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Statutory Authority: 44-7-250

Document Number: 4108

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S 01/28/2010 Referred to Committee

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provided for in the Regulation

Resubmitted: March 25, 2010

Document No. 4108

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-7-250

61-84. Standards for Licensing Community Residential Care Facilities

**Synopsis:**

South Carolina Code Ann. Section 1-23-120 directs that staff of State agencies review their regulations every five years and update them if necessary. Regulation 61-84, Standards for Licensing Community Residential Care Facilities, was published in the State Register on May 23, 1986, May 24, 1991, and was subsequently revised and published in the *State Register* on July 27, 2001. Since that time there has been changes in applicable laws, *e.g.*, criminal record checks of direct care staff, and there have been certain guidelines, directives, interpretations, and changes in Division policy that have led to the necessity to amend these regulations in order to make them more up-to-date.

A Notice of Drafting for this amendment of R.61-84 was published in the *State Register* on May 22, 2009.

**Changes made to the proposed regulation during legislative review as requested by**

**the Senate Medical Affairs Committee by its letter dated March 23, 2010:**

Section 103.J Licensing Fees, was revised to remove fee increases and additional fees, and return to the existing text in Regulation 61-84. The Statement of Need and Reasonableness, the Fiscal Impact Statement and the Determination of Costs and Benefits were revised to remove information related to fee increases and additional fees.

**DHEC’s Section-by-Section Discussion of Revisions**

**as submitted to the General Assembly on January 28, 2010**:

TABLE OF CONTENTS:

The table has been updated and is being replaced in entirety with classifications and punctuation added for consistency with the text of the regulation.

BODY OF DOCUMENT:

Section 100 includes definitions and references:

101.F. – This proposed subsection added and defines “Airborne Infection Isolation”.

101.H. – This subsection defines “Annual” and is revised from “once every 365 days” to “at least every twelve to thirteen (12 to 13) months.”

101.L. – This proposed subsection added and defines “Blood Assay for *Mycobacterium* *tuberculosis* (BAMT)”.

101.O. – This proposed subsection added and defines “Contact Investigation”.

101.BB. – This proposed subsection added and defines “Incident”.

101.GG. – This proposed subsection added and defines “Latent TB Infection (LTBI)”.

101.HH. – This subsection defines “Legend Drug” and is revised for wording clarity.

101.LL. – This subsection defines “Local Transportation” and is revised to include “as addressed by the resident written agreement” and deletes the term “and needs.”

101.PP. – This subsection defines “Peak Hours” and is revised to include a requirement for reporting facility peak hours to the Department.

101.WW. – This proposed subsection added and defines “Private Sitter”.

101.YY. – This proposed subsection added and defines “Quarterly”.

101.III. – This proposed subsection added and defines “Risk Assessment”.

Section 102. References:

102.B.16. – This proposed subsection added a reference for “Guidelines for Preventing the Transmission of *Mycobacterium* *tuberculosis* in Health Care Settings” (2005).

Section 103. License Requirements:

103.B. – This subsection is revised for wording clarity.

103.D. – This subsection is deleted.

103.F. – This subsection is revised to clarify who may or may not occupy resident rooms, other bedrooms within the facility or resident recreational or dining areas.

103.I. – This subsection is revised to clarify the requirements for submitting an application for license.

103.K. – This subsection is deleted.

103.J. – This subsection is revised to address a licensing fee increase from $10 per licensed bed to an incremental change from $15 to $20 per licensed bed over a three year period. In addition, the subsection is revised to address an initial license fee of $500 for proposed facilities with 16 or more beds and $250 for proposed facilities with less than 16 beds. Also, in instances where facilities are adding licensed beds, the subsection addresses an initial proposed license bed increase fee of $500 for proposed facilities with 16 or more beds and $250 for proposed facilities with less than 16 beds.

Section 200. Enforcing Regulations:

202.E. – This subsection is revised to address the posting of inspection reports.

Section 302. Violation Classifications:

302.E. – This subsection is revised to address factors that may result in enforcement actions.

302.F. – This subsection is revised and adjusted for consistency with S.C. state statute.

302.G. – This subsection addresses Departmental decisions regarding enforcement actions and the appeal process available to affected parties. Also clarification for code of applicable laws.

Section 400. Policies and Procedures:

401.A. – This subsection requires facility policies and procedures to be written.

Section 500. Staff/Training:

501.B. – This subsection addresses the employment requirement for direct care staff/direct care volunteers to include a criminal record check in accordance with applicable law, as amended. This also addresses criminal background checks for contracted private sitters.

502.A. – This subsection addresses the applicable code of laws requiring an administrator to be licensed.

503.B. – This subsection is revised to clarify that direct care duties include “supervision” of residents.

504.A. – This introductory only subsection is revised to update staff and private sitter training requirements and requires documentation of the training.

504.B. – This subsection addresses the designation and training of staff responsible for resident recreational activities and requires documentation of the training.

506. – This proposed section is added to address contractual requirements for private sitters, including, but not limited to, policy and procedure requirements; the requirement to check for prior convictions pursuant to Section 501.B.; orientation to the facility; health assessment and determination of TB status; and exclusion from minimum staffing requirements of Section 503.A.

Section 601. Incidents/Accidents – Subsection title revised.

601.A-I. – This subsection is revised and addresses changes in incident reporting to the Department and updates examples of incidents to be included in a report as well as the statutory requirement to report resident abuse to the South Carolina Long Term Care Ombudsman Program.

Section 604. Administrator Change:

604. – This subsection addresses reporting requirements for a change of administrator and the hours the new appointee will be working. In addition, there is a stylistic change for clarity.

Section 700. Resident Records:

701.B.6. – This subsection is revised to require daily and/or monthly notes of observation according to resident’s condition.

701.B.10. – This subsection is revised to address the conditions under which a resident photograph is updated.

702. – This subsection addresses documentation requirements for resident assessments.

Section 800. Admission/Retention:

801.B-C. – This subsection is revised to clarify the conditions under which individuals are not eligible for admission or retention in a community residential care facility and to clarify levels of violation classifications.

Section 900. Resident Care/Services:

901.A.8. – This subsection is revised to address the requirement for Resident’s Bill of Rights and grievance procedures to be documented.

902.H. – This subsection addresses the availability of resident funds quarterly reports.

Section 1000. Rights and Assurances:

1001.L. – This subsection clarifies resident freedom to use the telephone.

Section 1100. Resident Physical Examination and TB Screening:

1101.A. – This subsection is revised to include permitting physicians licensed in states other than South Carolina to perform the admission physical examination and to rearrange numerically the required components of the physical examination.

1101.F. – This subsection is revised for consistency and clarity with revised Section 1702.

1101.G. – This subsection is revised for consistency and clarity with revised Section 1702. In addition, there are stylistic changes for clarity.

Section 1200. Medication Management:

1201.A. – This subsection addresses the availability of medications and supplies.

1202. – This subsection title is revised to include treatment orders.

1202.A. – This subsection addresses physician orders for medications and treatments.

1202.B. – This subsection addresses the signing and dating of physician orders.

1203. – This subsection title is renamed to include treatment administration.

1203.A. – This subsection addresses the administration and documentation of treatments.

1205.B. – This subsection addresses medication containers, *i.e*., the multi-dose system.

1206.A. – This subsection addresses the storage of refrigerated medications and adds the requirement for thermometers in medication storage refrigerators.

1206.C. – This subsection addresses control and accountability of controlled medications.

Section 1300. Meal Service:

1306.A. – This subsection addresses menu planning and documentation requirements; adds the requirement that all special diet menus be signed and dated by a dietitian, physician or other authorized healthcare provider.

1309.A. – This subsection addresses the use of alcohol-based waterless hand sanitizers.

Section 1400. Emergency Procedures/Disaster Preparedness:

1401.B.1.c. – This subsection revises the sheltering plan requirement for Berkeley and Dorchester counties.

1403. – This subsection is revised to require that the continuity of essential services plan be written.

Section 1500. Fire Prevention:

1503.C. – This subsection revises the fire response training requirement for residents to assist other residents in case of fire.

Section 1700. Infection Control and Environment:

1702.A-D. – This subsection is revised to address the requirement for a facility to conduct an annual tuberculosis risk assessment to determine the facility’s risk classification; updates the requirement for staff/volunteer/private sitter and resident tuberculosis screening in accordance with the 2005 CDC guidelines. Proposed items added include the use of alternative tuberculosis screening elements, the BAMT. This subsection also addresses resident isolation requirements that include reference to an Airborne Infection Isolation room as required by the CDC if the resident with contagious pulmonary tuberculosis remains in the facility.

