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Document No. 5136
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-340

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

Preamble:

Pursuant to S.C. Code Sections 44-7-110 et seq., the Department of Health and Environmental Control (“Department”) is required to adopt substantive and procedural regulations considered necessary by the Department and approved by the S.C. Board of Health and Environmental Control (“Board”) to carry out the Department’s Certificate of Need duties. The Department proposes amending R.61-15 for consistency with statutory requirements, to establish an electronic application process, to revise the application format and additional information required for the application process, and update exemption and non-applicability determination processes. The Department also proposes adding, removing, and modifying definitions contained within the regulation. The Department may update language and processes related to public hearings on Certificate of Need applications, the application and review process and related notifications, voidance and extension procedures, and periodic and final reporting requirements regarding issued Certificates of Need. Additionally, the proposed amendments may revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review. The proposed amendments may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the June 24, 2022, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments:

Section	Type of Change	Purpose
Entire Regulation	Technical Correction	Amended each instance of “these regulations” to “this regulation” for clarity and consistency.
Table of Contents	Technical Correction Reorganization	Amended language and sections to reflect technical corrections and reorganization proposed in regulation text.
Chapter 1 Title	Revision	Amended language to reflect reorganization made in regulation text.
101. Purpose.	Revision	Amended to add the word “care” to make the terminology consistent throughout the regulation.
Former 102. Applicability.	Revision	Recodified this section for clarity. Amended to increase the threshold amounts consistent with LAC and recommendation and language from prior legislation.

Section	Type of Change	Purpose
New 102. Definitions. (Former 103)		
Affected Persons	Technical Correction Reorganization	Amended to reformat the definition and move part of the definition to Section 402.
Competing Applicants	Technical Correction Reorganization	Amended to reformat the definition.
Fees	Technical Correction Deletion	Amended to reformat the definition and delete the language that is clarified in other sections of the regulation.
Health Care Facility	Revision Technical Correction	Amended to reformat the definition and to revise language to reflect the statutory definition.
Health Service	Revision Technical Correction	Amended to reformat the definition and to revise language to reflect the State Health Plan definition.
Total Project Cost	Technical Correction	Amended to reformat the definition and to correct grammatical error.
Board Department Like Equipment with Similar Capabilities Person Solely for Research To Develop When Used in Connection With Health Services To Offer When Used in Connection With Health Services	Technical Correction	Amended to reformat these definitions for readability.
Ambulatory Surgical Facility Arrangement for Financing Children and Adolescents in Need of Mental Health Treatment in a Residential Facility	Deletion	Deleted these definitions because they are otherwise defined in the Certification of Need and Health Facility Licensure Act.

Section	Type of Change	Purpose
Facility for Chemically Dependent or Addicted Persons Freestanding or Mobile Technology Hospital Institutional Health Services Nursing Home Psychiatric Hospital Residential Treatment Facility for Children and Adolescents		
Good Cause	Deletion	Deleted because it is no longer defined in statute.
Controlling Interest Indigent Care Majority Ownership Non-Capital Cost	Addition	Added definitions to clarify their meaning in the context of this regulation for the regulated community.
New 103. Applicability. (Former 102)	Reorganization	Recodified this section from 102 to 103 for clarity.
103.1.c.	Revision	Amended to increase the threshold amounts consistent with the LAC recommendation and language from prior legislation.
103.1.d.	Technical Correction	Amended to add the word “a” to make it consistent with statutory language.
103.1.e.	Revision	Amended to remove language that is no longer needed in regulation.
103.1.f.	Revision Technical Correction	Amended to increase the threshold amounts consistent with the LAC recommendation and language of prior legislation.
103.3.	Revision Technical Correction	Amended to add a word for consistency with statute and amended to remove language that is no longer needed in regulation. Further amended for clarification.

Section	Type of Change	Purpose
104. Exemption Determinations.		
104.1.a.	Technical Correction	Amended for consistency.
104.1.b.	Technical Correction	Amended for consistency.
104.1.c.	Revision	Amended to add language clarifying the requirements for an exemption.
104.2	Technical Correction	Amended for consistency.
104.3.	Revision	Amended to change timeframe from 12 months to 18 months to allow applicants more time for project implementation and further amended for clarity and consistency.
104.4.	Revision Technical Correction	Amended to increase threshold amounts, to add a word for clarification, and to update the regulation section numbers referenced therein.
105. Determinations of Non-Applicability.		
105.1.a.	Revision	Amended to update section number references.
105.1.b.	Revision	Amended to increase threshold amounts and to clarify and simplify language in line with LAC recommendation.
105.2	Technical Change	Amended for consistency.
105.3.	Revision	Amended to change timeframe from 12 months to 18 months to allow applicants more time for project implementation. Amended to change the word “proposal” to “project” for consistency.
105.4	Technical Change	Amended for consistency.
105.5.	Revision	Amended to change a particular division of the Department (“DHEC Division of Health Facilities Construction”) to the “Department” for clarity and consistency.
105.5.b.	Technical Correction	Amended to change semicolon to period.
106. South Carolina Health Plan.	Technical Correction	Amended to correct punctuation and number formatting.
201. Public Notification.	Reorganization Technical Correction	Recodified the section for consistency.

