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Document No. 4800

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44‑71‑10 et seq.

61‑78. Standards for Licensing Hospices.

**Synopsis:**

The Department of Health and Environmental Control (“Department”) amends R.61‑78, Standards for Licensing Hospices. The amendments incorporate 2017 Act No. 61, which comprises changes to the Hospice Licensure Act, S.C. Code Sections 44‑71‑10 et seq. These regulatory amendments include requirements to register multiple locations and updated requirements for medication disposal to comply with the new statutory changes. The statutory changes also expand Joint Annual Report requirements to outpatient hospices; however, existing wording of R.61‑78 adequately executes those requirements. The Department had a Notice of Drafting published in the *State Register* on June 23, 2017.

Section‑by‑Section Discussion of Amendments:

TABLE OF CONTENTS

The table of contents was updated to reflect amended sections.

**Section 61‑78.100. DEFINITIONS**

The definitions of 100.CC Multiple Location, 100.HH Parent Hospice, and 100.PP Primary Office were added. The remaining definitions were updated to reflect the new codification.

**Section 61‑78.213. Multiple Locations**

New Section 213 was added to delineate the requirements for multiple locations. Section 213.A requires hospices to register multiple locations with the Department prior to establishing, operating, maintaining, or representing as such. Section 213.B requires hospices to file an application for the registration of a multiple location. Section 213.C states that the registration of a multiple location is effective until the expiration of the license of the parent hospice.

**Section 61‑78.214. Exceptions to Licensing Standards (formerly 61‑78.213)**

Section 214 (formerly 213) was renumbered to adjust the codification.

**Section 61‑78.401. General**

Section 401 was amended to include multiple locations as being subject to monetary penalties, denial, suspension, or revocation for violations of any statute, rule, or regulation.

**Section 61‑78.1608. Disposition of Medications**

Section 1608.B was amended to refer to patients receiving services in hospice facilities only. Section 1608.C was added to require that upon the death of a patient receiving outpatient services, the hospice shall comply with S.C. Code Section 44‑71‑85. The remaining subsections were renumbered to adjust the codification.

**Section 61‑78.2106. Utility Rooms**

Sections 2106.A and 2106.B were amended to change work station to nurses’ station for clarity and consistency.

**Section 61‑78.2201. Fire Protection**

Section 2201.D was amended to change work station to nurses’ station for clarity and consistency.

**Instructions:**

Amend R.61‑78 pursuant to each individual instruction provided with the text of the amendments below.

**Text**:

61‑78. Standards for Licensing Hospices.

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

SECTION 200 LICENSE REQUIREMENTS

201. Scope of Licensure

202. License Application

203. Compliance

204. Issuance of License

205. Licensing Fees

206. Late Fee

207. License Renewal

208. Change of License

209. Hospice Name

210. Licensed Area

211. Licensed Bed Capacity

212. Persons Received in Excess of Licensed Bed Capacity

213. Multiple Locations

214. Exceptions to Licensing Standards

**Revise Section 61‑78.100 to read:**

**Section 100 – DEFINITIONS**

For the purpose of this regulation, the following definitions shall apply:

 A. Administrator. The individual designated by the governing body to be responsible for the day‑to‑day management of the Hospice and when licensed to provide Inpatient Services, Hospice Facility.

 B. Advanced Practice Registered Nurse. An individual who has Official Recognition as such by the South Carolina Board of Nursing.

 C. Airborne Infection Isolation (AII). A room designed to maintain Airborne Infection Isolation (AII), formerly called a negative pressure isolation room. An Airborne Infection Isolation (AII) room is a single‑occupancy patient‑care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation (AII) rooms to minimize the transmission of infectious agents that are usually spread from person‑to‑person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. Airborne Infection Isolation (AII) rooms may provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of six to twelve (6 to 12) air changes per hour (ACH), and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter.

 D. Architect. An individual currently registered as such by the South Carolina State Board of Architectural Examiners.

 E. Attending Physician. The physician who is identified by the patient as having the most significant role in the determination and delivery of medical care to the patient.

 F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific care, treatment, or services to patients such as, advanced practice registered nurse, physician assistant.

