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Document No. 4288

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-70-10 et seq.

61-121. Standards for Licensing In-Home Care Providers

**Synopsis:**

South Carolina Act No. 0018, effective May 11, 2011, enacted the In-Home Care Providers Act, Section 44-70-10 et seq. S.C. Code of Laws, 1976, as amended. The Act at Section 44-70-40 directed the Department to promulgate regulations for the licensure of in-home care providers. This regulation was promulgated to comply with the Act and will address the minimum standards for licensing in-home care providers. See the Sectional Discussion below and the Statement of Need and Reasonableness herein.

A Notice of Drafting for this regulation was published in the State Register on December 23, 2011.

Sectional Discussion of New Regulation

Section 100 provides the purpose and scope of the regulation, definitions of key terms in the regulation, references, and requirements for licensure.

Section 200 discusses inspections and investigations and provides for consultations.

Section 300 describes violation classifications, factors the Department considers before initiating enforcement actions, and the process for hearings and appeals to decisions made by the Department.

Section 400 requires in-home care providers to develop written policies and procedures.

Section 500 addresses minimum requirements of in-home care provider staff including criminal background and drug screening, training, and the health status of employees.

Section 600 provides the requirements for when in-home care providers must report incidents to the Department, as well as reporting when an administrator changes, and closure of the in-home care provider business.

Section 700 discusses the contents of clients’ records. It requires clients to be assessed and a care plan initiated for the clients. It describes maintenance procedures for client records.

Section 800 requires in-home care providers to only accept clients that are appropriate for the level of care the in-home care provider is authorized to provide.

Section 900 discusses the care in-home care providers are authorized to provide to clients.

Section 1000 provides a declaration of clients’ rights.

Section 1100 requires planning for disasters and notification of clients and responsible parties or family in the event of a disaster.

Section 1200 addresses the severability of portions of the regulation.

Section 1300 provides for situations not covered by the regulation to be managed in accordance with best practices as determined by the Department.

**Instructions:** Add new R. 61-121, In-Home Care Providers, to Chapter 61 regulations.

~~Indicates Matter Stricken~~

Indicates New Matter

**Text:**

61-121. Standards for Licensing In-Home Care Providers

Statutory Authority: Section 44-70-10 et seq., S.C. Code of Laws, 1976, as amended.

TABLE OF CONTENTS

SECTION 100. PURPOSE AND SCOPE, DEFINITIONS, REFERENCES, AND REQUIREMENTS FOR LICENSURE.

101. Purpose and Scope.

102. Definitions.

103. References.

104. Requirements for Licensure. (II)

SECTION 200. ENFORCING REGULATIONS.

201. General.

202. Inspections and Investigations.

203. Consultations.

SECTION 300. ENFORCEMENT ACTIONS.

301. General.

302. Violation Classifications.

303. Appeals.

SECTION 400. POLICIES AND PROCEDURES. (II)

SECTION 500. STAFF AND TRAINING.

501. General.

502. Inservice Training. (I)

503. Administrator. (II)

504. Staff Members. (I)

505. Health Status. (I)

SECTION 600. REPORTING.

601. Incidents. (I)

602. Administrator Change.

603. Provider Closure.

SECTION 700. CLIENT RECORDS.

701. Content. (II)

702. Assessment. (II)

703. Care Services Plan. (I)

704. Record Maintenance.

SECTION 800. ACCEPTANCE AND RETENTION. (I)

SECTION 900. CLIENT CARE SERVICES. (I)

901. General.

902. Transportation. (I)

SECTION 1000. RIGHTS AND ASSURANCES. (II)

SECTION 1100. DISASTER PREPAREDNESS.

1101. Disaster Preparedness. (II)

1102. Emergency Call Numbers.

SECTION 1200. SEVERABILITY.

SECTION 1300. GENERAL.

APPENDIX: TUBERCULOSIS (TB) RISK ASSESSMENT WORKSHEET.

SECTION 100. PURPOSE AND SCOPE, DEFINITIONS, REFERENCES, AND REQUIREMENTS FOR LICENSURE.

101. Purpose and Scope.

 This regulation implements the provisions of the South Carolina In-Home Care Providers Act codified at Section 44-70-10 et seq., S.C. Code of Laws, 1976, as amended. This regulation will apply to all in-home care providers in South Carolina.

102. Definitions.

 For the purposes of these regulations the following definitions apply:

 A. Administrator. The individual designated by the licensee to have the authority and responsibility to manage the in-home care provider, is in charge of all functions and activities of the provider.

 B. Assessment. A procedure for determining the needs of a potential client to ascertain if the provider can adequately meet those needs, and to secure information for use in the development of a client focused care services plan. Consideration of each client’s needs, strengths, and weaknesses shall be included in the assessment.

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

 D. 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, interferon-gamma release assays (IGRA).

 E. Caregiver. Individual employed or contracted by the in-home care provider who provides services to clients.

 F. Client. A person that receives services or care from an in-home care provider licensed by the Department.

 G. Consultation. A visit to a licensed provider by individuals authorized by the Department to provide information to providers to enable and encourage providers to better comply with Department regulations.

 H. 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.

 I. Department. The South Carolina Department of Health and Environmental Control.

 J. 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.

 K. Health Assessment. An evaluation of the health status of a staff member by a physician, other authorized healthcare provider, or registered nurse, pursuant to written standing orders or protocol approved by a physician’s signature. The standing orders or protocol shall be reviewed annually by the physician, with a copy maintained for ready access by Department staff.

