

Regulation 61-15

Certification of Need for Health Facilities and Services

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S.C. Department of Health and
Environmental Control

2600 Bull Street | Columbia, SC 29201

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CHAPTER 1
DEFINITIONS AND APPLICABILITY

SECTION 101. Definitions.

1. **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.

2. **Board.** The State Board of Health and Environmental Control.

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.

5. **Department.** The S.C. Department of Health and Environmental Control.

6. **Fees.** The Department may charge and collect fees to cover the cost of operating the program. The fees for review of Certificate of Need projects include: (a) initial filing fee; (b) application fee; and (c) issuance fee.

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.

8. **Health Service.** At a minimum, clinically related, diagnostic, treatment, or rehabilitative services, and includes alcohol, drug abuse, and mental health.

9. **Hospital.** A facility that is organized and administered to provide overnight medical or surgical care or nursing care for an illness, injury, or infirmity and must provide on-campus emergency services; that may provide obstetrical care: and in which diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

10. **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.

11. **Like Equipment with Similar Capabilities.** A medical equipment in which functional and technological capabilities are identical to the equipment to be replaced; 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.

12. **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.

13. **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.

14. **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.

15. **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.

16. **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.

17. **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.

18. **Total Project Cost.** The estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect 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 or buildings will be calculated based on the total value (purchase price) of the equipment or building being leased.

SECTION 102. Applicability.

1. A person or nursing home 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 nursing home;

b. A change in the existing bed complement of a nursing home 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 nursing home in excess of five million dollars (\$5,000,000) which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure. 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 nursing home 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 nursing home 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. The offering of a health service by or on behalf of a nursing home 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 by or on behalf of a nursing home which is to be used for diagnosis or treatment if the total project cost is in excess of three million dollars (\$3,000,000). 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 three million dollars (\$3,000,000). 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. Until January 1, 2027, 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 hospital;

b. A change in existing bed complement of a hospital through the addition of one or more beds or a change in the classification of licensure of one or more beds.

Effective January 1, 2027, no Certificate of Need is required pursuant to this subsection.

3. A home health agency required by the *Licensure of Home Health Agencies Act* to obtain a Certificate of Need prior to licensure shall apply pursuant to the procedures set forth in this regulation.

4. 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.

5. 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.

6. 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 103. 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 relocation of a licensed hospital in the same county in which the hospital is currently located, as long as:

i. Any Certificate of Need issued to the hospital for a project to be located at the hospital's existing location has been fulfilled, withdrawn, or has expired; and

ii. The proposed site of relocation is utilized in a manner that furthers health care delivery and innovation for the citizens of the State of South Carolina;

b. The purchase, merger, or otherwise the acquisition of an existing hospital by another person or health care facility.

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

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

b. Other documentation requested by the Department in order to determine compliance with this regulation; and

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

3. The written exemption determination described in this section shall no longer be required effective January 1, 2027.

4. The following projects are exempt from Certificate of Need review and do not require a written determination from the Department: crisis stabilization unit facilities.

SECTION 104. 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. The construction of a new hospital with up to fifty (50) beds in a county currently without a hospital;

b. Acquisition by or on behalf of a nursing home of medical equipment which is to be used for diagnosis or treatment if any question exists as to whether the total project cost is below three million dollars (\$3,000,000) or adjusted, as in Section 102.1.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 this regulation; and

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

3. 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. Hospitals owned and operated by the federal government;

b. Any federal hospital sponsored and operated by this State;

c. Hospitals 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.

SECTION 105. 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:

- a. that a Certificate of Need is being applied for;
- b. a description of the scope and nature of the project; and
- 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.

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.

2. A non-refundable filing fee of five hundred dollars (\$500) shall be received by the Bureau of Operations Support, 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. Within fifteen (15) calendar days of acceptance of the application, the Department may request additional information as may be necessary to complete the application. Should additional information be required for an application to be considered complete, the applicant will have fifteen (15) calendar days from the date of the request to submit the requested information. If the applicant does not submit the requested information within fifteen (15) calendar days, the application will be deemed withdrawn.

2. 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 Certificate of Need application fee. The applicant shall have fifteen (15) calendar days from the date of receipt of the invoice to pay the fee by valid check or credit card made payable to the S.C. Department of Health and Environmental Control. Should the application fee not be received from the applicant within fifteen (15) calendar days from receipt of the Department's invoice, 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).

3. 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 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. 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, 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 ninety (90) 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 twenty (120) 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.

SECTION 306. Public Hearing.

A public hearing must be requested in writing by an affected person as defined in this regulation 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 regulation 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 other provisions in this regulation. The Department must identify any provisions in this regulation that 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 regulation.

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). The Department must receive payment from the applicant within fifteen (15) calendar days from receipt of the certificate for the Certificate of Need to remain valid.

SECTION 310. Project Changes During Review Period.

If an applicant amends 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 this regulation. 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 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 this regulation:

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 Certificate of Need may be appealed by an affected person pursuant to applicable law, including S.C. Code Title 44, Chapter 1; Title 1, Chapter 23; and Title 44, Chapter 7.

2. 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.

CHAPTER 5 GENERAL PROVISIONS

SECTION 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 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. 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 result 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 of the Certificate of Need.

2. 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. 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 result 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 result in the transfer and the subsequent voidance of the Certificate of Need.

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 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 result 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;
 - 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 Certificate of Need review, pursuant to Section 102 of this regulation, 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 the Health Facility Licensure Act, S.C. Code Ann. Sections 44-7-110 *et seq.*, as amended.

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 802.10 through 802.14)

Site Suitability (Section 802.15)

Special Consideration (Section 802.16 through 802.18)

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 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.

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

d. 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).

e. 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.

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

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

h. The applicant should document the balance between competition in the marketplace and how the proposed project impacts patient choice in the service area.

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.

5. 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 their representative's record of cooperation and compliance with State and Federal regulatory programs will be considered.

6. 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.

7. 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.

8. Efficiency:

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

9. 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.

10. 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 ensure proper implementation (e.g., utilization and/or supervision) of the project.

c. If the applicant presently owns existing facilities or services, they should demonstrate a satisfactory staffing history.

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

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.

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.

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.

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.

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.

15. 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.

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.

17. 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.