 G. Consultation. A visit by Department representative(s) to provide information to the licensee in order to facilitate compliance with these regulations.

 H. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the South Carolina Controlled Substances Act.

 I. Counseling Services. Counseling includes bereavement counseling, as well as dietary, spiritual, and any other counseling services provided to the individual and family or responsible party.

 J. Department. The South Carolina Department of Health and Environmental Control (DHEC).

 K. Dietitian. A person who is registered by the Commission on Dietetic Registration and licensed by the South Carolina Department of Labor, Licensing and Regulation.

 L. Dietary Counseling. Education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient’s condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient’s plan of care.

 M. Direct Care Staff Member/Direct Care Volunteer. Individuals who provide care to patients within the parameters of their training and/or as determined by state law or statute.

 N. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, other authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician’s signature. The standing orders or protocol shall be reviewed annually by the physician, with a copy maintained at the Hospice.

 O. Hospice Aide. An individual supervised by a registered nurse who renders assistance with personal care to patients needing assistance with activities of daily living, and who meets minimum qualifications and training as set by the Hospice.

 P. Hospice. A centrally administered, interdisciplinary healthcare program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including but not limited to home, Outpatient Services and Inpatient Services provided directly or through written agreement.

 Q. Hospice Facility. An institution, place, or building in which a licensed Hospice provides room, board, and Inpatient Services on a twenty‑four (24) hour basis to individuals requiring Hospice care pursuant to the orders of a physician. Prior to construction or establishment of a new Hospice Facility, or increasing the number of beds in an existing facility, a Hospice Facility shall obtain a Certificate of Need from the Department.

 R. Inpatient Services. A continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party provided by a Hospice for individuals intended to stay one (1) or more nights in an institution, place, or building licensed by the Department to provide room, board, and applicable care on a twenty‑four (24) hour basis, such as a Hospice Facility, community residential care facility, nursing home, hospital, or general infirmary.

 S. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.

 T. Interdisciplinary Team or Group. A group designated by the Hospice to provide or supervise care, treatment, and services provided by the Hospice. The group must include at least the following individuals: a physician, a registered nurse, a social worker, and a pastoral or other counselor.

 U. Investigation. A visit by Department representative(s) to an unlicensed or licensed Hospice or Hospice Facility for the purpose of determining the validity of allegations received by the Department.

 V. Legend Drug.

 1. Medication required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

 a. “Caution: Federal law prohibits dispensing without prescription”;

 b. “Rx only” or;

 2. Medication required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only; or

 3. Any medication products designated by the South Carolina Board of Pharmacy to be a public health threat; or

 4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

 W. License. A certificate issued by the Department providing for the establishment and maintenance of a Hospice and, when specified on the face of the certificate, Hospice Facility in accordance with this regulation.

 X. Licensed Nurse. A person licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse or a person licensed as a registered nurse or licensed practical nurse who resides in another state that has been granted multi‑state licensing privileges by the South Carolina Board of Nursing. This person may practice nursing in any facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

 Y. Licensee. The individual, corporation, or public entity with whom rests the ultimate responsibility for maintaining statutory and regulatory standards for the licensed Hospice and, if applicable in accordance with the license issued, Hospice Facility.

 Z. Life‑limiting Condition. A condition with no reasonable hope for a cure and will certainly prevent a child from surviving to adulthood.

 AA. Medication. A substance that has therapeutic effects, including, but not limited to, legend drugs, nonlegend and herbal products, vitamins, and nutritional supplements.

 BB. Minor. A person seventeen (17) years of age or younger who has not been emancipated in accordance with state law.

 CC. Multiple Location. A properly registered additional site, other than the licensed primary office, from which a parent hospice organization provides hospice services.

 DD. Nonlegend Medication. A medication which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws of this state and the federal government.

 EE. Occupational Therapist. A person currently licensed as such by the South Carolina Board of Occupational Therapy Examiners.

 FF. Outpatient Services. A continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party provided by a Hospice and intended for individuals not staying one or more nights in an institution, place, or building licensed by the Department to provide room, board, and applicable care on a twenty‑four (24) hour basis, such as a Hospice Facility, community residential care facility, nursing home, hospital, or general infirmary.