 L. Incident. An unusual unexpected adverse event resulting in harm, injury, or death of staff or client.

 M. In-Home Care. In-home care means care:

 1. Primarily intended to assist an individual with an activity of daily living or in meeting a personal rather than a medical need, but not including skilled care or a specific therapy for an illness or injury;

 2. Given to assist an individual in an activity of daily living such as walking, getting in and out of bed, bathing, dressing, feeding, using the toilet, preparing special diets, and supervising self-administered medication; and

 3. Personal in nature but not mandating the continuing attention or supervision from trained and licensed medical personnel.

 N. In-Home Care Provider (provider). A business entity, corporation, or association, whether operated for profit or not for profit, that for compensation directly provides or makes provision for in-home care services through its own employees or agents or through contractual arrangements with independent contractors or through referral of other persons to render in-home care services when the individual making the referral has a financial interest in the delivery of those services by those other persons who would deliver those services. An in‑home care provider does not include:

 1. A home health agency or hospice or an entity licensed pursuant to Section 44‑7‑260; or

 2. An individual or agency who provides only a house cleaning service; or

 3. A direct care entity defined by S.C. Code Section 44‑7‑2910 (B)(1)(e), a direct caregiver or caregiver defined by S.C. Code Section 44‑7‑2910 (B)(2)(e), or an individual who provides a service or services defined by S.C. Code Section 44‑21‑60; or

 4. An individual hired directly by the person receiving care or hired by his family; or

 5. A church or another religious institution recognized pursuant to 26 U.S.C. 501(c)(3) by the U.S. Internal Revenue Service that provides in-home care services without compensation or for a nominal fee collected to cover incidental expenses directly related to such care.

 O. Inspection. A visit by individuals authorized by the Department to a proposed or licensed in-home care provider for the purpose of determining compliance with Department regulation.

 P. Investigation. A visit by individuals authorized by the Department to a proposed or to a licensed or unlicensed in-home care provider for the purpose of determining the validity of allegations received by the Department relating to this regulation.

 Q. License. A certificate issued by the Department to an in-home care provider to provide in-home care as defined by this regulation.

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

 S. Licensee. The individual, corporation, organization, or public entity that has received a license to provide in-home care to clients and with whom rests the ultimate responsibility for compliance with this regulation.

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

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

 V. Responsible Party. A person who is authorized by law to make decisions on behalf of a client, to include, but not be limited to, a court-appointed guardian or conservator, or health care or other durable power of attorney.

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

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

 Y. Suspension of License. An action by the Department requiring a provider to cease operations for a period of time or to require a provider to cease admitting clients, until such time as the Department rescinds that restriction.

103. References.

 A. The following Departmental publication is referenced in this regulation: R.61-20, Communicable Diseases.

 B. The following non-Departmental publications are referenced within this regulation:

 1. Omnibus Adult Protection Act, S.C. Code Section 43-35-5 et seq.;

 2. Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005; 54 (No. RR-17);

 3. Nurse Practice Act, S. C. Code Section 40-33-5 et seq.;

 4. South Carolina Board of Nursing Position Statement concerning Assisting with Medications dated January 1996 and revised November 2011.

 C. The Department shall enforce new laws that may change the above noted standards and at its discretion adopt revisions to the above noted references.

104. Requirements for Licensure. (II)

 A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise and/or market) as an in-home care provider in South Carolina without first obtaining a license from the Department. When it has been determined by the Department that services are being provided and the owner has not been issued a license from the Department to provide such care services, the owner shall cease operation immediately and ensure the safety, health, and well-being of its clients. Current and/or previous violations of the S.C. Code and/or Department regulations may jeopardize the issuance of a license for the provider or the licensing of any other provider, or addition to an existing provider which is owned and/or operated by the licensee. The provider shall provide only the care services it is licensed to provide pursuant to the definitions in Section 901.B.1 through 901.B.18 of this regulation. (I)

 B. Compliance. An initial license shall not be issued to a proposed provider that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed provider is in substantial compliance with the licensing standards. A copy of the licensing standards shall be maintained by the provider and accessible to all staff members. In the event a licensee who is already licensed as an in-home care provider, or other activity licensed by the Department, makes application for another in-home care license, the currently licensed in-home care services provider and/or activity must be in substantial compliance with the applicable standards prior to the Department issuing a new or amended license. Providers shall comply with applicable local, state, and federal laws, codes, and regulations.

 C. 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 of the provider’s business office or readily available to the public.

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

 3. A license is not assignable or transferable and is subject to suspension or 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 provider at a specific location(s). A license shall be valid for one year from the date of issuance and shall be renewed annually.

 D. Provider Name. No proposed provider shall be named nor shall any existing provider have its name changed to the same or similar name as any other provider licensed in South Carolina. The Department shall determine if names are similar. The geographic area in which a provider is located must be included as part of the name if the provider is part of a franchise with multiple locations.

 E. 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 and 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. The application shall set forth the full name and address of the provider for which the license is sought and of the owner in the event the owner’s name and address is different from that of the provider, the names of the persons in control of the provider. 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 South Carolina Office of the Secretary of State if required to do so by South Carolina state law.

 1. When submitting an application for an initial or renewal license, the provider shall include evidence of either liability insurance coverage or a surety bond in lieu of liability insurance coverage. Such coverage shall be maintained for the duration of the license period. The minimum amount of coverage is one hundred thousand dollars ($100,000) per occurrence and three hundred thousand dollars ($300,000) aggregate.

 2. The provider shall ensure the organization and its contractors have appropriate indemnity coverage to compensate clients for injuries and losses resulting from services provided.

