Agency Name: Department of Health and Environmental Control

Statutory Authority: 44-7-110 through 44-7-394 and 44-41-10(d)

Document Number: 4740

Proposed in State Register Volume and Issue: 40/12

House Committee: Regulations and Administrative Procedures Committee

Senate Committee: Medical Affairs Committee

120 Day Review Expiration Date for Automatic Approval: 05/09/2018

Final in State Register Volume and Issue: 42/5

Status: Final

Subject: Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

History: 4740

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

- 12/23/2016 Proposed Reg Published in SR

- 01/09/2018 Received by Lt. Gov & Speaker 05/09/2018

H 01/09/2018 Referred to Committee

S 01/09/2018 Referred to Committee

S 03/01/2018 Resolution Introduced to Approve 1074

H 04/17/2018 Resolution Introduced to Approve 5244

- 05/09/2018 Approved by: Expiration Date

- 05/25/2018 Effective Date unless otherwise

 provided for in the Regulation

Document No. 4740

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44‑7‑110 through 44‑7‑394 and 44‑41‑10(d)

61‑16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

**Synopsis:**

The Department of Health and Environmental Control is amending Regulation 61‑16. These amendments are necessary to incorporate recent changes in state law as well as changes to current practices and standards. The amendment incorporates provisions allowing dietitians to prescribe diets and other dietary services; incorporate requirements of S.C. Code Sections 44‑41‑410 through ‑480 relating to the provision of abortion services; incorporate existing inspection and construction fees; and incorporate new safe haven requirements.

A Notice of Drafting was published in the *State Register* on September 23, 2016.

Section‑by‑Section Discussion of Amendments:

TABLE OF CONTENTS

The table of contents was updated to reflect amended sections.

**Section 61‑16.101. Definitions**

The definition of 101.G Dietitian has been redefined as an individual who is registered by the Commission on Dietetic Registration and currently licensed as a dietitian by the South Carolina Department of Labor, Licensing and Regulation.

**Section 61‑16.201. License Requirements**

Section 201.E was amended to delete an unnecessary statutory reference and to require that a hospital shall comply with Chapter 41 of Title 44 of the S.C. Code of Laws. Former Section 201.G was relocated to new Section 201.H. Section 201.G (formerly 202) was amended to require that annual license fees include any outstanding inspection fees.

**Section 61‑16.202. Licensing Fees**

Section 202 has been deleted and moved to Section 201.G.

**Section 61‑16.202. Exceptions to Licensing Standards (formerly 61‑16.203)**

Section 202 (formerly 203) was renumbered to adjust the codification.

**Section 61‑16.302. Inspections and Investigations**

New Section 302.F was added to delineate inspection fees the Department is authorized to collect pursuant to S.C. Code Section 44‑7‑270.

**Section 61‑16.1303. Providing a Safe Haven for Abandoned Babies**

Section 1303.A was amended to require that facilities accept infants not more than sixty (60) days old, pursuant to a statutory change.

**Section 61‑16.1505. Diets**

Section 1505 introductory paragraph was amended to include dietitians. Section 1505.A was amended to require that diets be prescribed, dated and signed or authenticated by the physician or dietitian. New Section 1505.F was added to allow facility policy to permit a dietitian to order or prescribe patient diets, including therapeutic diets; order laboratory tests to monitor the effectiveness of diets; and/or make subsequent modifications to patient diets based on lab results, if permitted by the facility’s policies.

**Section 61‑16.1903. Submission of Plans**

New Section 1903.D was added to require the licensee to pay inspection fees during the construction phase of a project. A Construction Inspection Fees table was added to clearly delineate the required construction inspection fees.

**Instructions:**

Amend Regulation 61-16 pursuant to each individual instruction provided with the text of the amendments below.

**Text**:

61‑16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

**Revise Section 200 of Table of Contents to read:**

TABLE OF CONTENTS

SECTION 200. LICENSE REQUIREMENTS AND FEES

201. License Requirements.

202. Exceptions to Licensing Standards.

**Revise Section 61‑16.101.G to read:**

 G. Dietitian: An individual who is registered by the Commission on Dietetic Registration and currently licensed as a dietitian by the South Carolina Department of Labor, Licensing and Regulation.