 GG. Palliative Care. Treatment that enhances comfort and improves the quality of an individual’s life during the last phase of life.

 HH. Parent Hospice. A properly licensed Hospice that, in addition to its primary office, also provides hospice services from a multiple location.

 II. Patient. A person who receives care, treatment, or services from a Hospice licensed by the Department.

 JJ. Pharmacist. An individual currently registered as such by the South Carolina Board of Pharmacy.

 KK. Physical Assessment. An assessment of a patient by a physician or other authorized healthcare provider that addresses those issues identified in Section 1200 of this regulation.

 LL. Physical Therapist. An individual currently registered as such by the South Carolina Board of Physical Therapy Examiners.

 MM. Physician. An individual currently licensed by his or her state medical licensing board to practice medicine within that state.

 NN. Physician Assistant. An individual currently licensed as such by the South Carolina Board of Medical Examiners.

 OO. Plan of Care. A documented regimen of care, treatment, and services prepared by the Hospice for each patient based on assessment data and implemented for the benefit of the patient.

 PP. Primary Office. The main office of a Hospice program from which a parent hospice provides hospice services to patients and their families and from which a parent hospice performs oversight, administrative, and coordination of care duties for any multiple location.

 QQ. Quality Improvement Program. The process used by the Hospice to examine its methods and practices of providing care, identifying the opportunities to improve its performance, and taking actions that result in higher quality of care for the Hospice’s patients.

 RR. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a thirty‑six (36) month period. The time period determinant of repeat violation status is not interrupted by licensee changes.

 SS. Respite Care. Short‑term care provided to an individual to relieve the family members, responsible party, or other persons caring for the individual.

 TT. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court‑appointed guardian or conservator, or person with a health care or other durable power of attorney.

 UU. Restraint. Any means by which movement of a patient is inhibited, including physical, mechanical, and/or chemical. In addition, devices shall be considered a restraint if a patient is unable to easily release from the device.

 VV. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

 WW. Social Worker. An individual who is licensed by the South Carolina Board of Social Worker Examiners.

 XX. Speech Therapist. An individual currently licensed as such by the South Carolina Board of Speech‑Language Pathology and Audiology.

 YY. Staff Member. A person who is a compensated employee of the Hospice on either a full or part‑time basis.

 ZZ. Suspension of License. An action by the Department requiring a Hospice to cease operations for a period of time or to require a Hospice to cease admitting patients until such time as the Department rescinds that restriction.

 AAA. Terminally Ill. A medical prognosis that, if the disease runs its usual course, limits an individual’s life expectancy to twenty‑four (24) months or less; or, if the individual is twenty‑one (21) years of age or less includes a Life‑limiting Condition.

 BBB. Volunteer. An individual who performs tasks at the Hospice at the direction of the administrator or his or her designee without compensation.

**Add Section 61‑78.213 to read:**

**213. Multiple Locations**

 A. A Hospice shall not establish, operate, or maintain a multiple location or represent itself as such without first registering the multiple location with the Department and receiving approval of the registration from the Department confirming that the Hospice has properly filed the application to amend its license and include the multiple location.

 B. Hospices desiring to obtain approval for the registration of a multiple location shall file with the Department an application on a form prescribed, prepared, and furnished by the Department.

 C. A multiple location registration shall be effective until the expiration of the license of the parent hospice in effect at the time of the initial approval of the multiple location.

**Revise Section 61‑78.213 to read:**

**214. Exceptions to Licensing Standards**

The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well‑being of the patients are not compromised, and provided the standard is not specifically required by statute.

**Revise Section 61‑78.401 to read:**

**401. General**

When the Department determines that a Hospice, Hospice Facility, or multiple location is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such Hospice, Hospice Facility, or multiple location, the Department, upon proper notice to the licensee, may impose a monetary penalty, and deny, suspend, or revoke its license.

**Revise Section 61‑78.1608 to read:**

**1608. Disposition of Medications (I)**

 A. Upon discharge or death of a patient, a Hospice in possession of unused medications belonging to the patient that do not constitute a controlled substance under 21 U.S.C. Section 802 shall release the unused medications to the patient, family member, or responsible party, as appropriate.

