Department of Disabilities and Special Needs, except an addition of one or more beds to the total number of beds of the departments' health care facilities existing on July 1, 1988;

5. Certificate of Need review is not applicable to the following projects and a written non-applicability determination from the Department is not required. However, written notification shall be provided to DHEC Division of Health Facilities Construction prior to undertaking the following projects:

a. An expenditure by or on behalf of a health care facility for non-medical projects, such as refinancing existing debt, parking garages, laundries, roof replacement, computer systems, telephone systems, and heating and air conditioning systems;

b. The upgrading of medical facilities, which do not involve additional square feet to the facility or additional health services;

Revise Section 106 to read:

SECTION 106. ~~State~~South Carolina Health Plan

1. With the advice of the health planning committee, the D~~d~~epartment shall prepare a ~~State~~ South Carolina Health Plan for use in the administration of the Certificate of Need Program. The plan at a minimum must include:

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 ~~State~~ 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 ~~State~~ South Carolina Health Plan.

3. Upon approval by the health planning committee, the ~~State~~ 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.

Revise Section 202 to read:

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 × 11-inch paper, one side only, and 3-hole punched on the left side.

2. Application

a. Proposal Page and Part A. Questionnaire (~~Pages 42 through 45~~See Appendix)

b. Part B. Additional Information

(1) Document that the applicant has published notification of this project in a local newspaper as required by Section 201 of these Regulations.

(2) Describe the project setting forth the proposed change in services or facilities in as much detail as possible. State whether the project will change the existing licensed or survey bed capacity, will encompass the development of a new service, or result in the discontinuance of an existing service. If a new facility is proposed, list all services to be provided.

(3) Provide the total cost of the project, indicating design fees, land cost, interest cost, construction cost, equipment cost, and any other cost involved in the project. Provide an estimate of the construction cost from a licensed architect or engineer; in the case of equipment, ~~an~~ valid/current estimate from a vendor is acceptable.

(4) State the specific location of the facility or service and/or equipment, including, where applicable, specific areas of an existing facility to be affected by the project. Provide room numbers of all patient rooms affected. Sufficient detail should be provided to allow the Department to visually inspect the site. The number of private and semi-private patient rooms shall be identified.

(5) Provide details regarding any proposed construction and/or renovations. Discuss alternatives to new construction and why these alternatives were rejected. For a multi-floor project, construction and/or renovation must be described, by floor, to include any additions and/or deletions made to each floor. Provide evidence that the applicant has adequately planned for any temporary move or relocation of any department, facility, or services, which may be necessary during the construction period. Document that plans exist to assure adequate protection (from fire, noise, dust, etc.) and continuation of all services during the proposed construction period.

(6) If a replacement facility or ancillary service is being constructed, describe plans for disposition of the existing facility or ancillary service area upon completion of the project.

(7) Provide a timetable for development and completion of the project to include, at a minimum, the date of site acquisition, date of architectural contract, architectural design schedule, date of closing for financing, date of valid construction contract, date that all necessary permits (grading, building, sewer, etc.) will be obtained, and date of start of construction. The timetable shall be presented in one month increments commencing with the month following receipt of the Certificate of Need and ending with the execution of a contract or purchase order for equipment only projects.

(8) Provide the following ownership information:

(a) Proposed name of facility;

(b) Name and address of licensee or prospective licensee. (Note: The licensee is defined as the legal entity who, or whose governing body, has the ultimate responsibility and authority for the conduct of the facility or service; the owner of the business. The licensee must be the entity to whom the Certificate of Need is issued.)

(c) Complete title of the licensee's governing body.

(d) Name, title and mailing address of presiding officer of the governing body.

(e) Name and mailing address of all persons and/or legal entities having any ownership interest or owner's equity of the licensee to include a schedule of percent and type ownership claim of each.

(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 ~~5~~ five percent or more or any person with any agreement, contract, option, arrangement, or intent to acquire ownership interest of ~~5~~ 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.