Section	Type of Change	Purpose
202. Application.	Deletion	Amended to remove language that is no longer needed in regulation.
301. Submission of Application.	Revision	Amended to further streamline the application process, to clarify when the filing fee must be submitted, and to update the name of the Department's Bureau responsible for administering the CON program.
302. Additional Information.		
Former 302.1.	Deletion	Amended to remove language that is no longer needed in regulation.
New 302.1.	Revision Reorganization	Amended to add clarifying language and to recodify the section.
New 302.2.	Revision Reorganization	Amended to add clarifying language and to recodify the section.
New 302.3	Reorganization	Recodified the section.
303. Payment of Filing and Application Fees.		
303.1.	Technical Correction	Amended to correct capitalization and grammar.
New 303.2.	Reorganization	Amended to move language from the Definitions section regarding fee clarification.
New 303.3. (Former 303.2)	Technical Correction Reorganization	Recodified the section and corrected grammar for consistency.
304. Relative Importance Criteria.		
304.2.	Revision	Amended to clarify review period.
305. Review Time Frames.		
305.1.	Revision	Amended to remove language that is no longer needed in regulation.
305.2.	Revision Reorganization	Amended to add language from former Section 305.2.a., to add language allowing for electronic notifications, and to correct grammar due to added language.
305.2.a. and b.	Reorganization Deletion	Moved language from 305.2.a to 305.2 for clarity and deleted 305.2.b because the language is no longer needed in regulation.

Section	Type of Change	Purpose
306. Public Hearing.	Technical Correction	Amended for corrected grammar and consistency.
307. Department Review.	Revision	Amended to clarify Department review
New 308. Certificate of Need Issuance Fee. (Former 309)	Reorganization Revision	Recodified Section 309 to former Section 308, added clarifying language, and amended to remove language that is no longer needed in regulation.
New 309. Project Changes During Review Period. (Former 308)	Revision Reorganization	Amended to add clarifying language and recodified the section.
New 310. Validity of Certificate of Need Issued. (Former 311)	Reorganization Technical Correction	Recodified the section, and corrected punctuation and capitalization.
New 311. Prohibited Contact. (Former 312)	Reorganization	Recodified the section.
401. Appeals.		
401.1.	Revision Technical Correction	Amended to clarify who may appeal a decision and to correct capitalization for consistency.
401.2	Revision	Amended to clarify who may file a request for final review in opposition to the staff decision on a Certificate of Need.
402. [Reserved]	Deletion	Section no longer needed in the regulation.
501. Findings of the Department.	Deletion	Amended to remove language that is no longer needed in regulation.
New 501. Periodic Reports. (Former 502)	Reorganization	Recodified Section 502 to Section 501.
503. Distribution of Procedures Criteria.	Deletion	Amended to remove language that is no longer needed in regulation.
New 502. Review Under Applicable Plan. (Former 504)	Reorganization	Recodified Section 504 to Section 502.
601. Voidance and Extension of Certificates of Need.	Revision Technical Correction	Amended to add language to clarify the voidance (matter of law) and to delete the inconsistent language. Amended to correct grammar and number formatting.
602. Extension Request.	Revision	Amended extension request submission requirements for clarity.

Section	Type of Change	Purpose
603. Criteria for Extension.	Technical Correction	Amended to correct capitalization.
604. Non-Transferability of Certificate of Need.	Revision Technical Correction	Amended to clarify controlling interest and majority ownership, to remove language not consistent with statute, and to correct grammar.
605. Project Changes After Receipt of Certificate of Need.	Technical Correction	Amended to correct grammar.
607. Periodic Reporting of Certificate of Need Implementation.		
607.1	Technical Correction	Amended to correct grammar.
607.3	Technical Correction Addition	Amended to correct punctuation, and to add “a listing of non-capital costs” to the requirements for the final completion report as recommended by the LAC.
701. Penalties.	Revision Technical Correction	Amended to clarify language, remove duplicative language, and to correct grammar.
702. Reserved.	Deletion	Deleted this section because it is not needed in the regulation.
801. Applicability and Weighting.	Revision Technical Correction	Amended to correct references to amended sections. Amended to correct number formatting.
802. Criteria for Project Review.		
802.2.b.	Revision	Amended to correct state agency reference.
802.3.	Revision Reorganization Technical Correction	Amended to remove language that is no longer needed in regulation, corrected punctuation, and recodified items.
802.4.d through 802.12	Reorganization	Recodified these sections to new Section 802.7. based on public comments.
New 802.5. (Former 802.13)	Reorganization Technical Correction	Recodified former Section 802.13 to 802.5, and corrected grammar and punctuation.
New 802.6. (Former 802.14)	Reorganization	Recodified former Section 802.15 to 802.6.
New 802.7.a. through e. (Former 802.15-16)	Reorganization	Amended to combine former Sections 802.15 and 802.16 and recodify to 802.7.a through e based on public comments.