 B. Upon death of a patient receiving services in a Hospice Facility, a Hospice Facility in possession of unused medications belonging to the patient that constitutes a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to an applicable person under 21 C.F.R. Section 1317.30 for disposal in accordance with requirements of the federal Drug Enforcement Administration. In the alternative, a facility that constitutes a long‑term care facility under 21 C.F.R. 1300.01 may dispose of the unused medications in accordance with 21 C.F.R. Sections 1317.30 and 1317.80.

 C. Upon death of a patient receiving outpatient services, a Hospice shall comply with S.C. Code Section 44‑71‑85.

 D. Upon discharge of a patient, a Hospice in possession of unused medications belonging to the patient that constitutes a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to the “ultimate user” under 21 U.S.C. Section 802. In the alternative, a facility that constitutes a long‑term care facility under 21 C.F.R. 1300.01 may dispose of the unused medications in accordance with 21 C.F.R. Sections 1317.30 and 1317.80 if authorized by the patient.

 E. Expired biologicals, medical supplies, and solutions shall be disposed of in accord with Hospice Facility policy.

**Revise Section 61‑78.2106 to read:**

**2106. Utility Rooms**

 A. Soiled Utility Room: A Hospice Facility shall include at least one (1) soiled utility room per nurses’ station containing a clinical sink, work counter, waste receptacle and soiled linen receptacle.

 B. Clean Utility Room: A Hospice Facility shall include at least one (1) clean utility room per nurses’ station containing a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

**Revise Section 61‑78.2201 to read:**

**2201. Fire Protection**

 A. A Hospice Facility shall include a partial, manual, automatic, and supervised fire alarm system. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

 B. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

 C. A Hospice Facility shall include an NFPA 13 sprinkler system.

 D. A Hospice Facility shall maintain a fire alarm pull station in or near each nurses’ station.

**Fiscal Impact Statement**:

As noted in the Fiscal Impact Statement for House Bill 3132 requested by the Senate Medical Affairs committee, the Department estimates an expenditure impact of eighty‑three thousand sixty‑three dollars ($83,063) on the General Fund for at least the first year after promulgation of these amendments.

**Statement of Need and Reasonableness**:

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

DESCRIPTION OF REGULATION: R.61‑78, Standards for Licensing Hospices.

Purpose: The purpose of these amendments to R.61‑78 is to incorporate recent changes to the Hospice Licensure Act, S.C. Code Sections 44‑71‑10 et seq., enacted by the General Assembly by 2017 Act No. 61. These amendments include requirements to register multiple locations and new requirements for medication disposal.

Legal Authority: 1976 Code Sections 44‑71‑10 et seq.

Plan for Implementation: The DHEC Regulation Development Update (accessible at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>) provides a summary of and link to the regulation amendments. Additionally, printed copies of the regulation are available for a fee from the Department’s Freedom of Information office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of these amendments and any associated changes.

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 to the Hospice Licensure Act. The amendments to R.61‑78 enable registration of multiple locations and update medication disposal requirements to the new statutory requirements.

DETERMINATION OF COSTS AND BENEFITS:

As noted in the Fiscal Impact Statement for House Bill 3132 requested by the Senate Medical Affairs committee, the Department estimates an expenditure impact of eighty‑three thousand sixty‑three dollars ($83,063) on the General Fund for at least the first year after promulgation of these amendments. Hospice providers will pay a licensure fee of one hundred dollars ($100) per multiple location, plus fifty dollars ($50) for each county where the multiple location provides services. Implementation of these amendments benefit the regulated community by executing recent changes to the Hospice Licensure Act.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61‑78 seek to support the Department’s goals relating to 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 amendments are not implemented, the regulation will be maintained in its current form without realizing the benefits of the recently enacted changes to the Hospice Licensure Act.

**Statement of Rationale:**

These amendments are necessary to incorporate recent changes to the Hospice Licensure Act, S.C. Code Sections 44‑71‑10 et seq. The amendments to R.61‑78 enable registration of multiple locations and update medication disposal requirements to the new statutory requirements.