(13) Discuss any serious problems, such as costs, availability, or accessibility in obtaining care of the type proposed, experienced by patients in the absence of this project.

(14) Where a project ~~effects~~ affects an increase or decrease in bed capacity, provide annual occupancy rates for the facility based on licensed beds, for the past three years by category (i.e. general acute, psychiatric, obstetric, nursing home, etc.).

(15) Identify the method of financing the cost of the project, including the start-up costs. Provide documentation that the applicant can obtain such financing. Alternative sources and/or methods of financing ~~should~~ must be identified and the method chosen demonstrated to be the most feasible option.

(16) For an addition to an existing facility or service, provide a current annual budget and at least a three fiscal year projected budget for both the overall facility and the proposed project ~~on forms provided by the department~~. The projections must be developed by an accountant. For a new facility or service, provide a projected annual budget for not less than three fiscal years following the completion of the proposed project ~~on forms provided by the department~~. The projections must be ~~developed~~ attested to by an accountant. These budgets must at a minimum include how proposed charges, proposed cost of service, utilization, depreciation, reimbursement rates and contractual adjustments were calculated. ~~All~~ Any assumptions made in the application ~~used~~ must be specifically noted~~shown~~.

(17) ~~Document that the~~ Provide a list of proposed charges for the project. ~~that are comparable to those established by other facilities for similar services within the health service area or state.~~ The charges provided may be used for comparison with the average charges in the final completion report as required in Section 607.3.b.

(18) Document that the proposed project is economically feasible, both immediately and long-term. In the case of existing facilities, indicate what impact ~~will~~ the proposed project will have on patient charges and cost per unit of service~~?~~.

(19) State how the project will foster cost containment and improve quality of care through the promotion of such services as ambulatory and home health care, preventive health care, promotion of shared services, economies of scale, and design and construction economies.

(20) In the case of projects involving additional long-term care beds, discuss how the plans of other agencies, organizations, or programs responsible for providing and financing long-term care have been considered.

(21) Provide a three-year projected manpower budget in full-time equivalents (FTE's) detailing the existing and proposed nursing, other professional, and non-professional personnel required for the staffing of the new project. ~~Include the name of the Nurse Supervisor or Director, if available.~~

(22) Provide the number of existing and proposed medical staff by specialty, to include physicians ~~and dentists~~ employed by, or with admission privileges to, the facility. Include the name of the Chief of the Medical Staff, if available.

(23) Indicate those physicians who have expressed a willingness to utilize the proposed services or to refer patients to the facility for the provision of services.

(24) Discuss the availability of health manpower resources for the provision of the proposed services, including the contemplated program and plan for recruiting and training personnel.

(25) Describe the previous experience of the applicant in the proposed health care field. If the applicant has no prior experience, specify the anticipated sources of technical assistance, either from specific individuals or organizations.

(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.

(~~27~~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.

(3) A plot plan of the project site showing existing buildings, roads, parking areas, walks, service and entrance courts, existing utilities (electricity, telephone, water, railroads, sewer, gas, etc.) and other natural land features necessary for adequate analysis of site conditions.

(4) A legal description of the project site indicating its physical characteristics and existing easements.

(5) A square foot program of space and/or equipment elements, and scale drawings describing the existing space and proposed alterations and additions.

(6) Documentation from the appropriate zoning authorities that the proposed site is or can be zoned for the intended use. ~~Evidence that the site will be properly zoned for the proposed project.~~

(7) Documentation from appropriate sources that utilities supplied to the site are adequate for the project to include electricity, gas, water, and sewerage.

(8) Endorsement from the community that the project is desirable. This may include but is not limited to members of the medical community, citizen's groups, governmental elected officials, and other health and social service disciplines in the community.

(9) Documentation that the proposed project has been approved by the health facility's planning committee and governing body.