Section	Type of Change	Purpose
New 802.8 (Former 802.17)	Reorganization Technical Correction	Recodified former Section 802.17 to 802.8 and corrected punctuation.
802.18.	Deletion	Deleted language because it is in the application requirements.
New 802.10 (Former 802.20)	Reorganization Revision	Recodified former Section 802.20 to 802.10 and amended language for clarity, consistency, and accuracy.
New 802.11 (Former 802.21)	Reorganization Technical Correction	Recodified former Section 802.21 to 802.10 and corrected punctuation.
New 802.12-13 (Former 802.22-23)	Reorganization	Recodified former Sections 802.22-23 to 802.12-13.
New 802.13 (Former 802.24-25)	Reorganization	Combined former Sections 802.24-25 and recodified as new Section 802.13.
New 802.14 (Former 802.26 and 29)	Reorganization Addition	Combined former Section 802.26 and 802.29 and recodified as new Section 802.14. Changed subsection title to “Zoning and Site Suitability.”
802.27	Deletion	Amended to remove language that is no longer needed in regulation.
New 802.15 (Former 802.28)	Reorganization	Recodified former Section 802.28 to new Section 802.15.
802.30	Deletion	Deleted language because it is provided on the CON application.
New 802.16 (Former 802.31)	Reorganization Technical Correction	Recodified former Section 802.31 to new Section 802.16 and corrected for punctuation.
802.32	Deletion	Deleted language because it is provided on the CON application.
New 802.17 (Former 802.33)	Reorganization	Recodified former Section 802.33 to new Section 802.17.
New 802.18	Addition	Added quantitative quality of care metrics to the project review criteria to align with LAC recommendation.
Appendix	Deletion	Deleted Appendix to streamline the application and to align the regulation for implementation of electronic application process.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to the Office of Policy and Communications; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Public Comment Form at <https://forms.office.com/g/9VMEXLWtq0>. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 24, 2022, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 8, 2022, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: <http://www.scdhec.gov/Agenda>. Public hearing procedures are subject to change in response to COVID-19 protocols. If applicable, the Department will provide notice of these changes twenty-four (24) hours in advance of the public hearing.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>.

Preliminary Fiscal Impact Statement:

The Department does not anticipate the implementation of this regulation will require any additional resources. There is no anticipated additional cost to the Department or state due to any inherent requirements of this regulation. There are no external costs anticipated.

Statement of Need and Reasonableness:

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

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

Purpose: The Department proposes to amend R.61-15, Certification of Need for Health Facilities and Services, for consistency with statutory requirements, to establish an electronic application process, to revise the application format and additional information required for the application process, and update exemption and non-applicability determination processes. The Department also proposes adding, removing, and modifying definitions contained within the regulation. The Department may update language and processes related to public hearings on Certificate of Need applications, the application and review process and related notifications, voidance and extension procedures, and periodic and final reporting requirements regarding issued Certificates of Need. Additionally, the proposed amendments may also revise the project review criteria and the monetary thresholds that trigger a Certificate of Need review. The proposed amendments may also include corrections for clarity and readability, grammar, punctuation, codification, and other such regulatory text improvements.

Legal Authority: 1976 Code Sections 44-7-110 through 44-7-340.

Plan for Implementation: The amendments will take legal effect upon General Assembly approval and upon publication in the State Register. Department personnel will then take appropriate steps to inform the

regulated community of the amendments. Additionally, a copy of the regulation will be posted on the Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, for a fee, from the Department's Freedom of Information Office.

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

R.61-15 has not been substantively revised since 2003 and needs to be updated to reflect current technology and industry standards. In February 2022, the Legislative Audit Council (LAC) issued *A Review of the S.C. Department of Health and Environmental Control Certificate of Need Program*, wherein the LAC provided a list of recommendations for the Certificate of Need program. The Department's Agency Response to the LAC report indicated initiating the promulgation process in 2022 to address the recommendations through regulatory revisions.

The LAC recommendations that the Department is addressing in this proposed revision include standardizing the information required for Certificate of Need applicants to ensure consistency in its evaluation process, requiring Certificate of Need applicants to provide information on net patient charges when project impact on patient charges is a factor in the evaluation process; requiring Certificate of Need applicants to report on non-capital expenses related to a project; and increasing the thresholds for equipment and capital expenditures for the Certificate of Need program and provide the adjustment of those thresholds pursuant to the Medical Care Index component of the Consumer Price Index.

The Department's proposed amendments are in line with the abovementioned LAC recommendations, and additionally include moving to a more streamlined and modernized application format and process, increasing the timeframes for the exemption and non-applicability determinations from 12 months to 18 months, and streamlining and consolidating the project review criteria from 33 criteria to 17 criteria. Overall, the Department's proposed amendments aim to increase flexibility and minimize the undue burden to the regulated community.

DETERMINATION OF COSTS AND BENEFITS:

The Department anticipates the proposed amendments will decrease costs and increase benefits to the regulated community by improving the application process and increasing the monetary thresholds that trigger Certificate of Need review. The Department anticipates the proposed amendments will decrease the costs necessary to maintain the current Certificate of Need application and review processes. The Department anticipates the benefits will include increased time and resources to process and review Certificate of Need applications. The proposed amendments remove the requirement that Certificate of Need applications be submitted as paper applications and allow the Department to move towards implementation of an electronic application process.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties associated with the estimations beyond those normally inherent in estimating future costs and benefits.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments to R.61-15 seek to improve the Certificate of Need application and review processes involved in determining whether there is need for, among other items, construction or other establishment of a new health care facility. This supports the Department's mission to improve the quality of life for all South Carolinians by protecting and promoting the health of the public and the environment.