1705.A. – This subsection addresses health screening requirements for pets prior to resident contact. The change was proposed in error to occur at 1705.B in the *State Register* Notice of Drafting, but will occur at 1705.A. and the change, as proposed, was not altered; only the section where placed.

Section 2200. Fire Protection Equipment and Systems:

2201.D. – This subsection addresses fire extinguishers located in the kitchen.

2207.D. – This subsection deletes portable partitions from the furnishings/equipment that must be in accordance with NFPA 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films. In addition, there is a stylistic change for clarity.

2207.E. – This proposed subsection item is added to address designated smoking/non-smoking areas of the facility.

2207.F. – The change was proposed in error and is not included in the text as the fire code addresses areas where signage is required.

Section 2700. Physical Plant:

2702.J. – This subsection revises the requirement for mirrors in resident rooms. In addition, there is a stylistic change for clarity.

2704.D. – This subsection addresses the communal use of bar soap in resident bathing areas. In addition, there is a stylistic change for clarity.

2715.A. – This subsection addresses fixed line telephone service. In addition, there is a stylistic change for clarity.

2717.A. – This subsection is revised to delete examples of outdoor areas routinely used by residents where unsafe physical hazards exist.

**Instructions:**

Amend Regulation 61-84, Standards for Licensing Community Residential Care Facilities, pursuant to each individual instruction provided below with the text of the amendments.

**Text:**

The following sections have been added, deleted, or revised. All other sections of R.61-84 will remain.

Table of Contents:

The table has been updated and is being replaced in entirety with classifications and punctuation added for consistency with the text of the regulation.

Replace Table of Contents to read:

Table of Contents

SECTION 100 - DEFINITIONS AND LICENSE REQUIREMENTS

101. Definitions.

102. References.

103. License Requirements (II).

SECTION 200 - ENFORCING REGULATIONS

201. General.

202. Inspections/Investigations.

203. Consultations.

SECTION 300 - ENFORCEMENT ACTIONS

301. General.

302. Violation Classifications.

SECTION 400 - POLICIES AND PROCEDURES

401. General (II).

SECTION 500 - STAFF/TRAINING

501. General (II).

502. Administrator (II).

503. Staffing (I).

504. Inservice Training (II).

505. Health Status (I).

506. Private Sitters (II).

SECTION 600 - REPORTING

601. Incidents.

602. Fire/Disasters (II).

603. Communicable Diseases and Animal Bites (I).

604. Administrator Change.

605. Accounting of Controlled Substances (II).

606. Emergency Placements.

607. Facility Closure.

608. Zero Census.

SECTION 700 - RESIDENT RECORDS

701. Content (II).

702. Assessment (II).

703. Individual Care Plan (II).

704. Record Maintenance.

SECTION 800 - ADMISSION/RETENTION

801. General (I).

SECTION 900 - RESIDENT CARE/SERVICES

901. General.

902. Fiscal Management (II).

903. Recreation.

904. Transportation (I).

905. Safety Precautions/Restraints (I).

906. Discharge/Transfer.

SECTION 1000 - RIGHTS AND ASSURANCES

1001. General (II).

SECTION 1100- RESIDENT PHYSICAL EXAMINATION AND TB SCREENING

1101. General (I).

SECTION 1200 - MEDICATION MANAGEMENT

1201. General (I).

1202. Medication and Treatment Orders (I).

1203. Administering Medication/Treatments (I).

1204. Pharmacy Services (I).

1205. Medication Containers (I).

1206. Medication Storage (I).

1207. Disposition of Medications (I).

SECTION 1300 - MEAL SERVICE

1301. General (II).

1302. Food and Food Storage.

1303. Food Equipment and Utensils (II).

1304. Meals and Services.

1305. Meal Service Personnel (II).

1306. Diets.

1307. Menus.

1308. Ice and Drinking Water (II).

1309. Equipment (II).

1310. Refuse Storage and Disposal (II).

SECTION 1400 - EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1401. Disaster Preparedness (II).

1402. Emergency Call Numbers.

1403. Continuity of Essential Services (II).

SECTION 1500 - FIRE PREVENTION

1501. Arrangements for Fire Department Response/Protection (I).

1502. Tests and Inspections (I).

1503. Fire Response Training (I).

1504. Fire Drills (I).

SECTION 1600 - MAINTENANCE

1601. General (II).

SECTION 1700 - INFECTION CONTROL AND ENVIRONMENT

1701. Staff Practices (I).

1702. Tuberculin Skin Testing (I).

1703. Housekeeping (II).

1704. Infectious Waste (I).

1705. Pets (II).

1706. Clean/Soiled Linen and Clothing (II).

SECTION 1800 - QUALITY IMPROVEMENT PROGRAM

1801. General (II).

SECTION 1900 - DESIGN AND CONSTRUCTION

1901. General (II).

1902. Local and State Codes and Standards (II).

1903. Construction/Systems (II).

1904. Submission of Plans and Specifications.

SECTION 2000 - GENERAL CONSTRUCTION REQUIREMENTS

2001. Height and Area Limitations (II).

2002. Fire-Resistive Rating (I).

2003. Vertical Openings (I).

2004. Wall and Partition Openings (I).

2005. Ceiling Openings (I).

2006. Firewalls (I).

2007. Floor Finishes (II).

2008. Wall Finishes (I).

2009. Curtains and Draperies (II).

SECTION 2100 - HAZARDOUS ELEMENTS OF CONSTRUCTION

2101. Furnaces and Boilers (I).

2102. Dampers (I).

SECTION 2200 - FIRE PROTECTION EQUIPMENT AND SYSTEMS

2201. Firefighting Equipment (I).

2202. Automatic Sprinkler System (I).

2203. Fire Alarms (I).

2204. Smoke Detectors (I).

2205. Flammable Liquids (I).

2206. Gases (I).

2207. Furnishings/Equipment (I).

SECTION 2300 - EXITS

2301. Number and Locations of Exits (I).

SECTION 2400 - WATER SUPPLY/HYGIENE

2401. Design and Construction (II).

2402. Disinfection of Water Lines (I).

2403. Temperature Control (I).

2404. Stop Valves.

2405. Cross-connections (I).

2406. Design and Construction of Wastewater Systems (I).

SECTION 2500 - ELECTRICAL

2501. General (I).

2502. Panelboards (II).

2503. Lighting.

2504. Receptacles (II).

2505. Ground Fault Protection (I).

2506. Exit Signs (I).

2507. Emergency Electric Service (I).

SECTION 2600 - HEATING, VENTILATION, AND AIR CONDITIONING

2601. General (II).

SECTION 2700 - PHYSICAL PLANT

2701. Facility Accommodations/Floor Area (II).

2702. Resident Rooms.

2703. Resident Room Floor Area.

2704. Bathrooms/Restrooms (II).

2705. Doors (II).

2706. Elevators (II).

2707. Corridors (II).

2708. Ramps (II).

2709. Landings (II).

2710. Handrails/Guardrails (II).

2711. Screens (II).

2712. Windows/Mirrors.

2713. Janitor's Closet (II).

2714. Storage Areas.

2715. Telephone Service.

2716. Location.

2717. Outdoor Area.

SECTION 2800 - SEVERABILITY

2801. General.

SECTION 2900 - GENERAL

2901. General.

**SECTION 100 - DEFINITIONS AND LICENSE REQUIREMENTS**

**Add eight new definitions to Section 101 in alphabetical order and adjust outline; revise three existing definitions to read:**

**101. Definitions**

F. Airborne Infection Isolation (AII). A room designed to maintain Airborne Infection Isolation, formerly called a negative pressure isolation room. An Airborne Infection Isolation room is a single-occupancy resident care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation 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 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.

G. Alzheimer’s Special Care Unit or Program. A facility or area within a facility providing a secure, segregated special program or unit for residents with a diagnosis of probable Alzheimer’s disease and/or related dementia to prevent or limit access by a resident outside the designated or separated areas, and that advertises, markets, or otherwise promotes the facility as providing specialized care/services for persons with Alzheimer’s disease and/or related dementia or both.