(10) For the facilities or services not licensed by the Department of Health and Environmental Control, provide documentation of coordination and support from the appropriate licensing agency.

d. Part D. Assurances

The applicant must furnish written assurance of each of the following where applicable:

(1) That the applicant has or will have a fee simple title or such other estate or interest in the site including necessary easements and rights-of-way, sufficient to assure use and possession for the purpose of the construction and operation of the facility.

(2) That approval by the department of the final drawings and specifications, which will be prepared by an architect and/or engineer legally registered under the laws of the State of South Carolina, will be obtained.

(3) That the applicant will submit to the Department for prior approval, changes that substantially alter the scope of work, function, utilities, major items of equipment, safety or cost of the facility during construction.

(4) That the applicant will cause the project to be completed in accordance with the Certificate of Need application.

(5) That the applicant will cause the project to be completed in accordance with approved plans and specifications by maintaining competent and adequate architectural and engineering services throughout the construction administration phase of the project. That, at the completion of the project, the architect of record shall be required to issue a statement that to the best of his knowledge and belief, based upon available records, supplemental documents, and periodic observation of the work, the project was constructed according to those documents approved by the Department.

(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 ~~without a~~ unless the Certificate of Need has been fulfilled. ~~or exemption by the Department being received by the appropriate individual.~~

(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 ~~should~~ 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 ~~services~~ 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.

Revise Section 301 to read:

CHAPTER 3 DISPOSITION OF APPLICATION

SECTION 301. Submission of Application

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 and Environmental Control, 2600 Bull Street, SC, 29201. Applicants are encouraged to involve the Ddepartment in the development of proposed projects prior to the submission of an application.

Revise Section 302 to read:

SECTION 302. Additional Information

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. The Department shall notify the applicant in writing when the application is not acceptable for filing.

2. Within thirty (30) calendar days from acceptance of an application, the Department will request any additional information pertinent to the project as may be deemed necessary to make the application complete. Should additional information be required for an application to be considered complete, the applicant will have thirty (30) calendar days from the date of the request to submit the requested information. If the applicant does not submit the requested information within thirty (30) calendar days, the application will be deemed to have been withdrawn.

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. If the information requested is not received by the Department within thirty (30) calendar days of this second request, the application will be deemed to have been withdrawn.

4. If any deadline provided for in this section falls on a weekend or State holiday, the deadline will be extended until the next calendar day that is not a weekend or State holiday.

Revise Section 303 to read:

SECTION 303. Payment of Filing and Application Fees

1. When the application is determined to be complete, the Department shall invoice the applicant, by certified mail, for the certificate of need application fee. The applicant shall have fifteen (15) calendar days from the date of receipt of the invoice to pay the fee by valid check or credit card made payable to the S.C. Department of Health and Environmental Control. Should the application fee not be received within fifteen (15) calendar days from receipt of the Department's invoice by the applicant, the application will be considered withdrawn.

2. If any deadline provided for in this section falls on a weekend or State holiday, the deadline must be extended until the next calendar day that is not a weekend or State holiday.

Revise Section 304 to read:

SECTION 304. Relative Importance Criteria

1. Upon determination by the Department that an application is complete, the Department shall notify the applicant, by certified mail, of the relative importance of the project review criteria to be used in reviewing the application. The applicant will have thirty (30) calendar days from the date of receipt of this

notice to submit any additional information. If, subsequent to this notice, the Department determines that the relative importance of the review criteria has changed, the Department must again notify the applicant 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.

Revise Section 305 to read:

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 ~~within 60 days~~ of the date of publication in the State Register unless a public hearing is held. ~~or up to 60 days from the date the applicant received the notification of the relative importance of the project review criteria. The time frame can be extended in the following cases:~~ 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. Where the applicant requests extension of the review period. The applicant may request a maximum of a 60-day extension. In the case of competing applications, all applicants must agree to the extension requested by an applicant.~~

~~b. Where the Department extends the review period. In such a case, the Department must notify the applicant in writing that the review period has been extended and the reason(s) for the extension. The Department may extend this review period for a maximum of 60 days.~~

~~Note: On any one project, only one of the above exceptions to the 60-day review period may be granted.~~

~~e~~a. ~~Where~~ If a public hearing is ~~required as described in~~ held pursuant to Section 306. ~~In this case~~, the Department will render ~~a~~ its decision no later than 150 calendar days ~~within 60 days from the date of such public hearing.~~ from the date the affected persons are notified that the application is complete.

b. [Reserved]

Revise Section 306 to read:

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.

