Agency Name: Department of Health and Environmental Control

Statutory Authority: 44-7-110 et seq.

Document Number: 4551

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Status: Withdrawn due to end of two-year session

Subject: Certification of Need for Health Facilities and Services

History: 4551

By Date Action Description Jt. Res. No. Expiration Date

- 12/26/2014 Proposed Reg Published in SR

- 01/29/2015 Received by Lt. Gov & Speaker 05/29/2015

H 02/03/2015 Referred to Committee

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- 06/03/2016 Withdrawn due to end of two-year session

Document No. 4551

**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 amendments to R.61-15 will support the Department’s goal of administering the Certificate of Need Program in a more efficient and cost-effective manner. To that end, the Department oversaw the development of a web-based application to replace the existing paper-based application. The computerization of the application will both simplify and speed the application submission and review process.

A Notice of Drafting for these proposed amendments was published in the *State Register* on November 28, 2014.

Section-by-Section Discussion of Amendments:

SECTION CITATION/EXPLANATION OF CHANGE:

**The Department amends R.61-15 to delete and/or rename several provisions that have been supplanted by the adoption of the web-based Certificate of Need application:**

R.61-15, revise the Table of Contents to reflect proposed changes in text.

R.61-15, delete Section 102(3) regarding the Department’s rendering of formal determination letters regarding the applicability of CON.

R.61-15, revise Section 104 (Exemption Determinations) to set forth the procedures and substance of exemption determinations that conform with the functionality of the web-based Certificate of Need (“CON”) application.

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

R.61-15, revise Section 201 (Public Notification) regarding the procedure for an applicant to affirm that notice of a new CON application was published in a newspaper in accordance with statutory requirements.

R.61-15, revise Section 202 (Application) to replace the requirements of a paper-based Certificate of Need (“CON”) application with a web-based CON application.

R.61.15, revise Section 301 (Submission of Application) to set forth new procedures regarding the payment of a non-refundable filing fee to the Department in conjunction with the filing of a web-based CON application.

R.61-15, Appendix (Application). Delete exemplar of a paper-based CON application that was supplanted by the adoption of a web-based application.

**Instructions:** Amend R.61-15 pursuant to each individual instruction provided with the text below:

~~Indicates Matter Stricken~~

Indicates New Matter

**Text:**

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

Statutory Authority: 1976 Code Sections 44-7-110 et seq.

**Revise Table of Contents to Read:**

**Table of Contents**

**CHAPTER 1--PURPOSE, APPLICABILITY AND DEFINITIONS**

Section 101. Purpose

Section 102. Applicability

Section 103. Definitions

Section 104. Exemption Determinations

~~Section 105. Determinations of Non-Applicability~~

Section 105~~106~~. South Carolina Health Plan

**CHAPTER 2--APPLICATION PROCEDURES**

Section 201. Public Notification

Section 202. Application

**CHAPTER 3--DISPOSITION OF APPLICATION, REVIEW AND DECISION**

Section 301. Submission of Application

Section 302 Additional Information

Section 303. Payment of Filing and Application Fees

Section 304. Relative Importance Criteria

Section 305. Review Time Frames

Section 306. Public Hearing

Section 307. Department Review

Section 308. Department Decision

Section 309. Certificate of Need Issuance Fee

Section 310. Project changes during Review Period

Section 311. Validity of Certificate of need issued

Section 312. Prohibited Contact

**CHAPTER 4 -- APPEALS**

Section 401. Notification of Decision

Section 402. [Reserved]

**CHAPTER 5 -- GENERAL PROVISIONS**

Section 501. Findings of the Department

Section 502. Periodic Reports

Section 503. Distribution of Procedures Criteria

Section 504. Review Under Applicable Plan

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

Section 601. Voidance and Extension procedures

Section 602. Extension Request

Section 603. Criteria for Extension

Section 604. Non-Transferability of Certificate of Need

Section 605. Project Changes After Receipt of Certificate of Need

Section 606. Total Project Cost

Section 607. Periodic Reporting of Certificate of need Implementation

**CHAPTER 7--PENALTIES FOR NON-COMPLIANCE**

Section 701. Penalties

Section 702. [Reserved]

**CHAPTER 8--PROJECT REVIEW CRITERIA**

Section 801. Applicability and Weighting

Section 802. Criteria for Project Review

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

~~QUESTIONNAIRE -- PART A~~

~~APPLICATION~~

**Revise Chapter 1, Section 102, Applicability, to read:**

***CHAPTER 1***

***PURPOSE, APPLICABILITY AND DEFINITIONS***

**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 healthcare 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. A capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the South Carolina Health Plan;

 e. If no capital expenditure is made, the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan. For purposes of this section, operating costs include expenditures incurred by the health care facility and any person or other entity on behalf of the health care facility to establish a new service. A person or other entity shall not be allowed to incur costs thereby attempting to enable a health care facility to avoid Certificate of Need review and establish a new service as described above;

 f. The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of six hundred thousand dollars ($600,000);

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

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

 3~~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 Chapter 1, Section 104, Exemption Determinations, to read:**

**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; 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.

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

 e. 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.

 f. 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.