H. Annual. A time period that requires an activity to be performed at least every twelve to thirteen (12 to 13) months.

I. Architect. An individual currently registered as such by the S.C. State Board of Architectural Examiners.

J. Assessment. A procedure for determining the nature and extent of the problem(s) and needs of a resident/potential resident to ascertain if the facility can adequately address those problems, meet those needs, and to secure information for use in the development of the individual care plan. Included in the process are an evaluation of the physical, emotional, behavioral, social, spiritual, nutritional, recreational, and, when appropriate, vocational, educational, legal status/needs of a resident/potential resident. Consideration of each resident’s needs, strengths, and weaknesses shall be included in the assessment.

K. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific treatments, care, or services to residents. Examples of individuals who may be authorized by law to provide the aforementioned treatment/care/services may include, but are not limited to, advanced practice registered nurses, physician’s assistants.

L. Blood Assay for *Mycobacterium tuberculosis* (BAMT). A general term to refer to *in vitro* diagnostic tests that assess for the presence of tuberculosis (TB) infection with *M. tuberculosis*. This term includes, but is not limited to, IFN-γ release assays (IGRA).

M. Boarding House. A business/entity which provides room and board to an individual(s) and which does not provide a degree of personal care to more than one individual.

N. Community Residential Care Facility (CRCF). A facility which offers room and board and which, unlike a boarding house, provides/coordinates a degree of personal care for a period of time in excess of 24 consecutive hours for two or more persons, 18 years old or older, not related to the licensee within the third degree of consanguinity. It is designed to accommodate residents’ changing needs and preferences, maximize residents’ dignity, autonomy, privacy, independence, and safety, and encourage family and community involvement. Included in this definition is any facility (other than a hospital), which offers or represents to the public that it offers a beneficial or protected environment specifically for individuals who have mental illness or disabilities. These facilities may be referred to as “assisted living” provided they meet the above definition of community residential care facility.

O. Contact Investigation. Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection (LTBI) or TB disease, and treatment of these persons, as indicated.

P. 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.

Q. Consultation. A visit to a licensed facility by individuals authorized by the Department to provide information to facilities to enable/encourage facilities to better comply with the regulations.

R. Dentist. An individual currently licensed to practice dentistry by the S.C. Board of Dentistry.

S. Dietitian. A person who is registered by the Commission on Dietetic Registration.

T. Department. The S.C. Department of Health and Environmental Control (DHEC).

U. Designee. A staff member designated by the administrator to act on his/her behalf.

V. Direct Care Staff Member/Direct Care Volunteer. Those individuals who provide assistance with activities of daily living to residents.

W. Discharge. The point at which residence in a facility is terminated and the facility no longer maintains active responsibility for the care of the resident.

X. Dispensing Medication. The transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person as permitted by law, to the ultimate consumer or his/her agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a resident.

Y. Existing Facility. A facility which was in operation and/or one which, as approved by the Department, began the construction or renovation of a building, for the purpose of operating the facility, prior to the promulgation of this regulation. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under this regulation.

Z. Facility. A community residential care facility licensed by the Department.

AA. Health Assessment. An evaluation of the health status of a staff member/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/protocol shall be reviewed annually by the physician, with a copy maintained at the facility.

BB. Incident. An unusual unexpected adverse event resulting in harm, injury, or death of staff or residents, accidents, *e.g*., medication errors, adverse medication reactions, elopement of a resident.

CC. Individual Care Plan (ICP). A documented regimen of appropriate care/services or written action plan prepared by the facility for each resident based on assessment data and which is to be implemented for the benefit of the resident.

DD. Initial License. A license granted to a new facility.

EE. Inspection. A visit by authorized individuals to a facility or to a proposed facility for the purpose of determining compliance with this regulation.

FF. Investigation. A visit by authorized individuals to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

GG. Latent TB Infection (LTBI). Infection with *M. tuberculosis*. Persons with Latent TB Infection carry the organism that causes TB but do not have TB disease, are asymptomatic, and are noninfectious. Such persons usually have a positive reaction to the tuberculin skin test and/or positive BAMT.

HH. Legend Drug.

1. A drug when, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements:

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

b. “Rx only” or;

2. A drug which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

3. Any drug products considered to be a public health threat, after notice and public hearing as

designated by the S.C. Board of Pharmacy; or

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

II. License. The authorization to operate a facility as defined in this regulation and as evidenced by a current certificate issued by the Department to a facility.

JJ. Licensed Nurse. A person to whom the S.C. Board of Nursing has issued a license as a registered nurse or licensed practical nurse.

KK. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care/services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

LL. Local Transportation. The maximum travel distance the facility shall undertake, at no cost to the resident, as addressed by the resident written agreement, to secure/provide health care for resident. Local transportation shall be based on a reasonable assessment of the proximity of customary health care resources in the region, *e.g.*, nearest hospitals, physicians and other health care providers, and appropriate consideration ofresident preferences.

MM. Medication. A substance that has therapeutic effects, including, but not limited to, legend, nonlegend, herbal products, over-the counter, nonprescription, vitamins, and nutritional supplements, etc.

NN. New Facility. All buildings or portions of buildings, new and existing building(s), that are:

1. Being licensed for the first time;

2. Providing a different service that requires a change in the type of license;

3. Being licensed after the previous licensee’s license has been revoked, suspended, or after the

previous licensee has voluntarily surrendered the license and the facility has not continuously operated.

OO. Nonlegend Drug. A drug 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.

PP. Peak Hours. Those hours from 7 a.m. to 7 p.m., or as otherwise approved in writing by the Department.

QQ. Personal Care. The provision by the staff members/direct care volunteers of the facility of one or more of the following services, as required by the individual care plan or orders by the physician or other authorized healthcare provider or as reasonably requested by the resident, including:

1. Assisting and/or directing the resident with activities of daily living;

2. Being aware of the resident’s general whereabouts, although the resident may travel independently in the community;

3. Monitoring of the activities of the resident while on the premises of the residence to ensure his/her health, safety, and well-being.

RR. Personal Monies. All monies which are available to the resident for his/her personal use, including family donations.

SS. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

TT. Physical Examination. An examination of a resident by a physician or other authorized healthcare provider which addresses those issues identified in Section 1101 of this regulation.

UU. Physician. An individual currently licensed to practice medicine by the S.C. Board of Medical Examiners.

VV. Physician’s Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

WW. Private Sitter. A private contractor not associated with or employed by the facility with whom the resident or the resident’s responsible party contracts to provide sitter or companion services.

XX. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care/services, identify the ways to improve its performance, and take actions that result in higher quality of care/services for the facility’s residents.

YY. Quarterly. A time period that requires an activity to be performed at least four (4) times a year within intervals ranging from eighty-one to ninety-nine (81 to 99) days.

ZZ. Ramp. An inclined accessible route that facilitates entrance to or egress from or within a facility.

AAA. Related/Relative. This degree of kinship is considered “within the third degree of consanguinity,” *e.g.*, a spouse, son, daughter, sister, brother, parent, aunt, uncle, niece, nephew, grandparent, great-grandparent, grandchild, or great-grandchild.

BBB. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is applicable in instances when there are ownership changes.

CCC. Resident. Any individual, other than staff members/volunteers or owner and their family members, who resides in a facility.

DDD. Resident Room. An area enclosed by four ceiling high walls that can house one or more residents of the facility.

EEE. Respite Care. Short-term care (a period of six weeks or less) provided to an individual to relieve the family members or other persons caring for the individual.

FFF. Responsible Party. A person who is authorized by law to make decisions on behalf of a resident, to include, but not be limited to, a court-appointed guardian (or legal guardian as referred to in the Resident’s Bill of Rights) or conservator, or health care or other durable power of attorney.

GGG. Restraint. A device which inhibits the movement of a resident, *e.g.*, posey vest, geri-chair.

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

III. Risk Assessment**.** An initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* in a particular healthcare setting. To perform a risk assessment, the following factors shall be considered: the community rate of TB, number of TB patients encountered in the setting, and the speed with which patients with TB disease are suspected, isolated, and evaluated. The TB risk assessment determines the types of administrative and environmental controls and respiratory protection needed for a setting.

JJJ. Sponsor. The public agency or individual involved in one or more of the following: protective custody authorized by law, placement, providing ongoing services, or assisting in providing services to a resident(s) consistent with the wishes of the resident or responsible party or specific administrative or court order.

KKK. Staff Member. An adult, to include the administrator, who is a compensated employee of the facility on either a full or part-time basis.

LLL. Suspend License. An action by the Department requiring a facility to cease operations for a period of time or to require a facility to cease admitting residents, until such time as the Department rescinds that restriction.