Revise Section 307 to read:

SECTION 307. Department Review

1. The Department may not issue a Certificate of Need unless an application is in compliance with the ~~State~~ 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 ~~State~~ 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 Health 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, ~~State~~ South Carolina Health Plan, project review criteria, and any regulations developed by the Department.

Revise Section 308 to read:

SECTION 308. Department Decision

On the basis of staff review of the record established by the Department, including but not limited to, the application, comments from affected persons and other persons concerning the application, data, studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Need. ~~The proposed decision becomes the final agency decision within ten days after the receipt of a notice of the proposed decision by the applicant unless a staff reconsideration or contested case hearing is requested pursuant to Chapter 4 Appeals of this Regulation.~~

~~2. The Department's proposed decision is not final until the completion of reconsideration or contested case proceedings.~~

Revise Section 309 to read:

SECTION 309. Certificate of Need Issuance Fee

Projects with a total project cost greater than one million four hundred thousand dollars ($1,400,000) will require payment of a Ceertificate of Nneed issuance fee of seven thousand five hundred dollars ($7,500) upon the granting of the certificate of need. An invoice will be enclosed with the certificate which will be sent by certified mail. The Department must receive payment within fifteen (15) calendar days from receipt of the certificate by the applicant for the certificate of need to remain valid.

Revise Section 310 to read:

SECTION 310. Project Changes During Review Period

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

Revise Section 312 to read:

SECTION 312. Prohibited Contact ~~with the Board~~

1. 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.

2. ~~Upon~~ From the date of publication of ~~the~~ notice in the local newspaper that an application is being filed and until the date ~~a~~ final review is requested under ~~contested case hearing is requested~~ ~~pursuant to~~ Section ~~403~~401 of these regulations:

~~1~~a. members of the Board and persons appointed by the Board to hold a final review conference on staff decisions ~~hear appeals from Department staff decisions~~ may not communicate directly or indirectly with any person in connection with the application; and

~~2~~b. no person shall communicate, or cause another to communicate, as to the merits of the application with members of the Board and persons appointed by the Board to hold a final review conference on ~~hear appeals from Department~~ staff decisions.

Revise Section 401 to read:

CHAPTER 4 APPEALS

SECTION 401. Appeal ~~Notification~~ of Decision

~~On the basis of staff review of the record established by the Department, including but not limited to, the application, comments from affected persons and other persons concerning the application, data, studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Need. Notice of the proposed decision must be sent to the applicant and to affected persons who have requested to be notified. The notification must include the particular reasons for the determination. The proposed decision becomes the final agency decision ten (10) days after the receipt of the notice of the proposed decision by the applicant unless a staff reconsideration is requested or a contested case hearing before the Board is requested.~~

1. A Department decision involving the issuance, denial, or revocation of a certificate of need may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; Title 1, Chapter 23; and Title 44, Chapter 7.

2. Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; Title 1, Chapter 23; and Title 44, Chapter 7.

Delete text of Section 402 and reserve to read:

SECTION 402. [Reserved]~~Staff Reconsideration~~

~~1. Any persons showing "good cause," as defined in these regulations, may request a staff reconsideration of the Department's proposed decision. Such request must be made in writing to the department within ten (10) days from the receipt of the notice of the proposed decision by the applicant, stating the specific reasons for such request. A request for staff's reconsideration must provide documentation that "good cause" as defined in Section 103.12 applies. The burden of proof is on the moving party.~~