**Revise Section 61‑16.201 to read:**

**Section 201. License Requirements.**

 A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a hospital or institutional general infirmary in South Carolina without first obtaining a license from the Department. Admission of patients or the provision of care, treatment, and/or services to patients prior to the effective date of licensure is a violation of S.C. Code Ann. Section 44‑7‑260(A) (1976, as amended). (I)

 B. A license shall be effective for a period of time specified by the Department.

 C. A new facility, or one that has not been continuously licensed under these or prior standards, shall not admit patients until permission is granted by the Department.

 D. Hospitals that provide services to patients requiring skilled nursing care must maintain a separate license for the areas where the services are provided.

 E. Upon receipt of a written request from the hospital authorities to the Department requesting such certification, any general hospital having a current license to operate may be certified as a suitable facility for the performance of abortions. A hospital shall comply with Chapter 41 of Title 44 of the S.C. Code of Laws. (I)

 F. Applicants for a license shall file application under oath on a form and frequency specified by the Department. An application shall be signed/authenticated by the owner, if an individual or partnership; or in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in case his address is different from that of the facility; the names of persons in control thereof and such additional information as the Department may require, including affirmative evidence of ability to comply with reasonable standards, rules and regulations as may be lawfully prescribed. No proposed hospital shall be named nor may an existing hospital have its name changed to the same or similar name as a hospital licensed in the State.

 G. Licensing Fees. The initial and annual license fee shall be ten dollars ($10.00) per licensed bed. Annual license fees must also include any outstanding inspection fees. Such fees shall be made payable by check or credit card to the Department.

 H. A facility shall request issue of an amended license, by application to the Department prior to any of the following circumstances:

 1. Change of ownership by purchase or lease;

 2. Change of facility’s name;

 3. Addition or replacement of beds (an inspection will be required prior to issuance of license);

 4. Deletion of beds; or

 5. Reallocation of types of beds as shown on license.

**Delete Section 61‑16.202 entirely:**

**Revise Section 61‑16.203 to read:**

**Section 202. Exceptions to Licensing Standards.**

The Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community requires the services of the facility. When an “exception” applies to an existing facility, it will continue to meet the standards in effect at the time it was licensed.

**Add Section 61‑16.302.F to read:**

**Section 302. Inspections and Investigations.**

 F. In accordance with S.C. Code Section 44‑7‑270, the Department may charge a fee for inspections. The fee for initial and biennial routine inspections shall be four hundred fifty dollars ($450.00) plus ten dollars ($10.00) per licensed bed. The fee for initial unit increase or service modification is two hundred fifty dollars ($250.00) plus ten dollars ($10.00) per licensed bed. The fee for follow‑up inspections shall be two hundred fifty dollars ($250.00) plus ten dollars ($10.00) per licensed bed.

**Revise Section 61‑16.1303.A to read:**

**Section 1303. Providing a Safe Haven for Abandoned Babies.**

Facilities and outpatient facilities shall:

 A. Accept temporary physical custody of an infant not more than sixty (60) days old who is voluntarily left by a person who does not express an intent to return for the infant and the circumstances create a reasonable belief that a person does not intend to return for the infant.

**Revise Section 61‑16.1505 to read:**

**Section 1505. Diets.**

Diets shall be prepared in conformance with orders of a physician or, if permitted by the facility’s policies, a dietitian. A current diet manual shall be readily available to attending physicians, food and nutrition service personnel, nursing personnel, and dietitians.

 A. Diets shall be prescribed, dated and signed or authenticated by the physician or dietitian.

 B. Facilities with patients in need of special or therapeutic diets shall provide for such diets.

 C. Notations shall be made in the medical record of diet served, counseling or instructions given, as identified by patient and/or nutritional assessment and patient’s tolerance of the diet.

 D. Diets shall be planned, written, prepared and served with consultation from a dietitian.

 E. Persons responsible for diets shall have sufficient knowledge of food values in order to make substitutions when necessary. All substitutions made on the master menu shall be documented.