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

It may be detrimental to the regulated community and public health if the proposed amendments to R.61-15 are not implemented because the Certificate of Need application process will continue to require the submission of paper copies and limit the Department's ability to modernize and improve efficiencies in the process required prior to undertaking, among other items, the construction or other establishment of a new health care facility. This is detrimental to the accessibility of the Certificate of Need application process as well as to the new health care facility. There is no anticipated detrimental effect on the environment if the proposed amendments are not implemented.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

R.61-15, Certification of Need for Health Facilities and Services, provides substantive and procedural regulations necessary to carry out the Department's Certificate of Need duties. The Department proposes amendments to address the recommendations from the Legislative Audit Council's February 2022, report, *A Review of the S.C. Department of Health and Environmental Control Certificate of Need Program*, that are within the Department's authority to implement through regulatory change, to bring the regulation into alignment with statutory requirements, and to improve Department processes.

~~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 through 44-7-340

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CHAPTER 1
PURPOSE, APPLICABILITY AND DEFINITIONS, AND APPLICABILITY

SECTION 101. Purpose.

The purpose of ~~these~~this Regulations is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health care facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State.

~~SECTION 102. Applicability.~~

~~1. 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 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 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.~~

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

SECTION ~~103~~102. Definitions.

~~1. Affected person means the~~**Affected Person.** ~~The applicant, a person residing within the geographic area served or to be served by the applicant, persons located in the health service area in which the project is to be located and who provide similar services to the proposed project, persons who before receipt by the Department of the proposal being reviewed have formally indicated an intention to provide similar services in the future, persons who pay for health services in the health service area in which the project is to be located and who have notified the Department in writing of their interest in Certificate of Need applications, the State Consumer Advocate and the State Ombudsman. Persons from another state who would otherwise be considered "affected persons" are not included unless that state provides for similar involvement of persons from South Carolina in its Certificate of Need process. A person may not file a request for final review in opposition to the staff decision on a Certificate of Need unless the person provided written notice to the Department during the staff review that he is an affected person and specifically states his opposition to the application under review. Affected persons may request in writing to be notified of a Department decision by regular mail or electronic mail in lieu of certified mail.~~

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

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

~~4. Board means the~~**2. Board.** ~~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~~**3. Competing Applicants.** ~~Two (2) 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 type 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).

4. **Controlling Interest.** Ownership interest in a company (corporation, limited liability company, partnership, or other entity) with enough voting shares or other interests to prevail in any motion. A majority of voting shares or interests is always a controlling interest.

~~7. Department means the~~ 5. **Department.** The S.C. 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. Fees mean the~~ 6. **Fees.** The Department may charge and collect fees to cover the cost of operating the program. The fees for review of eCertificate of nNeed 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 Certificate of Need 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.~~

~~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 South Carolina Health Plan.~~

~~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.~~

~~12. Health care facility for the purposes of Certificate of Need means acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care for the persons with intellectual disability, inpatient hospice facilities, radiation therapy facilities and any other facility for which Certificate of Need review is required by state law.~~ 7. **Health Care Facility.** Acute care

hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, hospice facilities, radiation therapy facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care facilities for persons with intellectual disability, narcotic (opioid) treatment programs, and any other facility for which Certificate of Need review is required by law.

~~13. Health service means clinically~~**8. Health Service.** Clinically related, diagnostic, treatment, or rehabilitative services, and includes alcohol, drug abuse, and mental health services for which specific standards or criteria are prescribed in the South Carolina Health Plan.

9. Indigent Care. Care provided to persons who do not have health insurance and who are not eligible for other health care such as Medicare, Medicaid, or private health insurance. 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.

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

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

~~16. Like equipment with similar capabilities means~~**10. Like Equipment with Similar Capabilities.** A medical equipment in which functional and technological capabilities are identical to the equipment to be replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and does not constitute a material change in service or a new service.

11. Majority Ownership. Ownership of more than 50% of the capital stock, limited liability company interests, partnership units, or other equity or ownership interests of a company.

12. Non-Capital Cost. Operating costs incurred that relate directly to the current project's implementation excluding exploration costs and capital costs. These costs shall include, but are not limited to, staff time, consultant fees, and legal/litigation costs, to the extent incurred.

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

~~18. Person means an~~**13. Person.** An individual, a trust or estate, a partnership, a corporation including an association, joint stock company, insurance company, and a health maintenance organization, a health care facility, a state, a political subdivision, or an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.

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

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

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

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

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

~~21. Solely for research means a~~**14. Solely for Research.** A service, procedure, or equipment which has not been approved by the U.S. 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.”²

~~22. To develop when used in connection with health services, means to~~**15. To Develop When Used in Connection With Health Services.** 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.

~~23. To offer when used in connection with health services means that the~~**16. To Offer When Used in Connection With Health Services.** The health care facility holds itself out as capable of providing or as having the means for the provision of, specified health services.

~~24. Total project cost is the~~**17. Total Project Cost.** The estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect’s fees, consultant fees, financing costs, and other capital costs properly charged under generally accepted accounting principles 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.

SECTION 103. Applicability.