~~2. If "good cause" has been demonstrated, the Department's staff shall reconsider the decision on the proposed project. Notification that the staff will reconsider its decision will be sent to (1) the person making the request for reconsideration; (2) the applicant; and (3) any person upon request.~~

~~3. The Department's staff shall reconsider the project and make a decision within 30 days from the receipt of the reconsideration request. If an affected person has already requested to be notified of the Department's decision, the Department will notify him of its reconsideration decision.~~

~~4. Following the Department's reconsideration of the project, the applicant or any affected person with standing to contest the granting or denial of an application may request a contested case hearing as provided for in Section 403 of these regulations.~~

Delete Sections 403 and 404:

~~**SECTION 403. Contested Case Hearing**~~

~~1. The applicant or other affected person with standing to contest the grant or denial of an application may request a contested case hearing before the Board, or its designee, regarding the Department's decision. Such request must be made in writing to the Department within ten (10) days from the receipt of the notice of such decision. The burden of proof in a contested case hearing must be upon the moving party. The contested case hearing before the Board or its designee is conducted as a contested case under the Administrative Procedures Act. The issues considered at the contested case hearing are limited to those presented or considered during the staff review and decision-making process. Once a contested care hearing has been requested, any additional applications or appeals will not be considered competing applications.~~

~~2. The Board's decision shall become final thirty (30) days after it is mailed, unless any party who participated in the contested case hearing and is adversely affected by the Board's decision, within such thirty-day period, appeals the decision to a court of competent jurisdiction consistent with State Law.~~

~~**SECTION 404. Judicial Review**~~

~~After the contested case hearing is concluded and a final board decision is made, a party who participated in the contested case hearing and who is affected adversely by the board's decision may obtain judicial review of the decision in the circuit court pursuant to the Administrative Procedures Act.~~

Revise Section 501 introductory paragraph & 501.4; remaining items 501.2, 501.3 & 501.5 remain the same:

CHAPTER 5 GENERAL PROVISIONS

SECTION 501. Findings of the Department

In the case of any proposed new institutional health service for the provision of health services to inpatients, the Ddepartment shall not grant a Certificate of Need, or otherwise make a finding that such proposed new institutional health service is needed, unless:

4. Patients will experience serious problems in terms of costs, availability or accessibility, or such other problems as may be identified by the Ddepartment, in obtaining care of the type proposed in the absence of the project; and

Revise Section 504 to read:

SECTION 504. Review Under Applicable Plan

All decisions on Certificate of Need applications shall be made based on the currently approved ~~State~~ 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 ~~State~~ South Carolina Health Plan within forty-five (45) calendar days of the date of withdrawal, no additional filing fee shall be required.

Revise Section 601 to read:

CHAPTER 6 VOIDANCE AND EXTENSION OF CERTIFICATES OF NEED

SECTION 601. Voidance and Extension Procedures

1. The Certificate of Need shall become void ~~six~~ twelve months (one year) from the date of issuance. ~~except for projects involving construction or replacement of or major renovations or additions to an acute care hospital. For these projects the Certificate of Need is valid for one year from the date of issuance. In either case, the Certificate of Need becomes void if a valid construction contract (or appropriate purchase order for service projects) is not properly negotiated.~~ 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 ~~six~~ 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. ~~If a valid construction contract (or appropriate purchase order for service projects) is not properly negotiated after~~ After the ~~six~~ 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 ~~six~~ 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.

Revise Section 602.1 to read:

1. A Certificate of Need extension shall be requested by the applicant at least thirty (30) calendar days before the expiration date and shall contain such information as the Department may reasonably require.