 F. Licensing Fees. The initial license fee shall be one thousand dollars ($1,000). The fee for annual license renewal shall be eight hundred dollars ($800). Such fee shall be made payable by check or credit card to the Department and is not refundable. If the application is denied, a portion of the fee may be refunded based upon the remaining months of the licensure year.

 G. Late Fee. Failure to submit a renewal application or fee within thirty (30) days of the expiration of a license may result in a late fee of twenty five percent (25%) of the licensing fee amount, 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.

 H. License Renewal. For a license to be renewed, applicants shall file an application with the Department, pay a license fee of eight hundred dollars ($800), 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.

 1. Prior to reinstatement of a suspended license, the licensee shall submit a reinstatement fee of four hundred dollars ($400).

 2. Prior to reinstatement of a revoked license, the licensee must apply for a license as provided for in Section 103.E of this regulation along with the initial licensing fee. Any time remaining from the revoked license is forfeited.

 I. Change of License.

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

 a. Change of ownership; and/or

 b. Change of provider location from one geographic site to another.

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

 3. An amendment fee of fifty dollar ($50.00) is required for each amendment.

 J. Pursuant to S.C. Code Section 44-70-80 (2011), fees collected will be retained by the Department and credited to a separate and distinct account to be used exclusively by the Department to carry out its responsibilities under this regulation.

 K. 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 clients are not compromised, and provided the standard is not specifically required by statute.

 L. The provider shall ensure that key provider staff members are accessible in person, by phone, or page during the hours of 9:00 A.M. to 5:00 P.M., Monday through Friday, except for those holidays recognized by the State of South Carolina. Those staff members shall have access to all records required for routine inspections and complaint investigations.

SECTION 200. ENFORCING REGULATIONS.

201. General.

 The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed provider in order to enforce this regulation.

202. Inspections and Investigations.

 A. Inspections by the Department shall be conducted prior to initial licensing of a provider and subsequent inspections conducted as deemed appropriate by the Department. (I)

 B. All providers are subject to inspection and/or investigation at any time without prior notice by individuals authorized by the S.C. Code of Laws. When staff members are absent, the provider shall provide information as to the expected return of staff. (I)

 C. Individuals authorized by South Carolina law shall be granted access to all properties and areas, objects, and records in a timely manner, and have the authority to require the provider to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (I)

 D. When there is noncompliance with the licensing standards, the provider shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of the inspection and/or investigation. The written plan of correction shall describe: (II)

 1. The actions taken to correct each cited deficiency;

 2. The actions taken to prevent similar recurrences; and

 3. The actual or expected completion dates of those actions.

 E. A copy of the most recent report of inspection conducted by the Department, including the provider response, shall be made available upon request, with the redaction of all client names.

203. Consultations.

 Consultations may be provided by the Department as requested by the provider or as deemed appropriate by the Department.

SECTION 300. ENFORCEMENT ACTIONS.

301. General.

 When the Department determines that an in-home care provider is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such provider, the Department, upon proper notice to the licensee, may impose a monetary penalty, deny, suspend, or revoke licenses.

302. Violation Classifications.

 Violations of standards in this regulation are classified as follows:

 A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the clients of the provider or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use by a provider may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

 B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of the clients of the provider. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

 C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

 D. Class I and II violations are indicated by notation after each applicable section, that is, “(I)” or “(II)”. Sections not annotated in that manner denote a Class III violation.

 E. In arriving at the decision to take enforcement action(s), the Department shall consider the following factors:

 1. Specific conditions and their impact or potential impact on the health, safety or well-being of the client(s) including, but not limited to: evidence that services contracted for are not routinely provided; clients exposed to air temperature extremes that jeopardize their health; unsafe condition while providing transportation services; indictment of an administrator for malfeasance or a felony, which by its nature creates a threat to the client; or direct evidence of abuse, neglect, or exploitation;

 2. Efforts by the provider to correct cited violations;

 3. History of compliance; and

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

 F. Monetary penalties assessed by the Department must be not less than one hundred dollars ($100) nor more than five thousand dollars ($5,000) for each violation of any of the provisions of this regulation. Each day a violation continues will be considered a subsequent offense. When a decision is made to impose monetary penalties, the following schedule may be used to determine the amount:

MONETARY PENALTY RANGES

|  |  |  |  |
| --- | --- | --- | --- |
|  Frequency of violation of standard within a 36-month period |  CLASS I |  CLASS II |  CLASS III |
| 1st | $ 200 - 1000 | $ 100 - 500 | $0  |
| 2nd |  500 - 2000 |  200 – 1000 |  100 - 500  |
| 3rd |  1000 - 5000 |  500 – 2000 |  200 - 1000 |
| 4th |  5000 |  1000 – 5000 |  500 - 2000 |
| 5th |  5000 |  5000 |  1000 - 5000 |
| 6th |  5000 |  5000 |  5000 |

303. Appeals.

 A Department decision involving the issuance, denial, or revocation of a license may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapters 1 and 70; and Title 1, Chapter 23. Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapters 1 and 70; and Title 1, Chapter 23.

SECTION 400. POLICIES AND PROCEDURES (II)

 A. Written policies and procedures addressing each section of this regulation shall be developed and implemented, and revised as required in order to accurately reflect the actual operations of a provider. The policies and procedures shall address the provision of any special care services offered by the provider including, but not limited to, how the provider shall meet specialized needs of the affected clients such as those with Alzheimer’s disease and/or related dementia, in accordance with any laws which pertain to that service offered. Providers shall establish a time period for periodic review of all policies and procedures. These policies and procedures shall be accessible at all times and a printed copy shall be available.