MMM. Volunteer. An adult who performs tasks at the facility at the direction of the administrator without compensation.

**102. References.**

**Add Section 102.B.16 to read:**

16. Guidelines for Preventing the Transmission of *Mycobacterium* *tuberculosis* in Health-Care Settings, December 30, 2005;

**103. License Requirements (II).**

**Revise five subsections in Section 103; delete two subsections; other subsection items remain the same; adjust outline in alphabetical order.**

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise/market) as a community residential care facility/assisted living facility in S.C. without first obtaining a license from the Department. Admission of residents prior to the effective date of licensure is a violation of Section 44-7-260(A)(6) of the S.C. Code of Laws, 1976, as amended. When it has been determined by the Department that room, board, and a degree of personal care to two or more adults unrelated to the owner is being provided at a location, and the owner has not been issued a license from the Department to provide such care, the owner shall cease operation immediately and ensure the safety, health, and well-being of the occupants. Current/previous violations of the S.C. Code and/or Department regulations may jeopardize the issuance of a license for the facility or the licensing of any other facility, or addition to an existing facility which is owned/operated by the licensee. The facility shall provide only the care/services it is licensed to provide pursuant to the definitions in Sections 101.N and 101.QQ of this regulation. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity licensed by the Department makes application for another facility or increase in licensed bed capacity, the currently licensed facility/activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or amended license to the existing facility. A copy of the licensing standards shall be maintained at the facility and accessible to all staff members/volunteers. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

D. Licensed Bed Capacity. No facility that has been authorized to provide a set number of licensed beds, as identified on the face of the license, shall exceed the bed capacity. No facility shall establish new care/services or occupy additional beds or renovated space without first obtaining authorization from the Department. Beds for use of staff members/volunteers are not included in the licensed bed capacity number, provided such beds and locations are so identified and used exclusively by staff members/volunteers. (I)

E. Persons Received in Excess of Licensed Bed Capacity. No facility shall receive for care or services persons in excess of the licensed bed capacity, except in cases of justified emergencies. (I)

**EXCEPTION**: In the event that the facility temporarily provides shelter for evacuees who have been displaced due to a disaster, then for the duration of that emergency, provided the health, safety, and well-being of all residents are not compromised, it is permissible to temporarily exceed the licensed capacity for the facility in order to accommodate these individuals (See Section 606).

F. Living Quarters for Staff Members. In addition to residents, only staff members, volunteers, or owners of the facility and members of the owner’s immediate family may reside in facilities licensed under this regulation. Resident rooms shall not be utilized by any individuals other than facility residents, nor shall bedrooms of staff members/family members of the owner or the licensee be utilized by residents. Staff members/family members of the owner or licensee/volunteers shall not use resident living rooms, recreational areas or dining rooms unless they are on duty.

G. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, services, personal safety, fire safety, or the well-being of any resident or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee’s failure to comply with the laws and regulations of this State.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but which are not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, *e.g.*, interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

6. Separate licenses are not required, but may be issued, for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

7. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

8. Facilities may furnish respite care provided compliance with the standards of this regulation are met.

H. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in S.C. The Department shall determine if names are similar. If the facility is part of a “chain operation” it shall then have the geographic area in which it is located as part of its name.

I. Application. Applicants for a license shall submit to the Department a complete and accurate application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes both the applicant’s oath assuring that the contents of the application are accurate/true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; 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. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his/her address is different from that of the facility, the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant’s ability to comply with these regulations. Corporations or limited partnerships, limited liability companies or any other organized business entity must be registered with the S. C. Office of the Secretary of State if required to do so by S. C. state law.

J. Licensing Fees. The annual license fee shall be $10.00 per licensed bed or $75.00 whichever is greater. Such fee shall be made payable by check or credit card to the Department and is not refundable. Fees for additional beds shall be prorated based upon the remaining months of the licensure year. If the application is denied or withdrawn, a portion of the fee may be refunded based upon the remaining months of the licensure year, or $75.00 whichever is lesser.

K. Late Fee. Failure to submit a renewal application or fee 30 days or more after the license expiration date may result in a late fee of $75.00 or 25% of the licensing fee amount, whichever is greater, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time-period specified by the Department may result in an enforcement action.

L. License Renewal. For a license to be renewed, applicants shall file an application with the Department, pay a license fee, and shall not be undergoing enforcement actions by the Department. If the license renewal is delayed due to enforcement actions, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable.

M. Change of License.

1. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership;

b. Change of licensed bed capacity;

c. Change of facility location from one geographic site to another.

2. Changes in facility name or address (as notified by the post office) shall be accomplished by application or by letter from the licensee.

N. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and wellbeing of the residents are not compromised, and provided the standard is not specifically required by statute.

**SECTION 200 – ENFORCING REGULATIONS**

**Section 202. Inspections/Investigations.**

**Revise Section 202.E to read:**

E. A copy of the most recent report of the resident care focused inspection and the most recent general inspection conducted by the Department, including the facility response, shall be available in a conspicuous place in a public area within the facility with the redaction of the names of those individuals in the report as provided by Sections 44-7-310 and 44-7-315 of the S.C. Code of Laws, 1976, as amended.

**SECTION 300 – ENFORCEMENT ACTIONS**

**Section 302. Violation Classifications.**

**Revise Section 302.E to read:**

E. In determining anenforcement action the Department shall consider the following factors:

1. Specific conditions and their impact or potential impact on health, safety or well-being of the residents including: deficiencies in medication management, such as evidence that residents are not routinely receiving their prescribed medications; serious waste water problems, such as toilets not operating or open sewage covering the grounds; housekeeping/maintenance/fire and life safety-related problems thatpose a health threat to the residents; power/water/gas or other utility and/or service outages; residents exposed to air temperature extremes that jeopardizetheir health; unsafe condition of the building/structure such as a roof in danger of collapse; indictment of an administrator for malfeasance or afelony, which by its nature, such as drug dealing, indicates a threat to the residents; direct evidence of abuse, neglect, or exploitation; lack of food or evidence that the residents are not being fed properly; no staff available at the facility with residents present; unsafe procedures/treatment being practiced by staff; (I)

2. Repeated failure of the licensee/facility to pay assessed charges for utilities and/or services

resulting in repeated or ongoing threats to terminate the contracted utilities and/or services. (II)

3. Efforts by the facility to correct cited violations;

4. Overall conditions of the facility;

5. History of compliance; and

6. Any other pertinent conditions that may be applicable to current statutes and regulations.

**Revise Section 302.F to read:**

F. When imposing a monetary penalty, the Department may invoke S.C. Code Ann. Section 44-7-320 (C) (1976, as amended) to determine the dollar amount or may utilize the following schedule:

**Frequency of violation**

**of standard within a**

**36-month period:**

**MONETARY PENALTY RANGES**

|  |  |  |  |
| --- | --- | --- | --- |
| **FREQUENCY** | **CLASS I** | **CLASS II** | **CLASS III** |
| 1st | $500 – 1,500 | $300 - 800 | $100 - 300 |
| 2nd | 1000 – 3000 | 500 – 1500 | 300 - 800 |
| 3rd | 2000 – 5000 | 1000 – 3000 | 500 – 1500 |
| 4th | 5000 | 2000 – 5000 | 1000 – 3000 |
| 5th | 5000 | 5000 | 2000 – 5000 |
| 6th | 5000 | 5000 | 5000 |

**Revise Section 302.G to read:**

G. Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a license and/or the imposition of monetary penalties where an enforcement order has been issued may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.

**SECTION 400 – POLICIES AND PROCEDURES**

**Section 401. General (II).**

**Revise Section 401.A to read:**

A. Written policies and procedures addressing each section of this regulation regarding resident care, rights, and the operation of the facility shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation. The policies and procedures shall address the provision of any special care offered by the facility which would include how the facility shall meet the specialized needs of the affected residents such as Alzheimer’s disease and/or related dementia, physically/developmentally disabled, in accordance with any laws which pertain to that service offered, *e.g.*, Alzheimer’s Special Care Disclosure Act. Facilities shall establish a time-period for review of all policies and procedures. These policies and procedures shall be accessible at all times and a hard copy shall be available or be readily accessible.