1. A person or health care facility as defined in this regulation is required to obtain a Certificate of Need from the Department 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 (1) or more beds, or change in the classification of licensure of one (1) or more beds;

c. An expenditure by or on behalf of a health care facility in excess of five million dollars (\$5,000,000) which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure except those expenditures exempted in Section 104. Starting July 1, 2025, and every fifth year thereafter, the Department must determine the increase or decrease in the ratio of the Consumer Price Index for all urban consumers (CPI-U), Medical Care Commodities in the US City Average, for the prior five (5)- year period published by the United States Department of Labor; the dollar threshold for expenditures by or on behalf of a health care facility pursuant to this item shall be adjusted accordingly, except that the dollar amount shall never be adjusted below five million dollars (\$5,000,000). The first adjustment shall be made on July 1, 2025, and subsequent adjustments shall be made every fifth year on July 1, or if July 1 is

a Saturday or Sunday, the next non-holiday business day following July 1. The Department shall post notice of the adjustments on its website, and the adjusted amount shall become effective as of the date of the posting on the Department's website. 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 that 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 that has not been offered by the facility in the preceding twelve (12) months and for which specific standards or criteria are prescribed in the South Carolina Health Plan; or

f. The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of two million dollars (\$2,000,000). Starting July 1, 2025, and every fifth year thereafter, the Department must determine the increase or decrease in the ratio of the Consumer Price Index for all urban consumers (CPI-U), Medical Care Commodities in the US City Average, for the prior five (5)- year period published by the United States Department of Labor; the dollar threshold for total project cost for the acquisition of medical equipment to be used for diagnosis or treatment pursuant to this item shall be adjusted accordingly, except that the dollar amount shall never be adjusted below two million dollars (\$2,000,000). The first adjustment shall be made on July 1, 2025, and subsequent adjustments shall be made every fifth year on July 1, or if July 1 is a Saturday or Sunday, the next non-holiday business day following July 1. The Department shall post notice of the adjustments on its website, and the adjusted amount shall become effective as of the date of the posting on the Department's website.

2. An applicant may not split or combine one (1) expenditure into two (2) or more expenditures for the purpose of avoiding Certificate of Need review, nor may the Department be allowed to combine projects together arbitrarily to bring them under Certificate of Need review.

3. A potential applicant may submit a written request to the Department for a formal determination as to the applicability of the Certificate of Need requirements for a particular project. Such a request shall contain a detailed description of the project, including the extent of modifications, changes in services, and total project costs. Additional information may be requested as may be reasonably necessary to make such applicability determination.

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 Certificate of Need 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 that have previously undergone Certificate of Need review, the Certificate of Need must be fulfilled prior to a change of ownership.

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 ~~the~~ Department in order for the ~~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; or

c. The permanent reduction in bed capacity, including the permanent closure of a health care facility, or reduction or permanent termination of any health service that has not been offered by the health care facility in the preceding twelve (12) months and for which specific standards or criteria are prescribed in the South Carolina Health Plan.

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~~ this regulations; and

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~~ eighteen (12/18) months from the date of issuance. If the ~~proposal~~ exempted project is not implemented within this ~~twelve~~ eighteen-month period, the exemption becomes void and another exemption must be requested in order for the applicant to undertake the ~~proposal~~ project. If no evidence of implementation is submitted within eighteen (18) months of issuance, a new exemption request must be submitted to the Department for review.

4. The following projects are exempt from Certificate of Need review ~~but~~ and do not require a written determination from the Department: the offices of a licensed private practitioner whether for individual or group practice. This exemption shall not apply to: (1) the construction or other establishment of a new health care facility, as in Section ~~402~~ 103.1.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~~ two million dollars (~~\$600,000~~ \$2,000,000) or adjusted, as in Section ~~402~~ 103.1.f.

SECTION 105. Determinations of Non-Applicability.

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

a. Replacement of like equipment with similar capabilities as defined by the Department in Section ~~403.16~~ 102; or

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~~ two million dollars (\$~~600,000~~2,000,000) or adjusted, as in Section 103.1.f.

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~~this regulations; and

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

3. If a determination of non-applicability is granted pursuant to Section 105.1, it is valid for a period of ~~twelve~~eighteen (~~12~~18) months from the date of issuance. If the ~~proposal~~project is not implemented within this ~~twelve~~eighteen (~~12~~18) month period, the non-applicability determination becomes void and another determination must be requested in order to undertake the ~~proposal~~project. If no evidence of implementation is submitted within eighteen (18) months of issuance, a new non-applicability request must be submitted to the Department for review.

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; or

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 (1) 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~~the Department 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; or

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

SECTION 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 affects caused by the duplication of any existing facility, service, or equipment.

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

3. Upon approval by the health planning committee, the South Carolina Health Plan must be submitted at least once every two (2) 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 (4) regional public hearings before adoption or revision of the Plan. Prior to revising the plan, the Department will publish a notice in the State Register, announcing a period for public comments and scheduling public hearings to receive public comments.

CHAPTER 2

APPLICATION PROCEDURES

SECTION 201. Public Notification.

1. Within twenty (20) calendar 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 (3) consecutive days. The notification must contain at least the following information:

- 1)a. that a Certificate of Need is being applied for;
- 2)b. a description of the scope and nature of the project; and
- 3)c. the estimated project capital cost.

2. No application may be accepted for filing by the Department unless accompanied by documentation from the newspaper that publication has been made for three (3) consecutive days within the prior twenty (20) day period.

SECTION 202. Application.

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

2. Application

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

b. Part B. Additional Information

(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.~~

~~(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.~~

CHAPTER 3 DISPOSITION OF APPLICATION

SECTION 301. Submission of Application.

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

~~Two copies of the application along with a~~ 2. A non-refundable filing fee of five hundred dollars (\$500) shall be forwarded to received by the Bureau of Health Facilities and Services Development Planning and Construction, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC, 29201, within twenty (20) calendar days of the public notification pursuant to Section 201 and the Certificate of Need application pursuant to Section 301.1.