 B. By its application, the provider agrees to comply with all standards in this regulation. The policies and procedures shall describe the means by which the provider shall assure that the standards described in this regulation.

SECTION 500. STAFF AND TRAINING.

501. General.

 A. Appropriate staff members in numbers and training shall be provided to ensure the needs and conditions of clients are met and performed in compliance with this regulation, and that staff members are capable of responding to any emergency on site that might arise. Training requirements and qualifications for the tasks each performs shall be in compliance with all local, state, and federal laws. (I)

 B. Before becoming licensed as an in-home care provider, a prospective licensee must undergo a criminal record check and submit to a drug test, as provided by S.C. Code Section 44-70-60(A). (I)

 C. Before being employed as an in-home caregiver by a licensed in-home care provider, a person shall undergo a criminal background check as provided by S.C. Code Sections 44-70-60(B) and 44-7-2910 and submit to a drug test as provided by S.C. Code Section 44-70-60(B). (I)

 D. Licensed in-home care providers and individuals employed as in-home caregivers by licensed in-home care providers are subject to random drug testing as provided for in S.C. Code Section 44-70-70. The provider may choose the method of random testing that most suitably meets the provider’s needs. The provider’s policies and procedures must address random drug testing and describe the procedure chosen. (II)

 E. Drug testing shall be conducted and may be performed by a commercial drug testing laboratory or may be performed in-house. The drug testing procedure must be included in the provider’s policies and procedures. At a minimum, a five (5) panel drug screen will be utilized that tests for cannabis, cocaine, amphetamines, opiates, and phencyclidine.

 F. The provider shall ensure that direct caregivers employed by the provider do not have prior convictions or have pled no contest (nolo contendere) to abuse, neglect, or exploitation of a child or a vulnerable adult as defined in S. C. Code Section 43-35-10 et seq for child or adult abuse, neglect or mistreatment, or other similar felonies. The provider shall coordinate with appropriate abuse-related registries prior to the employment of staff to ensure compliance with this provision.

G. No supervision and/or care services shall be provided to individuals who are not clients of the provider. (I)

 H. The provider shall maintain accurate information on all staff members including, but not limited to, current address, phone number, personal, work, and training backgrounds. Each staff member shall be assigned certain duties and responsibilities. Duties and responsibilities shall be set forth in writing.

 I. When a provider contracts with others to provide services normally furnished by the provider; for example, staffing, training, professional consultant, transportation, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and that these services are to be provided by qualified individuals. The outsource provider shall comply with this regulation in regard to client care~~,~~ services, and rights.

 J. Identification Badges.

 1. All staff members shall wear badges clearly stating their names, using at a minimum, either first or last names with appropriate initials and their job or trainee titles. All trainees or probationary staff must be explicitly identified as such on their badges. This information must be clearly visible and must be stated in terms or abbreviations reasonably understandable to the average person, as recognized by the Department of Health and Environmental Control.

 2. At the request of the client, identification badges may be removed, but must be maintained on the caregiver’s person.

502. Inservice Training. (I)

Staff members shall be provided the necessary training to perform the duties for which they are responsible. Documentation of all in-service training shall be signed and dated by both the individual providing the training and the individual receiving the training. A signature for the individual providing the training may be omitted for computer based training. The provider must be able to produce a transcript for computer based training for each individual employee. Electronic signatures are acceptable. Topics that contain a skill component, for example, medication assistance, lifting techniques, must be provided in a traditional instructor and student format. The following training shall be provided by appropriate resources, for example*,* licensed and/or registered persons, training personnel, video media, books, etc*.*, to all caregivers in the context of their job duties and responsibilities, prior to client contact and at a frequency determined by the provider, but at least annually, unless otherwise specified by certificate for example, first aid:

 A. Basic first aid;

 B. Medication assistance, for designated caregivers;

 C. Depending on the type of clients, care services for of persons specific to the physical and/or mental condition of the individual, for example, Alzheimer’s disease, related dementia, cognitive disabilities, or similar disabilities;

 D. Confidentiality of client information and records and the protecting of client rights, including prevention of abuse and neglect;

 E. Fire safety and disaster preparedness within twenty four (24) hours of client contact;

 F. Documentation and recordkeeping procedures;

 G. Ethics and interpersonal relationships;

 H. Proper lifting and transfer techniques, for designated caregivers; and

 I. Universal precautions.

503. Administrator. (II)

 A. The administrator shall exercise judgment that reflects that she or he is capable of meeting the responsibilities involved in operating an in-home care provider and to ensure that the in-home care provider is in compliance with these regulations. The administrator must demonstrate adequate knowledge of these regulations.

 B. A staff member shall be designated in writing to act in the absence of the administrator, for example, a listing of the lines of authority by position title, including the names of the persons filling these positions.

504. Staff Members. (I)

 A. The number and qualifications of staff members shall be determined by the number and condition of the clients. There shall be sufficient staff to provide supervision and care services to clients.

B. Minimum qualifications for direct care staff are:

 1. A caregiver must:

 a. Be able to read, write, and communicate effectively with client and supervisor;

 b. Be capable of completing assigned job duties;

 c. Be capable of following a care services plan with minimal supervision;

 d. Have a valid driver’s license and proof of insurance if transportation is a part of the caregiver’s duties. The provider must ensure the employee’s license is valid while transporting any client of the provider by verifying the official highway department driving record of the employed individual. A copy of the driving record must be maintained in the employee’s personnel file; and

 e. Be at least eighteen (18) years of age.

 C. Licensed nurses shall not provide nursing services that are not allowed pursuant to Section 901.B of this regulation.

 D. The provider will verify nurse licensure at time of employment and will ensure that the license remains active at all times during employment. The provider must maintain a copy of the current license in the employee’s personnel file.