Revise Section 604 to read:

SECTION 604. Non-Transferability of Certificate of Need

A Certificate of Need is nontransferable. A Certificate of Need or rights there under may not be sold, assigned, leased, transferred, mortgaged, pledged, or hypothecated, and any actual transfer or attempt to make a transfer of this sort results in the immediate voidance of the Certificate of Need. Any of the aforementioned transactions involving an entity directly or indirectly holding a Certificate of Need before fulfillment of the Certificate of Need results in the transfer and the subsequent voidance of the Certificate of Need. Fulfillment of the Certificate of Need occurs, although not limited to, the submission of an adequate final completion report as determined by the Department. Anyone having their Certificate of Need voided shall not be eligible to apply for a new Certificate for a period of one (1) year without Board approval. ~~The sale of transfer of the controlling interest or majority ownership in a corporation, partnership, or other entity holding, either directly or indirectly, a Certificate of Need, results in the transfer and voidance of a Certificate of Need.~~

~~2. Anyone having their Certificate of Need voided in this manner shall not be eligible to apply for a new Certificate for a period of one (1) year without Board approval.~~

Revise Section 605 to read:

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 Ddepartment will decide whether or not the amendment is substantial and thereby constitutes a new project.

Revise Section 606 to read:

SECTION 606. Total Project Cost ~~Maximum Capital Expenditures~~

In issuing a Certificate of Need, the Ddepartment shall specify the approved total project cost ~~maximum capital expenditure obligated under the certificate~~. A project is only approved for the amount specified in the ~~application~~ Certificate of Need. The Department will review ~~with~~ cost overruns ~~being reviewed~~ on an individual basis. ~~by the department.~~

Revise Section 607.1 to read:

SECTION 607. Periodic Reporting of Certificate of Need Implementation

1. The applicant is required to submit a ~~monthly~~ quarterly progress report that corresponds with the timetable included in the Certificate of Need application beginning ~~30~~ 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.

Revise Chapter 7--Penalties for Non-Compliance to read:

CHAPTER 7 PENALTIES FOR NON-COMPLIANCE

~~**SECTION 701. Health Services to be Offered or Developed**~~

~~Only those applications found to be needed shall be granted a Certificate of Need. Only those health services which are granted Certificates of Need shall be offered or developed within the State and no expenditure exceeding $4,000,000 shall be made in preparation for the offering or developing of a health service by or on behalf of any health care facility unless a Certificate of Need has been granted. Expenditures in preparation for the offering or development of a health service shall include expenditures for studies, surveys, designs, plans, working drawings, and specifications which are essential to the offering or development of the service. No arrangement or commitment for financing the offering or development of the health service shall be made by any person unless a Certificate of Need for such service has been granted.~~

SECTION 701. Penalties

Undertaking any activity requiring certificate of need review, as defined in Section 102 of these regulations, without prior approval of the Department or failing to comply with any of the above stated regulations ~~evidenced by the issuance of a Certificate of Need~~ shall be grounds for the denial, suspension, or revocation of the Certificate of Need ~~a license~~, or other penalties, under the provisions of Sections 44-7-320 through 44-7-340 of the Code of Laws of South Carolina, as amended. Any violation of this regulation is subject to provisions set forth in the statute.

SECTION 702. [Reserved]

Revise Section 801.3 to read:

3. A project does not have to satisfy every criterion in order to be approved, but no project may be approved unless it is consistent with the South Carolina ~~State~~ Health Plan. A project may be denied if the Department determines that the project does not sufficiently meet one or more of the criteria.

Revise Section 802.1 to read:

1. Need:
The proposal shall not be approved unless it is in compliance with the South Carolina ~~State~~Health Plan.

Revise Section 802.2.c to read:

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 ~~State~~ Health Plan should be explained.

Revise 802.31.a to read:

31. Medically Underserved Groups:

a. The applicant should address the contribution of the proposed service in meeting the health needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (e.g. low income persons, racial and ethnic minorities, women, the elderly, and handicapped persons), particularly those needs identified in the applicable ~~State~~South Carolina Health Plan as deserving of priority.

Revise 802.33 to read:

33. Elimination of Safety Hazards

The Department shall issue a Certificate of Need for a proposed capital expenditure if it is required to eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations; or to comply with State Licensure standards, or to comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State Plan for medical assistance approved under Title XIX of that Act, provided the Department has determined that the facility or service for which the capital expenditure is proposed is needed and the obligation of the capital expenditure is consistent with the ~~State~~ South Carolina Health Plan. Those portions of a proposed project which are not required to eliminate or prevent safety hazards or to comply with licensure, certification, or accreditation standards shall be reviewed against each of the applicable criteria for project review.