**SECTION 500 – STAFF/TRAINING**

**Section 501. General (II).**

**Revise Section 501.B to read:**

B. Staff members/direct care volunteers/private sitters of the facility shall not have a prior conviction or pled no contest (nolo contendere) to abuse, neglect, or exploitation of a child or a vulnerable adult as defined in S. C. Code Ann. Section 43-35-10, *et seq.* (1976, as amended). (I)

**Section 502. Administrator.**

**Revise Section 502.A to read:**

A. The facility administrator shall be licensed as a CRCF administrator in accordance with S.C. Code Ann. Section 40-35-30 (1976, as amended). In addition, all other applicable provisions of Title 40, Chapter 35, S.C. Code of Laws 1976, as amended, shall be followed.

**Section 503. Staffing (I).**

**Revise 503.B to read:**

B. The number and qualifications of staff members/volunteers shall be determined by the number and condition of the residents. There shall be sufficient staff members/volunteers to provide supervision, direct care and basic services for residents, *e.g****.*,** those with Alzheimer’s disease and/or related dementia or in an Alzheimer’s special care unit or program. The minimum number of staff members/volunteers that shall be maintained in all facilities:

**Section 504. Inservice Training (II).**

**Revise Section 504.A introductory only; subsection items 1-11 remain the same:**

A. Documentation of all inservice training shall be signed and dated by both the individual providing

the training and the individual receiving the training. The following training shall be provided by appropriate resources, *e.g.*, licensed/registered persons, video tapes, books, *etc.*, to all staff members/direct care volunteers and private sitters in the context of their job duties and responsibilities, prior to resident contact and at a frequency determined by the facility, but at least annually unless otherwise specified by certificate, *e.g.,* cardiopulmonary resuscitation (CPR):

**Revise Section 504.B to read:**

B. At least one staff person shall be trained and responsible for providing/coordinating recreational activities for the residents and shall receive appropriate training prior to contact with residents and at least annually thereafter. Documentation of staff training for providing/coordinating recreational activities shall be maintained.

**Add new Section 506 to read:**

**Section 506. Private Sitters (II).**

A. Unless the written agreement (See Section 901.A) between a resident and the facility prohibits the use of private sitters, the facility shall establish a formalized private sitter program directed by a facility staff member so that residents or their responsible party may contract for sitter services.

1. The facility shall assure that private sitters have been chosen in accordance with the Residents

Bill of Rights.

2. Facilities allowing the use of private sitters shall establish written policies and procedures for

private sitters that include an orientation to the facility consisting, at least, of the following:

a. Residents’ rights;

b. Confidentiality;

c. Disaster preparedness;

d. Emergency response procedures;

e. Safety procedures and precautions; and

f. Infection control.

3. There shall be accurate current information maintained regarding private sitters including:

a. Name, address and telephone number;

b. Documentation of orientation to the facility, including residents’ rights, regulation

compliance, policies and procedures, training, and duties;

c. Date of initial resident contact may be maintained by the facility, if applicable.

B. The facility shall maintain the following documentation regarding private sitters:

1. A health assessment (in accordance with Section 505.A) within twelve (12) months prior to

initial resident contact or his or her first day working as a private sitter;

2. A criminal record check (See Section 501.B.) completed prior to working as a private sitter;

3. Determination of TB status (See Section 1702.D.) prior to initial resident contact or his or her

first day working as a private sitter.

C. Private sitters shall not be included in the minimum staffing requirements of Section 503.B.

D. Private sitters shall sign in and sign out with facility staff upon entering or leaving the facility. Private sitters shall display identification in accordance with facility policies and procedures that is visible at all times while on duty.

**SECTION 600 – REPORTING**

**Revise Section 601 to read:**

**Section 601. Incidents.**

A. A record of each incident and/or accident, including usage of mechanical/physical restraints, involving residents, staff members or volunteers, occurring in the facility or on the facility grounds, shall be documented, reviewed, investigated, and if necessary, evaluated in accordance with facility policies and procedures, and retained.

B. Serious incidents and/or medical conditions as defined in Section 601.C and any sudden or unexpected illness or medication administration error resulting in death or inpatient hospitalization shall be reported immediately via telephone to the attending physician, the resident’s next-of-kin or responsible party, and the sponsoring agency.

C. A serious incident is one that results in death or a significant loss of function or damage to a body structure, not related to the natural course of a resident’s illness or underlying condition or normal course of treatment, and resulting from an incident occurring within the facility or on the facility grounds. A serious incident shall be considered as, but is not limited to:

1. Falls or trauma resulting in fractures of major limbs or joints;

2. Resident suicides;

3. Medication errors;

4. Criminal events or assaults against residents;

5. Medical equipment errors; or,

6. Resident neglect or exploitation, suspected or confirmed resident abuse.

D. The Department’s Division of Health Licensing shall be notified in writing within ten (10) days of the occurrence of a serious incident.

E. Reports submitted to the Department shall contain at a minimum: facility name, resident age and sex, date of incident, location, witness names, extent and type of injury and how treated, *e.g.*, hospitalization, identified cause of incident, internal investigation results if cause unknown, identity of other agencies notified of incident and the date of the report.

F. Incidents where residents have left the premises without notice to staff members of intent to leave and have not returned to the facility within twenty-four (24) hours shall be reported to the administrator or his or her designee, local law enforcement, and the resident’s responsible party, when appropriate. The Division of Health Licensing shall be notified in writing not later than ten (10) days of the occurrence. When residents who are cognitively impaired leave the premises without notice to staff members, regardless of the time-period of departure, the administrator or his or her designee, local law enforcement, next-of-kin, and sponsoring agency shall be contacted immediately by telephone or facsimile. DHL shall be notified not later than ten (10) days of the occurrence.

G. Medication errors and adverse medication reactions shall be reported immediately after discovery to the prescriber and other staff in accordance with facility policies and procedures.

H. Changes in a resident’s condition, to the extent that serious health concerns, *e.g.*, heart attack, are evident, shall be reported to the attending physician and the next-of-kin or responsible party in a timely manner, consistent with the severity or urgency of the condition in accordance with facility policies and procedures. (I)

I. Abuse and suspected abuse, neglect, or exploitation of residents shall be reported to the South Carolina Long-Term Care Ombudsman Program in accordance with S.C. Code of Law Section 43-35-25 (1976, as amended).

**Revise Section 604 to read:**

**Section 604. Administrator Change.**

DHL shall be notified in writing by the licensee within ten (10) days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual, the effective date of the appointment, and a copy of the administrator‘s license and the hours each day that the newly-appointed individual will be working as the administrator of the facility.

**SECTION 700 – RESIDENT RECORDS**

**Section 701. Content (II).**

**Revise Section 701.B(6) and (10) to read:**

B. Specific entries/documentation shall include at a minimum:

6. Notes of observation. In instances that involve significant changes in a resident’s medical condition and/or the occurrence of a serious incident, notes of observation shall be documented at least daily until the condition is stabilized and/or the incident is resolved. In all other instances, notes of observation for residents shall be documented at least monthly;

10. Photograph of resident. Resident photographs shall be at a minimum two and one half inches by three and one half inches (2 ½ by 3 ½ inches) in size, dated and no more than twenty-four (24) months old unless significant changes in appearance have occurred necessitating a more recent photograph.

**Revise Section 702 to read:**

**Section 702. Assessment (II).**

A written assessment of the resident in accordance with Section 101.J. shall be conducted by a direct care staff member as evidenced by his or her signature within a time-period determined by the facility, but no later than 72 hours after admission.

**SECTION 800 – ADMISSION/RETENTION**

**Section 801. General (I).**

**Revise Sections 801.B and C; Sections A, D and E remain the same:**

B. The facility shall admit and retain only those persons appropriate for placement in a CRCF in compliance with the standards of this regulation.

C. Persons not eligible for admission/retention are:

1. Any person who is likely to endanger him/herself or others as determined by a physician or other authorized healthcare provider;

2. Any person other than an adult; (II)

3. Any person needing hospitalization or nursing home care;

4. Anyone needing the continuous daily attention of a licensed nurse. Nursing care

may be furnished to residents in need of short-term intermittent nursing care (no more than fourteen (14) consecutive days) while convalescing from illness or injury, provided the nursing services, *e.g.*, the utilization of a home health nurse for sterile dressing changes or for observation related to a surgical site, are furnished by a licensed nurse facility staff member or a home health nurse.