 E. Job Orientation. All new staff members shall be oriented, prior to client contact, to acquaint them with the organization and policies of the provider, specific duties and responsibilities of staff members, and clients’ needs.

505. Health Status. (I)

 A. All staff members who have contact with clients shall have a health assessment within twelve (12) months prior to initial client contact. The health assessment shall include tuberculin skin testing as described in Section 505.C and a screening by a healthcare provider, using criteria determined by the healthcare provider, to determine the individual is free from communicable disease and is capable of performing assigned tasks.

 B. If a caregiver is working at multiple offices operated by the same licensee, copies of records for tuberculin skin testing and the pre-employment health assessment shall be accessible in each office.

 C. Tuberculin Skin Testing. (I)

 1. All in-home care providers shall conduct an annual TB risk assessment in accordance with Centers for Disease Control and Prevention (CDC) guidelines to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken. In-home care providers shall complete the risk assessment worksheet in the Appendix herein to help determine the provider’s requirement for TB testing.

 2. The risk classification, that is, low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for in-home caregivers and the frequency of screening. A risk classification shall be determined for each in-home care providers. In certain settings, for example, providers that encompass multiple sites or types of care, specific areas defined by geography, functional units, client population, job type, or location within the setting may have separate risk classifications.

 3. Prior to date of hire or initial client contact, the tuberculosis status of an in-home caregiver shall be determined in the following manner in accordance with the applicable risk classification:

 a. Low Risk:

 (1) Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All in-home caregivers (within three (3) months prior to patient contact) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed in-home caregiver 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.

 (2) Periodic TST or BAMT is not required.

 (3). Post-exposure TST or a BAMT for in-home caregivers 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 in-home caregivers 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 (8-10) weeks after that exposure to *M. tuberculosis* ended.

b. Medium Risk:

 (1) Baseline two-step TST or a single BAMT: All in-home caregivers (within three (3) months prior to client contact) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed in-home caregiver 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.

 (2). Periodic testing (with TST or BAMT): Annually, of all in-home caregivers who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, in-home caregivers with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the in-home caregiver about symptoms of TB disease, documenting the questioning of the in-home caregiver about the presence of symptoms of TB disease, and instructing the in-home caregiver to report any such symptoms immediately to the supervisor or 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.

 (3). Post-exposure TST or a BAMT for in-home caregivers 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 in-home caregivers 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 (8-10) weeks after that exposure to *M. tuberculosis* ended.

c. Baseline Positive or Newly Positive Test Result:

 (1). In-home caregivers with a baseline positive or newly positive test result for *M. tuberculosis* infection (that is, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, for example, 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). These in-home caregivers 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 (that is, the Department’s TB Control program).

 (2). In-home caregivers 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 approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician.

 (3). 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.

SECTION 600. REPORTING.

601. Incidents (I)

 A. A record of each incident and/or accident that occurs during staff contact with clients involving clients or staff members, shall be documented, and if necessary, reviewed, investigated, and evaluated in accordance with provider policies and procedures. Documents must be retained for six (6) years.

 B. Serious incidents and/or any sudden or unexpected illness or staff member error resulting in death or inpatient hospitalization shall be reported immediately via telephone to the client’s next-of-kin or responsible party.

 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 client’s illness or underlying condition, and resulting from an incident that occurs during staff contact with clients. 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. Client suicide;

 3. Criminal events or assaults against clients which are reported and filed with the police; and/or

 4. Allegations of client abuse, neglect, or exploitation, as defined in S.C. Code Section 43-35-5 et seq., by an employee.

 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: provider name, client age and sex, date of incident, location, witness name(s), extent and type of injury and how treated, for example, hospitalization, cause of incident, internal investigation results if applicable, identity of other agencies notified of incident and the date of any such report(s).

 F. The provider shall report any allegation of abuse, neglect, or exploitation of clients to the Adult Protective Services Program in the Department of Social Services in accordance with S.C. Code Section 43-35-25, or Child Protective Services, as appropriate.

602. Administrator Change.

The Department’s Division of Health Licensing shall be notified, in writing, by the licensee within ten (10) days of any change in administrator. Notice shall include, at a minimum, the name of the newly appointed individual and the effective date of appointment.

603. Provider Closure.

 A. Prior to the temporary closure of a provider, the Department’s Division of Health Licensing shall be notified, in writing, of the intent to close and the effective closure date. Within ten (10) business days prior to the closure, the provider shall notify the Department’s Division of Health Licensing of the provisions for the maintenance of the records, the identification of those clients that will require transfer to another provider, and the date of anticipated reopening. If the provider is closed for a period longer than one year, and there is a desire to reopen, the provider shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, as if it were for a new provider. In the event that the license expires during the period of temporary closure, the licensee shall submit a license renewal application and licensing fee on schedule as if the provider were operating.

 B. Prior to the permanent closure of a provider, the Division of Health Licensing shall be notified, in writing, of the intent to close and the effective closure date. Within ten (10) business days prior to the closure, the provider shall notify the Division of Health Licensing of the provisions for the maintenance of the records, the identification of those clients that will require transfer to another provider, and the dates and amounts of client refunds. On the date of closure, the license shall be returned to the Department’s Division of Health Licensing.

SECTION 700. CLIENT RECORDS.

701. Content. (II)

 A. The provider shall initiate and maintain an organized record for each client. The record shall contain sufficient documented information to identify the client and the provider and/or person responsible for the client’s care services; ensure appropriate care services are ~~is~~ provided as needed; and promote continuity of care services among providers that is consistent with acceptable standards of practice.