3. Applicants are encouraged to involve the Department in the development of proposed projects prior to the submission of an application.

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.~~

21. Within thirty (30) calendar days from acceptance of an application, the Department ~~will~~may 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.

32. 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.

43. 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.

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 ~~e~~Certificate of n~~eed~~ 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 from the applicant within fifteen (15) calendar days from receipt of the Department's invoice ~~by the applicant~~, the application will be considered withdrawn.

2. The application fee is one half of one percent (.5%, .005) of the total project cost (as defined in Section 102), which is payable when the application is deemed complete. The application fee shall not exceed seven thousand dollars (\$7,000).

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

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 (1) time ~~during the review period~~. The staff's reordering of the relative importance of the project review criteria does not extend the review period.

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

SECTION 305. Review Time Frames.

1. Upon determination by the Department that the application is complete, ~~and receipt of the application fee,~~ the Department shall publish in the State Register a notice that the review cycle for the project has begun. Any affected person who has notified the Department in writing that they desire to be notified of the beginning of the review period will 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 one hundred twenty (120) calendar days of the date of publication in the State Register unless a public hearing is held. If a public hearing is held pursuant to Section 306, the Department will render its decision no later than one hundred fifty (150) calendar days from the date the affected persons are notified that the application is complete. 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. Affected persons may request in writing to be notified by regular mail or electronic mail in lieu of certified mail.

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

~~b. [Reserved]~~

SECTION 306. Public Hearing.

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

SECTION 307. Department Review.

1. The Department may not issue a Certificate of Need unless an application is in compliance with the South Carolina Health Plan as described in this regulation, project review criteria, and other provisions in this regulations which must be identified by the Department. The Department may refuse to issue a Certificate of Need even if an application is in compliance with the South Carolina Health Plan but is inconsistent with project review criteria or ~~departmental~~ other provisions in this regulations. The Department must identify any provisions in this regulation that is are 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, South Carolina Health Plan, project review criteria, and any provisions in this regulations ~~developed by the Department~~.

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.

SECTION 309. Certificate of Need Issuance Fee.

Approved Projects with a total project cost greater than one million four hundred thousand dollars (\$1,400,000) will require payment of a Certificate of Need 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 from the applicant within fifteen (15) calendar days from receipt of the certificate ~~by the applicant for the eCertificate of a~~ Need to remain valid.

SECTION 310. Project Changes During Review Period.

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

SECTION 311. Validity of Certificate of Need Issued.

The Certificate of Need, if issued, is valid only for the project described in the application including location, beds, and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with ~~these~~this regulations. Implementation of the project or operation of the facility or medical equipment that is not in accordance with the Certificate of Need application or conditions subsequently agreed to by the applicant and the Department may be considered a violation of this ~~R~~regulation.

SECTION 312. Prohibited Contact.

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. From the date of publication of notice in the local newspaper that an application is being filed and until the date final review is requested under Section 401 of ~~these~~this regulations:

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

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 staff decisions.

CHAPTER 4 APPEALS

SECTION 401. Appeal of Decision.

1. A Department decision involving the issuance, denial, or revocation of a ~~e~~Certificate of ~~a~~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. 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 they are an affected person and specifically states their grounds for opposition to the application under review.~~

SECTION 402. [Reserved]

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 Department shall not grant a Certificate of Need, or otherwise make a finding that such proposed new institutional health service is needed, unless:~~

~~1. The capital and operating costs of the proposal and their potential impact on patient charges are reasonable;~~

~~2. Superior alternatives to such services in terms of cost, efficiency, or appropriateness do not exist and that the development of such alternatives is not practicable;~~

~~3. In the case of new construction, alternatives to new construction (e.g., modernization or sharing arrangements) have been considered;~~

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

~~5. In the case of a proposed addition of beds for the provision of nursing care service, the addition is consistent with the plans of other State agencies responsible for provision and financing of long term care (including home health) services.~~

SECTION ~~502~~501. Periodic Reports.

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

SECTION 503. ~~Distribution of Procedures Criteria~~

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

SECTION ~~504~~502. Review Under Applicable Plan.

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

CHAPTER 6

VOIDANCE AND EXTENSION OF CERTIFICATES OF NEED

SECTION 601. Voidance and Extension Procedures.

1. The Certificate of Need shall become void twelve months (one year) from the date of issuance unless implemented as described in this subsection or a timely extension request is received pursuant to Section 602. 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 will 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 (2) extensions of up to nine (9) months each. In order to obtain an extension, the applicant must have demonstrated substantial progress and must either be complying with the approved timetable or have submitted documentation satisfactory to the Department that extenuating circumstances beyond the control of the applicant have prevented compliance with the timetable. After the nine (9) month extension period, the Certificate of Need will expire and become void.

4. However, the Board may grant further extensions of the Certificate of Need of up to nine (9) months each if it determines that substantial progress has been made. A request to the Board must be made at least three (3) months prior to the expiration of the Certificate of Need and must contain justification for such extension.

SECTION 602. Extension Request.

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

2. ~~This information~~ The written request for an extension shall include at least the following:

- a. A detailed description of any changes in the configuration, costs, services, or scope of the project.

b. A detailed description and documentation of any progress on the project including preparation of construction drawings, the securing of necessary funds and building permits, and commencement of any construction.

c. An estimated timetable for commencement and completion of all remaining components of the project.

d. Documentation of compliance with the approved timetable or documented evidence that extenuating circumstance beyond the control of the applicant if the timetable was not met.