5. Any person who requires one of the following nursing services determined by the South Carolina Board of Nursing to require the skills of a licensed nurse for no more than fourteen (14) consecutive days:

a. Daily skilled monitoring/observation (except as permitted for no more than fourteen (14) consecutive days) due to an unstable or complex medical condition , *e.g*., brittle diabetes, dialysis patients with complications such as infections in the blood;

b. Serious aggressive, violent or socially inappropriate behavioral symptoms which cannot be controlled or improved in the facility;

c. Medications that require frequent dosage adjustment, regulation and/or monitoring, *e.g.*diabetics receiving sliding scale insulin;

d. Intravenous medications or fluids, regular intra-muscular and subcutaneous injections by staff. This does not include injections administered on a part-time or intermittent basis by non-staff licensed nurses. Routine injection(s) of insulin scheduled daily or less frequently are permitted;

e. Care of urinary catheter that cannot be managed independently by the resident;

f. Treatment of stage 2, 3 or 4 decubitus ulcers, or multiple pressure sores or other widespread skin disorder (important considerations include: signs of infection, full thickness tissue loss, or requirement of sterile technique);

g. Nasogastric tube feeding or having to be fed by a syringe or straw due to difficulties in swallowing. Gastronomy tube feedings that cannot be managed independently by the resident;

h. Suctioning of the nose and/or mouth;

i. Tracheostomy or sterile care of the tracheostomy that cannot be managed independently by the resident;

j. Receiving oxygen for the first time, which requires adjustment and evaluation of oxygen concentration;

k. Dependency in all activities of daily living for more than fourteen (14) consecutive days, *e.g*., bedridden; incapable of locomotion; unable to transfer; totally incontinent of urinary and/or bowel function; must be totally bathed and dressed and toileted and needs extensive assistance to eat. The facility should develop a transfer plan by the tenth (10th) day of total dependency for transfer on the fifteenth (15th) day if the resident is not improving; or

l. Sterile dressing changes. Licensed staff nurses or home health nurses may perform these

changes for no more than fourteen (14) consecutive days before discharge is appropriate.

6. Anyone not meeting facility requirements for admission; the facility may determine who is eligible for admission and retention in its policies, provided compliance with local, state, and federal laws and regulations is accomplished.

**SECTION 900 – RESIDENT CARE/SERVICES**

**Section 901. General.**

**Revise Section 901.A.8 to read:**

A. There shall be a written agreement between the resident, and/or his/her responsible party, and the facility. The agreement shall include at least the following:

8. Documentation of the explanation of the Resident’s Bill of Rights and the grievance procedure. (II)

**Section 902. Fiscal Management (II).**

**Revise Section 902.H to read:**

H. A report of the balance of resident finances shall be physically provided to each resident by the facility on a quarterly basis in accordance with the Resident’s Bill of Rights, regardless of the balance amount, *e.g.*, zero balance. Documentation of quarterly reports to residents shall be readily available for review.

**SECTION 1000 – RIGHTS AND ASSURANCES**

**Section 1001. General (II).**

**Revise Section 1001.L to read:**

L. Residents shall be permitted to use the telephone and shall be allowed privacy when placing or receiving telephone calls. This access shall include business hours from 7 a.m. through 8 p.m., seven (7) days a week, and other times when appropriate. This telephone service shall be available for use by residents and/or visitors for their private, discretionary use; pay phones for this purpose are acceptable. Telephones capable of only local calls are acceptable for this purpose, provided other arrangements exist to provide resident/visitor discretionary access to a telephone capable of long distance service.

**SECTION 1100 – RESIDENT PHYSICAL EXAMINATION AND TB SCREENING**

**Section 1101. General (I).**

**Revise Section 1101.A to read:**

A. A physical examination shall be completed for residents within thirty (30) days prior to admission and at least annually thereafter. Physical examinations conducted within thirty (30) days prior to admission by physicians licensed in states other than South Carolina are permitted for new admissions under the condition that residents obtain an attending physician licensed in South Carolina within thirty (30) days of admission to the facility and undergo a second (2nd ) physical examination by that physician within thirty (30) days of admission to the facility. The physical examination shall be updated to include new medical information if the resident’s condition has changed since the last physical examination was completed. The physical examination shall address:

1. The appropriateness of placement in a CRCF;

2. Medications/treatments ordered;

3. Self-administration status;

4. Identification of special conditions/care required, *e.g.*, a communicable disease, dental problems, podiatric problems, Alzheimer’s disease and/or related dementia, *etc.*; and,

5. The need of (or lack thereof) for the continuous daily attention of a licensed nurse.

**Revise Section 1101.F. to read:**

F. Isolation Provisions. Residents with contagious pulmonary tuberculosis shall be separated (See Section 1702.E) from all other noninfected residents until declared noncontagious by a physician or other authorized healthcare provider. Should it be determined that the facility cannot care for the resident to the degree which assures the health and safety of the resident and the other residents of the facility, the resident shall be relocated to a facility that can meet his/her needs.

**Revise Section 1101.G. to read:**

G. In the event that a resident transfers from a facility licensed by the Department to a CRCF, an additional admission physical examination shall not be required, provided the sending facility has had a physical examination conducted on the resident not earlier than twelve (12) months prior to the admission of the resident to the CRCF, and the physical examination meets requirements specified in Sections 1101.A - C above unless the receiving facility has an indication that the health status of the resident has changed significantly. A tuberculin skin test and/or BAMT shall be required within one (1) month after admission to the CRCF to which the resident transfers, to document baseline status for that facility. The receiving facility shall acquire a copy of the admission physical examination/tuberculin skin test and/or BAMT from the facility transferring the resident. (See Section 1702.E regarding tuberculin skin testing and/or BAMT.)

**SECTION 1200 – MEDICATION MANAGEMENT**

**Section 1201. General (I).**

**Revise Section 1201.A to read:**

A. Medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid shall be available and properly managed in accordance with local, state, and federal laws and regulations. Such management shall address the securing, storing, and administering of medications, medical supplies, first aid supplies, and biologicals, their disposal when discontinued or outdated, and their disposition at discharge, death, or transfer of a resident.

**Section 1202. Medication Orders (I).**

**Revise Section 1202 title to read:**

**Section 1202. Medication and Treatment Orders (I).**

**Revise Section 1202.A and B to read:**

A. Medications and treatments, to include oxygen, shall be administered to residents only upon orders (to include standing orders) of a physician or other authorized healthcare provider. Medications accompanying residents at admission may be administered to residents provided the medication is in the original labeled container and the order is subsequently obtained as a part of the admission physical examination. Should there be concerns regarding the appropriateness of administering medications due to the condition/state of the medication, *e.g.*, expired, makeshift or illegible labels, or the condition/state of health of the newly-admitted resident, staff members shall consult with or make arrangements to have the resident examined by a physician or other authorized healthcare provider, or at the local hospital emergency room prior to administering any medications.

B. All orders (including verbal orders) shall be received only by staff members authorized by the facility, and shall be signed and dated by a physician or other authorized healthcare provider no later than three (3) business days after the order is given.

**1203. Administering Medication (I).**

**Revise Section 1203 title to read:**

**1203. Administering Medication/Treatments (I).**

**Revise Section 1203.A to read:**

A. Doses of medication shall be administered by the same staff member who prepared them for administration. Preparation shall occur no earlier than one hour prior to administering. Preparation of doses for more than one scheduled administration shall not be permitted. Each physician ordered treatment or medication dose administered/supervised shall be properly recorded by initialing on the resident’s medication administration record (MAR) as the medication is administered or treatment record as treatment is rendered. Recording medication administration shall include medication name, dosage, mode of administration, date, time, and the signature of the individual administering or supervising the taking of the medication. The treatment record shall document the type of treatment, date and time of treatment and signature of the individual administering treatment. If the ordered dosage is to be given on a varying schedule, *e.g.*, “take two tablets the first day and one tablet every other day by mouth with noon meal,” the number of tablets shall also be recorded.

**Section 1205. Medication Containers (I).**

**Revise Section 1205.B to read:**

B. Medications for each resident shall be kept in the original container(s) including unit dose systems; there shall be no transferring between containers (except in instances such as in Section 1203.E above), or opening blister packs to remove medications for destruction or adding new medications for administration, except under the direction of a pharmacist. In addition, for those facilities that utilize the unit dose system or multi-dose system, an on-site review of the medication program by a pharmacist shall be conducted on at least a quarterly basis to assure the program has been properly implemented and maintained. For changes in dosage, the new packaging shall be available in the facility no later than the next administration time subsequent to the order.