 1. Records may be maintained on paper or electronically. All entries must be legible and complete. Records shall be separately signed and dated promptly by the individual responsible for ordering, providing or evaluating the care service furnished. Records may be signed electronically. If an entry is signed on a date other than the date it was made, the date of the signature shall be entered.

 2. All records must be readily accessible, in a timely manner, for inspections and investigations by Department staff.

 3. Providers that use electronic systems must provide for data backup and retrieval in the event of a system shutdown or power outage.

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

 1. An individualized plan for care services;

 2. Documentation of care services provided. Each visit by a caregiver to a client’s residence shall be documented. Documentation of visits shall include what care services were provided, any significant situation(s) encountered during the visit, the name of the caregiver providing the care services, the caregiver’s signature and date of care services provided;

 3. Special information, for example, allergies, pets, etc.; and

 4. A service agreement to include:

 a. An explanation of the specific care services furnished by the provider; for example, provision of special diet as necessary, assistance with bathing, toileting, feeding, dressing, and mobility;

 b. Disclosure of fees for all care services provided;

 c. Advance notice requirements to change fee amount;

 d. Transportation policy;

 e. Refund policy to include when monies are to be forwarded to client upon termination of care services;

 f. Termination of care services provisions to include the conditions under which the client may be refused further care services;

 g. Documentation of the explanation of the client’s rights and the grievance procedure; and

 h. Documentation attesting to the explanation of the items in the service agreement, which shall be signed by the provider and the client or the client’s responsible party or guardian.

702. Assessment. (II)

A written assessment of the client in accordance with Section 102.B of this regulation shall be conducted by a designated appropriate staff member as evidenced by his or her signature within a time period determined by the provider, but no later than seventy two (72) hours after the initial provision of care services.

703. Care Services Plan. (I)

 A. The provider shall develop a care services plan with participation by, as evidenced by their signatures, the client, administrator (or designee), and/or the responsible party when appropriate, within seven days of the initial provision of care services. The care services plan shall be reviewed and/or revised as changes in client needs occur.

 B. The care services plan shall describe:

 1. The needs of the client, including the services for which the client requires assistance, for example, what assistance, how much, who will provide the assistance, how often, and when;

 2. Requirements and arrangements for visits outside the client’s residence; and

 3. Dietary needs.

 C. The original and the most recent care services plan shall be maintained as part of the client record.

 D. In the case a provider cannot provide services with its own employees and must contract with others to provide care services, the care services plan shall delineate the responsibilities of the contractor and of the provider in meeting the needs of the client.

704. Record Maintenance.

 A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection and storage of client records.

 B. The client record is confidential, except for daily documentation that may be maintained in the client’s residence, and shall be made available only to individuals authorized by the provider and/or the S.C. Code of Laws. (II)

 C. Records generated by organizations and/or individuals contracted by the provider for care services shall be maintained by the in-home care provider.

 D. The provider shall determine the medium in which information is stored.

 E. Upon termination of care services to a client, the record shall be completed within thirty (30) days, and filed in an inactive or closed file maintained by the licensee. Prior to the closing of a provider for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations. The licensee shall notify the Department’s Division of Health Licensing, in writing, describing these arrangements and the location of the records.

 F. Records of clients shall be maintained for at least six (6) years following discharge of the client. Other regulation required documents, for example, reports of visit, complaint investigation reports, etc., shall be retained for at least twelve (12) months or since the last inspection by Department’s Division of Health Licensing, whichever is longer.

 G. Records of clients are the property of the provider and shall not be removed from the custody of the provider without court order

SECTION 800. ACCEPTANCE AND RETENTION (I)

 A. Individuals seeking care services shall be identified as appropriate for the level of care services, offered. The provider shall establish acceptance criteria that are consistently applied and comply with local, state, and federal laws and regulations.

 B. The provider shall accept and retain only those persons appropriate for care services that may be provided by an in-home care provider in compliance with the standards of this regulation.

 C. When the provision of care services by the provider does not meet the needs of the client, or if any client becomes in need of medical or nursing supervision, or if the provider does not have the capability to provide necessary care services, the provider shall recommend to the client, or responsible party, to seek care services from a source which can meet those needs. The recommendation shall be documented in the client’s record.

SECTION 900. CLIENT CARE SERVICES (I)

901. General.

 A. Care services shall be rendered effectively and safely in accordance with provider policies and procedures and the caregiver’s level of training, and precautions taken for clients with special conditions, for example, pacemakers, wheelchairs, Alzheimer’s disease and/or related dementia, etc. Appropriate assistance shall be provided to clients, as needed. Each provider is required to provide only those services and only to the acuity levels which are specifically designated in the service agreement between the client, or the client’s responsible party or guardian, and the provider.

 B. Care services provided by caregivers is strictly limited to non-medical tasks. Care services may include the following:

 1. Meal planning, preparation and limited assistance in eating. Caregivers must demonstrate a high level of cleanliness and practice basic principles of food safety;

 2. Bathing;

 3. Grooming;

 4. Dressing;

 5. Personal hygiene, including toileting;

 6. Assisting clients in and out of bed, chairs, or vehicles, and repositioning them when required;

 7. Assistance with walking, including the use of walkers, canes, and crutches;

 8. Cleaning the client’s home;

 9. Laundry care;

 10. Shopping for the client. Receipts must be provided to the client and all client funds must be accounted for;

 11. Running errands;

 12. Provide transportation to appointments, shopping, etc;

 13. Address safety hazards found in clients’ homes. Hazards that cannot be corrected by the caregiver must be reported to an administrator;

 14. Assistance with communication;

 15. Monitoring the client’s condition, that is, temperature, pulse rate, respiration rate, and blood pressure, if trained to do so;

 16. Medication assistance as allowed by the Nurse Practice Act and South Carolina Board of Nursing Position Statement concerning Assisting with Medications dated January 1996 and revised November 2011.;

 17. Strength and balance training; and

 18. Skin care.

 C. The provision of care services to clients shall be guided by the recognition of and respect for cultural differences to assure reasonable accommodations shall be made for clients with regard to differences, such as, but not limited to, religious practice and dietary preferences.