SECTION 603. Criteria for Extension.

The following criteria shall be used to determine whether substantial progress has been made by the applicant:

1. Site procurement: The applicant should have made definitive progress toward permanent acquisition of the intended site. Such progress may include purchase of property previously under option or consummation of long-term lease agreements.

2. Architectural Progress: The facility architect should have been employed and definitive progress should be made toward development of final drawings.

3. Financial Status: ~~†~~The applicant should document definitive progress toward finalizing any necessary loans or lease-purchase arrangements.

4. The applicant should provide reasonable assurance that the project will be under construction or implemented within the requested extension time frame.

SECTION 604. ~~Non-Transferability~~ Nontransferability of Certificate of Need.

1. 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 will 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 will 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.~~

2. The sale or transfer of the controlling interest or majority ownership in a corporation, partnership, or other entity holding, either directly or indirectly, a Certificate of Need, will result in the transfer and voidance of a Certificate of Need.

3. Fulfillment of the Certificate of Need occurs upon the submission of an adequate final completion report pursuant to Section 607.3.

SECTION 605. Project Changes After Receipt of Certificate of Need.

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

SECTION 606. Total Project Cost.

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

SECTION 607. Periodic Reporting of Certificate of Need Implementation.

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

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

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

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

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

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

CHAPTER 7 PENALTIES FOR NON-COMPLIANCE

SECTION 701. Penalties.

Undertaking any activity requiring ~~e~~Certificate of ~~n~~Need review, ~~as defined in~~ pursuant to Section 402103 of these regulations, without prior approval of the Department or failing to comply with any of the above stated regulations shall be grounds for the denial, suspension, or revocation of the Certificate of Need, or other penalties, under the provisions of ~~Sections 44-7-320 through 44-7-340 of the Code of Laws of South Carolina~~ the State Certification of Need and Health Facility Licensure Act, S.C. Code Ann. Sections 44-7-110 *et seq.*, as amended. ~~Any violation of this regulation is subject to provisions set forth in the statute.~~

SECTION 702. [Reserved]

CHAPTER 8 PROJECT REVIEW CRITERIA

SECTION 801. Applicability and Weighting.

1. The criteria listed in Section 802 are to be used in reviewing all projects under the Certification of Need program. These criteria have been grouped under the following general categories:

Need for the Proposed Project (Section 802.1 through 802.4)

Economic Consideration (Section 802.5 through 802.9)

Health System Resources (Section 802.2010 through 802.2514)

Site Suitability (Section ~~802.26 through 802.30~~15)

Special Consideration (Section 802.3416 through 802.3318)

2. The Department shall notify the applicant of the relative importance of the project review criteria to be used in reviewing the application. The relative importance assigned to each specific criterion is established by the Department depending upon the importance of the criterion applied to the specific project. The relative importance must be consistent for competing projects.

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 Health Plan. A project may be denied if the Department determines that the project does not sufficiently meet one (1) or more of the criteria.

SECTION 802. Criteria for Project Review.

1. Need:

The proposal shall not be approved unless it is in compliance with the South Carolina Health Plan.

2. Community Need Documentation:

a. The target population should be clearly identified as to the size, location, distribution, and socioeconomic status (if applicable).

b. Projections of anticipated population changes should be reasonable and based upon accepted demographic or statistical methodologies, with assumptions and methodologies clearly presented in the application. The applicant must use population statistics consistent with those generated by the ~~state demographer, State Budget and Control Board~~ South Carolina Revenue and Fiscal Affairs Office.

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

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

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

3. Distribution (Accessibility):

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

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

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

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

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

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

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

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

4. Acceptability:

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

b. Where documented opposition exists to a proposal, such opposition will be considered along with the application.

c. Possible transfer agreements should be confirmed and an intent to negotiate these arrangements should be documented by all parties.

d. ~~The applicant should document the initiation of any other required reviews or agency check-offs.~~

~~5. Financial Entries and Assumptions:~~

~~All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of this financial information.~~

~~6. Projected Revenues:~~

~~a. The proposed charges should be comparable to those charges established by other facilities for similar services within the service area or state. The applicant should document how the proposed charges were calculated.~~

~~b. The projected levels of utilization should be reasonably consistent with those experienced by similar facilities in the service area and/or state. In addition, projected levels of utilization should be consistent with the need level of the target population.~~

~~c. The projected collection and reimbursement rates should be reasonably consistent with those experienced/utilized by similar facilities.~~

~~d. Failure to provide contingency plans for any known factor which would jeopardize the stability of the revenue projections shall be grounds for rejection of the budget.~~

~~7. Projected Expenses:~~

~~Projections of construction costs, start-up costs, operating costs, debt service, depreciation, manpower costs, etc. should be consistent with those experienced by similar facilities offering a similar level and scope of services (with proper consideration given to such factors as inflation, cost of capital, etc.).~~

~~8. Beginning Cash Flow:~~

~~The applicant must have documented the availability of resources or sources of funds sufficient to cover capital requirements and start-up costs. The schedule of utilization and net revenues must be detailed with assumptions explicitly present.~~

~~9. Net Income:~~

~~The project should show an improvement in its net revenue position over time, especially the first three years, until a steady, positive net income trend is attained. Any projected deviations from this pattern should be explained.~~