**Section 1206. Medication Storage (I).**

**Revise Section 1206.A to read:**

A. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be locked, and of sufficient size for clean and orderly storage. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U.S. Pharmacopeia (36-46 degrees F.). If a multi-use refrigerator is used to store medications outside the secured medication storage area, a separate locked box shall be used to store medications, provided the refrigerator is near the medication storage area. Accurate thermometers (within ± 3 degrees) shall be provided in all refrigerators storing medications.

**Revise Section 1206.C to read:**

C. Records of receipt, administration and disposition of all controlled substances shall be maintained in sufficient detail to enable an accurate reconciliation.

**SECTION 1300 – MEAL SERVICE**

**Section 1306. Diets.**

**Revise Section 1306.A to read:**

A**.** If the facility accepts or retains residents in need of medically-prescribed special diets, the menus for such diets shall be planned by a professionally-qualified dietitian or shall be reviewed and approved by a physician or other authorized healthcare provider. The facility shall maintain documentation that each of these menus has been planned by a dietitian, a physician or other authorized healthcare provider. At a minimum, documentation for each resident’s special diet menu shall include the signature of the dietitian, the physician or other authorized healthcare provider, his/her title, and the date he/she signed the menu. The facility shall maintain staff capable of the preparation/serving of any special diet, *e.g.*, low-sodium, low-fat, 1200-calorie, diabetic diet. Facility staff preparing a resident’s special diet shall be knowledgeable of the procedure to prepare each special diet. The preparation of any resident’s special diet shall follow the written guidance provided by a registered dietitian, physician, or other authorized healthcare provider authorizing the resident’s special diet. For each resident receiving a special diet, this written guidance shall be documented in the resident’s record. (I)

**Section 1309. Equipment (II).**

**Revise Section 1309.A to read:**

A. Liquid or powder soap dispensers and sanitary paper towels shall be available at each food service handwash lavatory. Alcohol-based waterless hand sanitizers shall not be used in lieu of liquid or powder soap.

**SECTION 1400 – EMERGENCY PROCEDURES/DISASTER PREPAREDNESS**

**Section 1401. Disaster Preparedness (II)**

**Revise Section 1401.B.1.c to read:**

B. The disaster plan shall include, but not be limited to:

1. A sheltering plan to include:

c. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated residents that can be accommodated; sleeping, feeding, and medication plans for the relocated residents; and provisions for accommodating relocated staff members/ volunteers. The letter shall be updated annually with the sheltering facility and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one sheltering facility shall be located in a county other than these counties.

**Section 1403. Continuity of Essential Services (II).**

**Revise Section 1403 to read:**

There shall be a written plan to be implemented to assure the continuation of essential resident support services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.

**SECTION 1500 –FIRE PREVENTION**

**Section 1503. Fire Response Training (I).**

**Revise Section 1503.C to read:**

C. All residents capable of assisting in their evacuation shall be trained in the proper actions to take in the event of a fire, *e.g.*, actions to take if the primary escape route is blocked.

**SECTION 1700 – INFECTION CONTROL AND ENVIRONMENT**

**Section 1702. Tuberculin Skin Testing (I).**

**Revise Section 1702 to read:**

A. Tuberculin skin testing is a diagnostic tool for detecting *M. tuberculosis* infection. A small dose (0.1 mil) of purified protein derivative (PPD) tuberculin is injected just beneath the surface of the skin (by the intradermal Mantoux method), and the area is examined for induration (hard, dense, raised area at the site of the TST administration) forty-eight to seventy-two (48 to 72) hours after the injection (but positive reactions can still be measurable up to a week after administering the TST). The size of the indurated area is measured with a millimeter ruler and the reading is recorded in millimeters, including zero (0) mm to represent no induration. Redness/erythema is insignificant and is not measured or recorded. Authorized healthcare providers are permitted to perform tuberculin skin testing and symptom screening.

B. All facilities shall conduct an annual tuberculosis risk assessment (See Section 101.III) in accordance with CDC guidelines (See Section 102.B.16) to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

C. The risk classification, *i.e*., low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff/direct care volunteers and residents and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, *e.g.*, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, patient population, job type, or location within the setting may have separate risk classifications.

D. Staff/Direct Care Volunteers/Private Sitters Tuberculin Skin Testing

1. Tuberculosis Status. Prior to date of hire or initial resident contact, the tuberculosis status of staff/direct care volunteer/private sitters shall be determined in the following manner in accordance with the applicable risk classification:

2. Low Risk:

a. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff/direct care volunteers/private sitters (within three (3) months prior to contact with residents) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff/direct care volunteer or private sitter has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered and read to serve as the baseline prior to resident contact.

b. Periodic TST or BAMT is not required.

c. Post-exposure TST or a BAMT for staff/direct care volunteers upon unprotected exposure to

*M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

d. Post-exposure TST or a BAMT for private sitters upon unprotected exposure to *M. tuberculosis*: Written evidence of a contact investigation when unprotected exposure is identified shall be provided to the facility administrator. The private sitter shall provide documentation of a completed single TST or a BAMT prior to resident contact. If the TST or BAMT result is negative, the private sitter shall provide written evidence of an additional TST or BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended. (CDC: Guidelines for Preventing the Transmission of *Mycobacterium* *tuberculosis* in Health-Care Settings, December 30, 2005).

e. Baseline positive with or without documentation of treatment for latent TB infection (LTBI) (See Section 101.GG) or TB disease shall have a symptoms screen prior to employment and annually thereafter.

f. Upon hire, staff/direct care volunteers/private sitters with a newly positive test result for *M. tuberculosis* infection (*i.e.*, TST or BAMT) or signs or symptoms of tuberculosis, *e.g.*, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a physician. These staff members/direct care volunteers/private sitters will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.*, the Department’s TB Control program).

3. Medium Risk:

a. Baseline two-step TST or a single BAMT: All staff/direct care volunteers/private sitters (within three (3) months prior to contact with residents) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff/direct care volunteer/private sitter has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline prior to resident contact.

b. Periodic testing (with TST or BAMT): Annually, of all staff/direct care volunteers who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff/direct care volunteers with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff/direct care volunteers who have documented TB infection about symptoms of TB disease (including the staff’s and/or direct care volunteers’ responses concerning symptoms of TB disease), documenting the questioning of the staff/direct care volunteers about the presence of symptoms of TB disease, and instructing the staff/direct care volunteers to report any such symptoms immediately to the administrator. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

c. Periodic testing (with TST or BAMT): Annually, of all private sitters who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, private sitters with documented TB infection (positive TST or BAMT) shall provide the facility with written evidence of a symptom screen annually. Documentation of education about symptoms of TB disease (including responses concerning symptoms of TB disease) and written evidence of the questioning about the presence of symptoms of TB disease, and the report of any such symptoms shall be provided immediately to the facility administrator.

d. Post-exposure TST or a BAMT for staff/direct care volunteers upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation (See Section 101.O) when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff/direct care volunteers/private sitters who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

e. Post exposure TST or a BAMT for private sitters upon unprotected exposure to *M tuberculosis*: Written evidence of a contact investigation when unprotected exposure is identified shall be provided to the facility administrator. The private sitter shall provide documentation of a completed single TST or a BAMT prior to resident contact. If the TST or BAMT result is negative, the private sitter shall provide written evidence of an additional TST or BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

4. Baseline Positive or Newly Positive Test Result:

a. Baseline positive with or without documentation of treatment for latent TB infection (LTBI) or TB disease shall have a symptoms screen prior to employment and annually thereafter.

b. Upon hire, staff/direct care volunteers/private sitters with a newly positive test result for *M.tuberculosis* infection (*i.e.,* TST or BAMT) or signs or symptoms of tuberculosis, *e.g.,* cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician. These staff members/direct care volunteers/private sitters will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.,* the Department’s TB Control program).

c. Staff/direct care volunteers/private sitters who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician, and permitted to return to work only with written approval by the Department’s TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician.