 D. In the event of closure of a provider for any reason, the provider shall insure continuity of care services by promptly notifying the client, or the client’s responsible party or guardian, and arranging for referral to other providers. (II)

902. Transportation. (I)

The provider shall secure or provide transportation for clients as agreed upon in the care services plan.

SECTION 1000. RIGHTS AND ASSURANCES (II)

Client rights shall be guaranteed by the provider. A document that addresses the following shall be provided to the client:

 A. Care~~,~~ services, and items furnished by the provider, the charges, and those services that are the responsibilities of the client shall be delineated in writing. The client shall be made aware of such charges and/or care services and changes to charges and/or care services as verified by the signature of the client or responsible party or guardian;

 B. Confidentiality of client records, to include privacy and disclosure requirements;

 C. Respect for the client’s property by the providers’ employees;

 D. Clients shall be provided the opportunity to provide input into changes in care;

 E. Clients shall be free from abuse, neglect, and exploitation by the provider’s employees;

 F. The provider shall develop a grievance and/or complaint procedure which includes the address and phone number of the Division of Health Licensing, and a provision prohibiting retaliation should the grievance right be exercised. A copy must be provided to the client or responsible party or guardian as part of the service agreement. Documentation must be maintained as a permanent part of the client record;

 G. The telephone number, available services, and hours of operation of the provider;

 H. The client will receive care services with respect and dignity.

1100. DISASTER PREPAREDNESS.

1101. Disaster Preparedness (II)

 A. The provider shall develop a disaster plan.

 B. The disaster plan shall identify the care services obligations of the provider to be provided to the client during an emergency due to a disaster.

 C. The disaster plan will outline the process for notifying clients, responsible parties or family members in the event provider staff cannot provide care services to the client, due to disaster. The provider must notify county emergency preparedness service of the number and locations of clients that will require assistance from disaster preparedness or emergency services personnel in the event a provider can no longer provide care due to disaster. A provider’s caregiver shall not abandon a client in the event they are providing care services at the time of the disaster until properly relieved or it is safe to do so or after the appropriate notifications are made.

 D. The disaster plan shall be explained in detail to the client or the client’s responsible party or guardian. Documentation attesting to the explanation of the disaster plan shall be signed by the provider and the client or the client’s responsible party or guardian.

1102. Emergency Call Numbers

Emergency call data shall be readily available to the caregiver and shall include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

SECTION 1200. SEVERABILITY.

 In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 1300. GENERAL.

 Conditions arising which have not been addressed in these regulations shall be managed in accordance with the best practices as determined by the Department.

**APPENDIX**

Annual TB Risk Assessment

In-Home Care Providers

The Tuberculosis (TB) risk assessment worksheet of this appendix applies to Section 505.C.1 of this regulation and shall be used in performing TB risk assessments for in-home care providers. Providers with more than one type of setting shall apply this worksheet to each setting.

Contact the Department of Health and Environmental Control’s TB control program to obtain epidemiologic data necessary to conduct the TB risk assessment.

Provider: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of Clients: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_County:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Completed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Part A. Incidence of TB in the provider organization**

1. Number of TB cases identified in provider staff and clients combined in the past year? (Check only one box)

 ⬜ No cases within the last 12 months.

 ⬜ Less than 3 cases identified in the past year.

 ⬜ 3 or more cases identified in the past year.

 ⬜ Evidence of ongoing *M. tuberculosis* transmission.

2. Number of TB cases identified in your County in the last year? \_\_\_\_\_\_\_

 Information may be obtained from the TB Control section of the South Carolina Department of Health and Environmental Control’s web site.

3. Number of TB cases identified in the State of South Carolina the last year? \_\_\_\_\_\_\_

 Information may be obtained from the TB Control section of the South Carolina Department of Health and Environmental Control’s web site.

**Part B. TB Infection Control Procedure**

⬜ Yes ⬜ No Are all new hires screened for TB before initial client contact?

⬜ Yes ⬜ No Does the provider have a written procedure for managing confirmed or suspected TB cases? (See Section 400.A for the requirement of a written procedure.)

⬜ Yes ⬜ No Does the provider’s procedure assure prompt detection and appropriate management of infectious persons, including prevention of further transmission of TB?

**Part C. Assigning a Risk Classification (*check only one box*)**

⬜ If there have been no cases of TB identified in the provider in the past 12 months, this provider may be classified as LOW RISK.

⬜ If there have been less than 3 cases of TB identified in the provider in the past 12 months, this provider may be classified as LOW RISK.

⬜ If there have been 3 or more cases of TB identified in the provider in the past 12 months, this provider may be classified as MEDIUM RISK.

⬜ There is evidence of ongoing *M. tuberculosis* transmission and the provider has reported the events to the County Health Department and appropriate measures have been implemented. *(This is a temporary classification only warranting immediate investigation. After the ongoing transmission has ceased, the setting will be reassessed for classification).*

This TB risk assessment is performed annually to assess and assign an appropriate risk classification.