~~10. Debt Service:~~

- ~~a. Debt service (interest cost plus payment toward principal) should not be so large as to cause a negative net income.~~
- ~~b. Characteristics of the debt (interest, prepayment arrangements, etc.) should be consistent with those arrangements used by other health service entities in the State and consistent with accepted good business practices in terms of assumption and retirement of debt.~~
- ~~c. The applicant must document the impact the project will have on the facility's proposed level of patient charges.~~

~~11. Methods of Financing:~~

- ~~a. Possible alternatives should be identified.~~
- ~~b. Reasons for the selection of the proposed funding method should be stated and reasonable.~~

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

~~135. Record of the Applicant (Owner and/or Administrator):~~

- ~~a. The applicant's record should be one of successful operation with adequate management experience.~~
- ~~b. The applicant should have a demonstrated ability to obtain necessary capital financing.~~
- ~~c. If the applicant has no prior experience, sources of assistance should be specified (i.e., technical assistance from specific individuals or organizations).~~
- ~~d. The applicant's record or histheir representative's record of cooperation and compliance with State and Federal regulatory programs will be considered.~~

~~146. Ability to Complete the Project:~~

- ~~a. The applicant should have demonstrated that the project can be initiated and completed within the proposed time frame specified in the application.~~
- ~~b. The financial schedules and time frames contained in the application should be consistent with those usually experienced in the development of similar facilities or services.~~

~~157. Financial Feasibility:~~

- ~~a. The applicant must have projected both the immediate and long-term financial feasibility of the proposal. Such projection should be reasonable and based upon accepted accounting procedures.~~
- ~~b. All financial entries and assumptions contained in the application must be provided by an accountant who attests to the reliability of this financial information.~~

c. Projected utilization, revenues, expenses, and net income should be comparable to those experienced by providers of similar services, and the applicant must demonstrate that the project will attain a positive, net income trend within the first three (3) years of operation.

d. The applicant must document the availability of resources to cover capital and start-up costs, the ability to service any debt undertaken, and the ability to obtain capital financing, if necessary.

e. The impact of the project upon the applicant's cost to provide services and the applicant's net patient charges must be reasonable.

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

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

~~b. If the applicant had the option of lease or purchase, with all other factors being equal, he should demonstrate that his choice is the least costly in the long run.~~

~~c. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges should be reasonable. The impact of the project upon the cost and charges of other providers of similar services should be considered if the data are available.~~

~~17. Efficiency:~~

The proposed project should improve efficiency by avoiding duplication of services, promoting shared services, and fostering economies of scale or size.

~~18. Physical Design:~~

~~The proposed project should foster economies of design by use of design characteristics such as improved access and circulation within the facility, the relationship of services within the facility, and the use of shared space for centralized supply, storage, and common activities.~~

~~19. Alternative Methods:~~

a. The applicant should have considered any available or more effective alternatives which exist to the proposed service such as the use of less costly alternatives, outpatient services, shared services, or extended hours of service.

b. For new construction projects, modernization of existing facilities should be considered as an alternative, and the rejection of this alternative by the applicant should be justified.

~~20. Staff Resources:~~

a. The applicant should have a reasonable plan for the provision of all required staff (physicians, nursing, allied health and support staff, etc.).

b. The applicant should demonstrate that sufficient physicians are available to ~~insure~~ensure proper implementation (e.g., utilization and/or supervision) of the project.

c. If the applicant presently owns existing facilities or services, ~~he/she~~they should demonstrate a satisfactory staffing ~~“track record.”~~history.

d. Alternative uses of resources for the provision of other health services should be identified and considered.

~~24~~11. Support Services and Equipment:

a. Support services and equipment necessary to implement and sustain the proposed service should be identified, accessible, and of sufficient capacity.

b. Where possible, projects should utilize equipment already available and accessible to the population to be served.

~~22~~12. Distribution:

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

~~23~~13. Adverse Effects on Other Facilities:

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

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

~~24~~14. Adverse Effects on Training Programs:

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

~~25~~. ~~Access:~~

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

~~26~~15. ~~Zoning~~Site and Building Suitability:

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

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

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

~~27. Utilities:~~

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

~~28. Site Size:~~

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

~~29. Environmental Hazard:~~

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

~~30. Square Footage:~~

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

~~31~~16. 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 South Carolina Health Plan as deserving of priority.

b. The extent to which medically underserved populations currently use the applicant's services should be considered in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved.

c. Consideration of the documented performance of the applicant in meeting its obligation, if any, under any applicable Federal regulations requiring provision of uncompensated care, indigent care plan, community service, or access by minorities and handicapped persons to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant) should be given.

d. Consideration should be given to the extent to which Medicare, Medicaid, and medically indigent patients are served by the applicant.

~~32. Other Entities:~~

~~Consideration should be given to the special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. These entities may include medical and other health professions schools, multidisciplinary clinics and specialty centers.~~

3317. 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 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.

18. Quality of Care:

Applicants should describe metrics or benchmarks of quantitative quality metrics, if any, for the proposed facility, service, or equipment requiring a Certificate of Need. If the applicant is an existing provider, it should provide data on such metrics or benchmarks. If the applicant is a proposed provider, it should provide a plan on how it will meet such metrics or benchmarks.

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).

PART A – QUESTIONNAIRE		
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. Fax Number	E. Email
-		

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

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)			

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	

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. RTEs	-	-	-	-
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	-

11. Zoning of Construction Site	
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