 2. A request for an exemption shall be made using the Department’s internet website. ~~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.~~

 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;

**Delete Chapter 1, Section 105, Determinations of Non-Applicability:**

**~~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;~~

**Renumber Chapter 1, Section 105, South Carolina Health Plan, to Section 105:**

**SECTION 105~~106~~. South Carolina Health Plan**

 1. With the advice of the health planning committee, the Department shall prepare a 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 effects caused by the duplication of any existing facility, service or equipment.

 2. The South Carolina Health Plan must address and include projections and standards for specified health services and equipment which have a potential to substantially impact health care cost and accessibility. Nothing in this provision shall be construed as requiring the Department to approve any project which is inconsistent with the South Carolina Health Plan.

 3. Upon approval by the health planning committee, the South Carolina Health Plan must be submitted at least once every two years to the Board for final revision and adoption. Once adopted by the Board, the Plan may later be revised through the same planning and approval process, public review and comment, including four regional public hearings before adoption or revision of the Plan. Prior to revising the plan, the Department will publish a notice in the State Register, announcing a period for public comments and scheduling public hearings to receive public comments.

**Revise Chapter 2, Section 201, Public Notification, to read:**

***CHAPTER 2***

***APPLICATION PROCEDURES***

**SECTION 201. Public Notification.**

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

**Revise Chapter 2, Section 202, Application, to read:**

**SECTION 202. Application.**

The application required by Section 44-7-200(A) of the S.C. Code of Laws is online. An applicant shall submit an electronic Certificate of Need application as presented on the Department’s internet website.

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

 ~~2. Application~~

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

 ~~b. Part B. Additional Information~~

 ~~(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, 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 five percent or more or any person with any agreement, contract, option, arrangement, or intent to acquire ownership interest of five percent or more, of all corporations in the corporate organizational structure which have ultimate control of the licensee.~~

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

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

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

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

 ~~(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 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 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. 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. The projections must be 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. Any assumptions made in the application must be specifically noted shown.~~

 ~~(17) Provide a list of proposed charges for the project. 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 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.~~

 ~~(22) Provide the number of existing and proposed medical staff by specialty, to include physicians 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.~~

 ~~(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.~~

 ~~(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 unless the Certificate of Need has been fulfilled.~~

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

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

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

**Revise Chapter 3, Section 301, Submission of Application, to read:**

***CHAPTER 3***

***DISPOSITION OF APPLICATION***

**SECTION 301. Submission of Application**

~~Two copies of the application along with a n~~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, Columbia, SC, 29201, at the same time the online application is submitted. Applicants are encouraged to involve the Department in the development of proposed projects prior to the submission of an application.

**Delete Appendix – Application for Certification of Need, in its entirety:**

~~APPENDIX~~

~~APPLICATION FOR CERTIFICATION OF NEED~~

~~FOR A HEALTH FACILITY OR SERVICE~~

~~Proposal Prepared By:~~

~~Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

~~Organization:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

~~Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

~~City:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_State:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Zip Code:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

~~Telephone Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

~~Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Fax Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

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

~~Applicant’s Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

~~Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

~~Forward to:~~

~~Bureau of Health Facilities and Services Development~~

~~S.C. Department of Health and Environmental Control~~

~~2600 Bull Street~~

~~Columbia, S.C. 29201~~

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

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

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

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

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

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

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| **~~7. Ownership or Control of the Facility~~** ~~(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)~~  |

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| **~~8. 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~~  |

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| **~~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. RTFs~~  |
| ~~I. ICU/CCU~~  |
| ~~J. Other~~  |
| ~~K. TOTAL~~  |

|  |
| --- |
| **~~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~~  | ~~F. Square Footage of the Project~~  |
| ~~G. Anticipated Date of Beginning Construction~~  | ~~H. Anticipated Date of Licensing or Project Completion~~  |
| ~~I. Anticipated Date for Submission of Final Completion Report~~  |

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| **~~11. Zoning of Construction Site~~**  |

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

**Fiscal Impact Statement:**

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

**Statement of Need and Reasonableness:**

This Statement of Need and Reasonableness and Rationale was determined by staff analysis pursuant to S.C. Code Sections 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION:

Purpose: The amendments to R.61-15 will support the Department’s goal of administering the Certificate of Need Program in a more efficient and cost-effective manner. To that end, the Department oversaw the development of a web-based application to replace the existing paper-based application. The computerization of the application will both simplify and speed the application submission and review process.