E. Resident Tuberculosis Screening (I)

1. Tuberculosis Status. Prior to admission, the tuberculosis status of a resident shall be determined in the following manner in accordance with the applicable risk classification:

a. For Low Risk and Medium Risk:

1. Admission/Baseline two-step TST or a single BAMT: All residents within thirty (30) days prior to admission shall have completed the first step of the two step tuberculin skin test followed seven to twenty one (7 to 21) days later by a second test unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly-admitted resident has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered within one (1) month prior to admission to the facility to serve as the baseline. As an exception, a resident may be admitted with at least the first step of the TB screening process completed prior to admission and the second step within fourteen (14) days of admission.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for residents upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all residents who have had exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

b. Baseline Positive or Newly Positive Test Result:

1. Residents with a baseline positive or newly positive test result for *M. tuberculosis* infection (*i.e.*, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, *e.g.*, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). Routine repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician. These residents shall be evaluated for the need for treatment. If diagnosed with latent TB infection (LTBI) the resident shall be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.*, the Department’s TB Control program). For those residents diagnosed with TB disease, the facility shall assure that the affected residents follow the recommendations made by a physician with TB expertise (*i.e.,* the Department’s TB Control program).

2. Residents who are known or suspected to have TB disease shall be transferred from the facility if the facility does not have an Airborne Infection Isolation room (See Section 101.F), required to undergo evaluation by a physician, and permitted to return to the facility only with written approval by the Department’s TB Control program.

F. Individuals who have been declared in writing to be in an emergency crisis stabilization status may be admitted to the facility without the initial step of the two-step tuberculin skin test and/or while awaiting the result of a BAMT. These individuals shall be placed in an area separate from the general population. This admission to the facility may be made provided:

1. There is documentation at the facility of the declaration by Adult Protective Services of the South Carolina Department of Social Services or the South Carolina Department of Mental Health that the admission is, in fact, an emergency (NOTE: Only these agencies may declare these crisis stabilization admissions to be an emergency);

2. There is written evidence of a chest x-ray within one (1) month prior to admission and a written assessment by a physician or other authorized healthcare provider that there is no active TB and a negative assessment for signs and/or symptoms of tuberculosis; and,

3. The resident will receive the initial step of the two-step tuberculin test within twenty-four (24) hours of admission to the facility. The second step of the two-step tuberculin skin test must be administered within the next seven to fourteen (7 to 14) days.

**Section 1705. Pets (II)**

**Revise Section 1705.A to read:**

A. If the facility chooses to permit pets, healthy animals that are free of fleas, ticks, and intestinal parasites and have been screened by a veterinarian prior to resident contact, have received required inoculations, if applicable, and that present no apparent threat to the health, safety, and well-being of the residents, may be permitted in the facility, provided they are sufficiently fed and cared for and that both the pets and their housing are kept clean.

**SECTION 2200 – FIRE PROTECTION EQUIPMENT AND SYSTEMS**

**Section 2201. Firefighting Equipment (I).**

**Revise Section 2201.D to read:**

D. The kitchen shall be equipped with a minimum of one 20-BC-type fire extinguisher. Facilities with commercial fixed hood extinguishing systems shall be provided with an additional fire extinguisher of the K class type.

**Section 2207. Furnishings/Equipment (I).**

**Revise Section 2207.D to read:**

D. Wastebaskets, window dressings, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with NFPA 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films. As an exception, window blinds require no flame treatments.

**Add Section 2207.E to read:**

E. Smoking shall be allowed only in designated areas in accordance with the facility smoking policy. No smoking is permitted in resident rooms or staff bedrooms or bath/restrooms.

**SECTION 2700 – PHYSICAL PLANT**

**Section 2702. Resident Rooms.**

**Revise Section 2702.J to read:**

J. There shall be at least one (1) mirror in each resident room or resident bathroom. As an exception, when a resident’s condition is such that having a mirror may be detrimental to his/her well-being, *e.g.,* agitation and confusion associated with Alzheimer’s disease and/or related dementia, mirrors are not required.

**Section 2704. Bathrooms/Restrooms (II).**

**Revise 2704 D to read:**

D. There shall be at least one (1) handwash lavatory adjacent to each toilet. Liquid soap shall be provided in public restrooms and bathrooms used by more than one resident. Communal use of bar soap is prohibited. A sanitary individualized method of drying hands shall be available at each lavatory.

**Section 2715. Telephone Service.**

**Revise Section 2715.A to read:**

A. At least one (1) telephone shall be available on each floor of the facility with at least one (1) active main or fixed-line telephone service available.

**Section 2717. Outdoor Areas.**

**Revise Section 2717.A to read:**

A. Outdoor areas where unsafe, unprotected physical hazards exist shall be enclosed by a fence or a natural barrier of a size, shape, and density that effectively impedes travel to the hazardous area. (I)

**Fiscal Impact Statement:**

There will not be cost to the Department, the State and its political subdivisions.

**Statement of Need and Reasonableness:**

This statement of need and reasonableness was determined by staff analysis pursuant to the SC Code, Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: 61-84. Standards for Licensing Community Residential Care Facilities.

Purpose: This revision will update certain sections of the regulation that need to be addressed as determined by staff review. The Department proposes to amend Regulation 61-84 to update and enhance the following areas: definitions, *i.e.,* proposed new definitions of airborne infection isolation, blood assay for *Mycobacterium tuberculosis* (BAMT), contact investigation, incident, latent TB infection (LTBI), private sitter, quarterly and risk assessment; revision of definitions: annual, local transportation, and peak hours; Non-Departmental publications referenced in this regulation; compliance with structural and fire standards; the living quarters in the facility for individuals other than residents; application completion; the fiscal responsibilities of the proposed facility licensee and facility licensee; license fees; Department reports availability; conditions affecting the determination of enforcement action; determination of monetary penalty amounts; appeal procedure for enforcement actions; facility responsibilities for written policies and procedures; a criminal background check for direct care staff; administrator licensing law; facility staff provision of care; staff training documentation and verification; staff provision of resident recreational activities; private sitters for residents (proposed new Section at 506); facility compliance with reporting of incidents; change of administrator reporting responsibilities; time period for notes of observation; age of resident photograph; resident assessment documentation requirements; criteria for resident admission and retention; documentation requirements for statement of resident rights and grievance procedures; resident finances fiscal management documentation; resident use of telephone; content of resident physical examination; medication and first aid items availability; medication and treatment orders; time period for physician signing verbal orders; documentation of treatments; clarification of unit dose system; refrigeration of medications; documentation of controlled substances; menu approvals for medically prescribed diets; facility staff use of alcohol-based hand sanitizers; counties affected by letter of agreement for sheltering facilities; documentation of continuity of essential services; resident fire response training; tuberculin skin testing for residents and staff; health screening for facility pets; kitchen firefighting equipment; non-combustible or flame retardant materials; facility ‘no smoking’ areas; mirrors in resident rooms; use of bar soap in shared bathrooms; facility telephones for resident use; and barriers to natural or manmade bodies of water on or adjacent to the facility property. Additionally, changes will be proposed throughout the regulation to improve its overall quality, *i.e.,* stylistic changes and language clarifications. The table of contents will be updated, and other minor corrections will be proposed as needed. See Determination of Need and Reasonableness below.

Legal Authority: Section 44-7-250, S.C. Code of Laws (1976, as amended).

Plan for Implementation: This revision will take effect upon publication in the *State Register* following approval by the Board and the General Assembly. The revision will be implemented by providing the regulated community with copies of the regulation and enforced through inspections by DHEC.

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

This regulation revision is needed and reasonable because its development will satisfy a legislative mandate pursuant to S.C. Code Ann. Section 1-23-120.

The regulation was last amended July 27, 2001. Since that time there have been changes in applicable laws, *e.g.*, criminal record checks of direct care staff, and there have been certain guidelines, directives, interpretations, and changes in Division policy that have led to the necessity to amend these regulations in order to make them more up-to-date. The amendment is needed and reasonable because it will clarify/add to the current regulation in a manner that will improve methods to provide quality care and services to residents, and it will update the current regulation by incorporating certain exceptions/guidances that the Department has implemented since the last revision.

DETERMINATION OF COSTS AND BENEFITS:

There will be no cost to political subdivisions of the state. UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There will be no effect on the environment. The regulation revision will promote public health by updating standards for regulating community residential care facilities.

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

There will be an adverse effect on the public health if the regulation revision is not implemented since it is likely that continuing to utilize an outdated regulation for regulatory purposes would not advance the promotion of preventing negative health outcomes. There will be possible detrimental effect on public health in general and vulnerable adults specifically because the program will not have the resources to continue vigilant regulatory oversight of community residential care facilities in a timely, effective and efficient manner.

**Statement of Rationale:**

Department staff determined during its review of R.61-84 that it was appropriate to revise the regulation. R.61-84 was last amended in 2001. See the Statement of Determination of Need and Reasonableness above for more information regarding the factors influencing the Department staff decision to revise the regulation.