Revise/replace Application/Questionnaire at end of Section 802.33 and name is Appendix, to read:

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

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

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

PART A - QUESTIONNAIRE ~~(Page 1)~~
1. Name of Facility
2. Address, City, County, State, Zip Code

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)		

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

6. Licensee
A. Name of Licensee

B. Address, City, State, Zip Code

~~6.~~7. Ownership or Ceontrol of the ~~f~~Facility (~~attach~~Attach a list of names and addresses of the owners of the facility, indicating percent of ownership of each owner, the person responsible for the proposal, and the attorney(s) representing the proposal). Circle the appropriate information regarding ownership.			
A. Individual	B. Partnership	C. Corporation	D. Proprietary
E. Non-Profit	F. Government (Specify)		
G. Other: (Specify)			

~~**PART A - QUESTIONNAIRE (Page 2)**~~	
~~**7.**~~**8. ~~Is the~~ Proposed Site of the Property~~?~~**	
A. Owned	B. Leased
C. Length of Site Lease	
D. Option	E. Length of Option
F. Name and Address of Owner(s) of Real Property	

~~8.~~9. Total Bed Capacity for Which Application is Made				
	Existing Facilities			
	New Facility Only	Existing Beds	# Gained or Lost	Bed Total
Type of Beds				
A. Medical/Surgical				
B. Obstetrics				
C. Pediatrics				
D. Substance Abuse				
E. Psychiatric				
F. Rehabilitation				
G. Nursing Care				
H. ~~RTC's~~ RTFs				
I. ICU/CCU				
J. Other				

K. TOTAL				

~~PART A QUESTIONNAIRE (Page 3)~~	
~~9.~~10. Construction and Site	
A. Type of Construction	B. Number of Buildings Pertaining to Project
C. Number of Stories Pertaining to Project	D. Size of the Site in Acres
E. Size of the Project Site in Acres	~~E.~~F. Square Footage of the ~~Facility~~ Project
~~F.~~G. Anticipated Date of Beginning Construction	~~G.~~H. Anticipated Date of Licensing or Project Completion
I. Anticipated Date for Submission of Final Completion Report	

~~10.~~11. Zoning of Construction Site

~~11.~~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

Fiscal Impact Statement:

The Department estimates there will be no increased costs to the state or its political subdivisions by the revision of this regulation. See Statement of Need and Reasonableness below.

Statement of Need and Reasonableness:

(Please note that the information in this Statement was submitted to the General Assembly for review on June 1, 2011 and has not been amended pursuant to the letter dated March 23, 2012 from the Senate Medical Affairs Committee.)

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

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

Purpose: R.61-15, Certification of Need for Health Facilities and Services, is revised to incorporate applicable amendments from Act 278 of 2010 which amended Section 44-7-110 et seq., S.C. Code of Laws, 1976, as amended, effective July 1, 2010, and to make other revisions. The amendments include the following, in addition to incorporating provisions from Act 278: increase filing, application and issuance fees for certificate of need applications; clarify Section 604 regarding non-transferability and voidance of a Certificate of Need; add provisions to submit information related to quality of patient care as part of Section 202.2.b; streamline the program by relaxing reporting requirements and extending the period for an exemption or non-applicability determination to be valid; revise the Part A- Questionnaire; and, make other changes to R.61-15 to improve the overall quality of the regulation; such as deleting references to federal acts that are obsolete, revisions for clarity, language style, consistency, grammar, punctuation, codification and other stylistic changes. Numerous changes were made as a result of comments received from the regulated community.

Legal Authority: Section 44-7-110 et seq., S.C. Code of Laws, 1976, as amended (2010 Act No. 278).