Legal Authority: The legal authority for R.61-15 is S.C. Code Section 44-7-150(3).

Plan for Implementation: The amendments will take effect upon approval by the S.C. General Assembly, and publication in the *State Register*. An electronic copy of R.61-15, that includes these latest amendments, will be published on the Department’s Regulation Development website at: <http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/>. At this site, click on the Health Regulations category and scan down to R.61-15. Subsequently, this regulation will be published on the S.C. Legislature website in the S.C. Code of Regulations. Printed copies will be made available at cost by request through the DHEC Freedom of Information Office. The Department will also send an email to stakeholders and affected facilities and to other interested parties.

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

1. The Department amended portions of R.61-15 to facilitate the transition from a paper-based to a web-based Certificate of Need application.

2. The Department has amended R.61-15 to delete Section 102(3) regarding the Department’s rendering of formal determination letters.

3. The Department has amended R.61-15 to revise Section 104 (Exemption Determinations) to set forth the procedures and substance of exemption determinations that conform to the functionality of the web-based Certificate of Need (“CON”) application.

4. The Department has amended R.61-15 to delete Section 105 (Determinations of Non-Applicability) which is unnecessarily duplicative of statutory language or otherwise addressed in Section 104.

5. The Department has amended R.61-15 to revise Section 201 (Public Notification) regarding the procedure for an applicant to affirm that notice of a new CON application was published in a newspaper in accordance with statutory requirements.

6. The Department has amended R.61-15 to revise Section 202 (Application) to replace the requirements of a paper-based Certificate of Need (“CON”) application with a web-based CON application.

7. The Department has amended R.61-15 to revise Section 301 (Submission of Application) to set forth new procedures regarding the payment of a non-refundable filing fee to the Department in conjunction with the filing of a web-based CON application.

8. The Department has amended R.61-15 to delete the Appendix (Application) to remove the exemplar of a paper-based CON application that was supplanted by the adoption of a web-based application.

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

DETERMINATION OF COSTS AND BENEFITS:

The Department estimates the net cost to the Department resulting from this regulation revision to be approximately $79,000 annually, which will be associated with the cost of maintaining the web-based application. The benefit to the regulated community of the amendments to R.61-15 will include utilization of an efficient web-based Certificate of Need application and simplification of the processes for interacting with the Department during a Certificate of Need application review. The cost of the proposed regulation will be offset by the benefit to the Department and to the regulated community of utilizing an efficient web-based Certificate of Need application that will utilize standardized requests for information that will require less time to prepare and submit, will minimize costs associated with the prior application format, and will allow decisions to be made approximately four (4) months faster than with a paper-based system. The revised regulation will allow the regulated community to spend less time preparing and submitting Certificate of Need applications and other requests to the Department, and will allow the Department to conduct more efficient and timely reviews of Certificate of Need applications and other requests.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties in the estimates to the costs to the State or its political subdivisions beyond those normally inherent in estimating future costs.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The revisions of R.61-15 seek to enable the Department to more effectively fulfill the statutory purposes of the Certificate of Need program, which will benefit both the regulated community and the citizens of this State.

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

It may be detrimental to the regulated community and the public health if these revisions to R.61-15 are not implemented. Failure to implement these provisions would stand in the way of improvement of efficiency and effectiveness of the Certificate of Need process. Additionally, the Department’s authority to implement programs in conformance with State law, which are beneficial to public health and the environment, may be compromised if these amendments are not adopted in South Carolina. Application streamlining as well as regulatory text simplification and clarification should have a positive effect on public health and the public’s access to certain health care facilities and services.

**Statement of Rationale:**

R.61-15 contains the requirements for the State’s Certification of Need for Health Facilities and Services program. The regulation is promulgated pursuant to the State Certification of Need and Health Facility Licensure Act, S.C. Code Section 44-7-110, *et seq*. The Certificate of Need program promotes cost containment, prevents unnecessary duplication of health care facilities and services, guides the establishment of health facilities and services which will best serve public needs, and ensures that high quality services are provided in the State’s health facilities. Recent changes in the health care industry require the modernization of the Certificate of Need program. By simplifying the Department’s procedures and moving the application process to the web, the revised regulation will allow the Department to realize these goals in a more expeditious and efficient manner. The revisions will allow Certificate of Need applications to be prepared and filed with the Department more quickly than possible with a paper-based application system.