 F. Nothing in this regulation shall be read or interpreted to prohibit a facility’s policies from allowing a dietitian to:

 1. Order or prescribe patient diets, including therapeutic diets;

 2. Order laboratory tests to monitor the effectiveness of dietary plans and orders; and/or

 3. Make subsequent modifications to patient diets based on the results of laboratory tests.

**Revise Section 61‑16.1903 to read:**

**Section 1903. Submission of Plans.**

 A. When construction is contemplated either for new buildings, additions or major alterations or replacement to existing buildings, buildings being licensed for the first time, buildings changing license type, or facilities increasing occupant load/licensed capacity, plans and specifications shall be submitted to the Department for review. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. These submissions shall be made in at least three stages: schematic, design development, and final. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for supervision and inspections. The Department shall conduct periodic inspections throughout each project.

 B. When alterations are contemplated that are new construction, or projects with changes to the physical plant of a licensed facility which has an effect on: the function, use or accessibility of an area; structural integrity; active and passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under the said hood); door, wall and ceiling system assemblies; exit corridors; Increase the occupant load/licensed capacity; and projects pertaining to any life safety systems, require preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame‑spread rating or other safety criteria shall be documented with copies of the documentation and certifications, kept on file at the facility and made available to the Department.

 C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re‑approval from the Department.

 D. The licensee shall pay the following inspection fees during the construction phase of the project. The plan inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

|  |
| --- |
| **Construction Inspection Fees** |
| **Plan Inspection** |
| **Total Project Cost** | **Fee** |
| < $10,001.00 | $750 |
| $10,001 ‑ $100,000  | $1,500 |
| $100,001 ‑ $500,000 | $2,000 |
| > $500,000 | $2,500 plus $100 for each additional $100,000 in project cost |
| **Site Inspection** |
| 50% Inspection | $500 |
| 80% Inspection | $500 |
| 100% Inspection | $500 |

**Fiscal Impact Statement**:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any inherent requirements of this regulation. There are no external costs anticipated.

**Statement of Need and Reasonableness**:

The following is based on an analysis of the factors listed in 1976 Code Section 1‑23‑115(C)(1)‑(3) and (9)‑(11):

DESCRIPTION OF REGULATION: R.61‑16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

Purpose: The purpose of these amendments to R.61‑16 is to update statutory requirements recently enacted by the General Assembly. These amendments include incorporation of provisions allowing dietitians to prescribe diets and other dietary services; new requirements of S.C. Code Sections 44‑41‑410 through ‑480 relating to the provision of abortion services; adding existing inspection and construction fees; and new requirements relating to safe havens.

Legal Authority: 1976 Code Sections 44‑7‑110 through 44‑7‑394 and 44‑41‑70(a).

Plan for Implementation: Copies of the regulation will be available electronically on the South Carolina Legislature website and the Department regulation development website (<http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate>). Printed copies will be available for a fee from the Department’s Freedom of Information Office.

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

These amendments are necessary to incorporate recent statutory changes for abortion services and safe haven requirements. Additionally, the amendments incorporate provisions allowing dietitians to prescribe diets and other dietary services, and incorporate existing inspections and construction fees.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these amendments. There are no anticipated additional costs to the regulated community. Amendments to R.61‑16 update statutory requirements enacted by the General Assembly, update requirements for dietitians, and incorporate existing inspection and construction fees.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61‑16 seek to support the Department’s goals relating to the protection of public health through the anticipated benefits highlighted above. There is no anticipated effect on the environment.

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

There is no anticipated detrimental effect on the environment. If the revision is not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendments herein.

**Statement of Rationale:**

The Department of Health and Environmental Control is amending Regulation 61‑16. These amendments are necessary to incorporate recent changes in state law as well as changes to current practices and standards. The amendments incorporate provisions allowing dietitians to prescribe diets and other dietary services; incorporate requirements of S.C. Code Sections 44‑41‑410 through ‑480 relating to the provision of abortion services; incorporate existing inspection and construction fees; and incorporate new safe haven requirements.