Plan for Implementation: The amendments will make changes to and be incorporated into R.61-15 upon approval of the Board of Health and Environmental Control, the General Assembly, and publication in the State Register as a final regulation. The amendments will be implemented in the same manner in which the existing regulations are implemented. The Department will also provide notice of this amendment on its Regulatory Information website.

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

Act 278 of 2010 amended S.C. Code Ann. Section 44-7-110 et seq. and took effect July 1, 2010. The purpose of the amendments primarily was to clarify and streamline the Certificate of Need review process. The amendments will implement this streamlining initiative.

The amendments of Act 278 include the following: revise definitions; revise to establish and collect fees for exemption and non-applicability determinations; revise to delete the annual operating cost component requirement in Section 102.1.e; delete requirements for a certificate of need under conditions specified in Act 278; clarify projects for which certificate of need review is not applicable; clarify projects exempt from certificate of need review and which exempted projects require a written exemption; amend to add restrictions on reordering of project review criteria; amend to correct inconsistencies with current state law regarding prohibited contact; amend to add prohibited contact by elected officials; amend to revise review time periods; amend to further establish criteria to file a request for final review; amend to provide that all certificates of need are valid for one year from issuance; amend to grant extensions for nine months rather than for six months; amend to revise appeal procedures.

Other changes to the Regulations will involve modification of language to increase filing, application and issuance fees for certificate of need applications; clarify Section 604 regarding non-transferability and voidance of a Certificate of Need; add provisions to submit information related to quality of patient care as part of Section 202.2.b.; streamline the program by relaxing reporting requirements and extending the period for an exemption or non-applicability determination to be valid; revise the Part A- Questionnaire; and, make other changes to R.61-15 to improve the overall quality of the regulation, such as deleting references to federal acts that are obsolete, revisions for clarity, language style, consistency, grammar, punctuation, codification and other stylistic changes. Numerous changes were made as a result of comments received from the regulated community.

DETERMINATION OF COSTS AND BENEFITS:

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

The regulated community will be impacted with the increased fees for Certificate of Need review and the implementation of fees for written exemption determination requests and requests for determination of non-applicability. The maximum fee for a Certificate of Need has not ever been increased since being capped at $7000 for the application fee and $7500 for the issuance fee when these fees were implemented in June 1989. The filing fee has remained at $500 since being implemented in June 1989. In June 2003, the application fee was increased from .25% of the Total Project Cost to .5% of the Total Project Cost, which only affected fees for projects whose Total Project Cost was less than or equal to $1,400,000.

Section 44-7-150(5) of S.C. Code of Laws, 1976, as amended (2010 Act No. 278) authorizes the Department to charge and collect fees to cover the cost of operating the Certificate of Need program. This includes application fees, filing fees, issuance fees and non-applicability/exemption determination fees. All fees collected up to $750,000 are required to be deposited into the general fund. Certificate of Need Fees have not been increased since June 1989. Fees for the review of non-applicability and exemption determinations have never been collected, even though reviews have always been conducted. Last fiscal year, the Department was appropriated approximately half the funds needed to run the Certificate of Need Program. Increased fees and new fees are needed to cover the cost of the program.

UNCERTAINTIES OF ESTIMATES:

The revision of Regulation 61-15 will not create a burden for the public, the State or its political subdivisions.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There will be 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. However, there could be an adverse effect on the Department's ability to review applications and determinations according to time frames established in Section 44-7-210 if fees are not raised and implemented to ensure funding for adequate staffing.

Statement of Rationale:

Pursuant to the requirements of 2010 Act No. 278 the Department has promulgated these regulations to comply with the Act. Other revisions have been made since the last revision of R.61-15 became effective June 27, 2003. These amendments will increase filing, application and issuance fees for certificate of need applications; add provisions requiring the submission of information related to quality of patient care and make other changes to improve the overall quality of the regulation, such as deleting references that are obsolete, revisions for clarity, language style, consistency, grammar, punctuation, codification and other stylistic changes.