Date of next TB Risk Assessment Review (annually) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- |
| **Provider TB Risk Classification** |

|  |  |
| --- | --- |
| **Low Risk Setting**Less than 3 TB cases/year(see Part A)**AND**No risk factors are present(See Part B) | Low Risk TB Screening* Baseline two step TST or single BAMT upon hire and prior to client contact.
* If TST is positive or employee is symptomatic, obtain chest X-ray and refer to Health Department for a symptom assessment and medical evaluation.
* NO ANNUAL TST or BAMT required.
* Perform annual symptom assessment if documented prior positive TST or has documentation of prior active TB disease.
* Persons identified as a contact to an infectious case and having unprotected exposure will be evaluated in accordance with the Health Department’s contact investigation policies and procedures.
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| --- | --- |
| **Medium Risk** **Setting**3 or more TB cases/year(see Part A)**OR**Other risk factors apply (see Part B) | Medium Risk TB Screening* Baseline two step TST or single BAMT upon hire and prior to client contact.
* If TST is positive or employee is symptomatic, obtain chest X-ray and refer to Health Department for a symptom assessment and medical evaluation.
* Perform ANNUAL TB screening test (TST, BAMT or symptom assessment) for each employee.
* Perform annual symptom assessment if documented prior positive TST or has documentation of prior active TB disease treatment.
* Persons identified as contact to an infectious case and having unprotected exposure will be evaluated in accordance with the Health Department’s investigation policies and procedures.
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| --- | --- |
| **Potential** **Ongoing** **Transmission** **Setting**Evidence ofongoing *M.**tuberculosis* transmission*This is a**temporary* *classification only,* *warranting* *immediate* *investigation.* *After the ongoing* *transmission has**ceased, the* *setting will be* *reassessed for* *classification.* | Potential Ongoing Transmission TB Screening* Report to local health department immediately.
* Persons identified as a contact to an infectious case and having unprotected exposure will be evaluated in accordance with the Health Department’s contact investigation policies and procedures.
* Baseline two-step TST for TB or single BAMT for any new hire and prior to client contact while in this category.
* Consult and coordinate with the Health Department for guidance as to when transmission has ceased and a new risk assessment can be completed.
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**Sample Indications for Two-Step Tuberculin Skin Testing – TST**

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| --- | --- |
| **Employee & Client TST Situation** | **Recommended TST Testing** |
| 1. No previous TST or BAMT result. | 1. Two-step baseline TST or single BAMT completed upon hire and prior to client contact. |
| 2. Previous negative TST or BAMT result > 12 months before new employment. | 2. Two-step baseline TST or single BAMT completed upon hire and prior to client contact. |
| 3. a. Previous documented negative TST result within 12 months beforeemployment. b. Previous documented negative BAMT. | 3. a. Single TST needed for baseline testing; this will be the second step. b. Single BAMT needed. |
| 4. Previous documented positive TST result in millimeters. | 4. No TST or BAMT; need TB symptom assessment.  |
| 5. Undocumented history of prior positive TST result. | 5. Two-step baseline or single BAMT upon hire and prior to client contact. |

**Fiscal Impact Statement:**

The regulation will have no substantial fiscal or economic impact on the state or its political subdivisions. Upon approval by the General Assembly, the program will be funded by the regulated community through initial and annual license renewal fees. The cost to the regulated community will consist of an initial license fee and annual license renewal fees.

**Statement of Need and Reasonableness:**

This statement was determined by staff analysis pursuant to S.C. Code Ann Section 1-23-115 C(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R.61-121, Standards for Licensing In-Home Care Providers.

Purpose: This regulation will implement the provisions of the Licensure of In-Home Care Provider Act codified at Sections 44-70-10 et seq., S.C. Code of Laws, 1976, as amended.

Legal Authority: Sections 44-70-10 et seq., S.C. Code of Laws, 1976, as amended. (2011 Act 0018, Section 1, effective May 11, 2011)

Plan for Implementation: Copies of the regulation will be available electronically on the South Carolina Legislature Online website, and the Department regulation development website (<http://www.scdhec.gov/regulatory.htm>). Printed copies will be available for a fee from the Department’s Freedom of Information Office. Staff will educate the regulated community on the provisions of the Act and the requirements of the regulation.

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

The regulation is needed and reasonable because it will satisfy a legislative mandate to implement the provisions of the Licensure of In-Home Care Providers Act. This regulation will provide standards and procedures including license application and renewal procedures; criminal records checks for licensure applicants, which may include criminal offenses that may preclude licensure; drug testing of licensure applicants; responsibilities and duties of a licensee, including the requirements for bonding, record keeping and reporting; fees the Department may charge to process an application for a license, the issuance of a license, the renewal of a license, and the reinstatement of a revoked or suspended license; criteria that a licensee’s employee, agent, independent contractor, or referral must satisfy before providing in-home care service. These criteria must include, but are not limited to, personal information, completion of a minimum education requirement, completion of minimum training and continuing education requirements and screening for communicable diseases; standards for liability and other appropriate insurance coverage; and sanctions the Department may impose for violation of this chapter, including the suspension or revocation of a license or the imposition of a monetary penalty.

DETERMINATION OF COSTS AND BENEFITS:

Internal Costs: Implementation of this regulation will not require additional resources beyond those allowed for in the Act. Existing Department funding and staffing levels do not allow for the implementation of new programs. The Act states that the Department may propose by regulation a fee for processing an application, a fee for issuance of a license, a fee for renewal of a license and a fee for reinstatement of a revoked or suspended license, the proceeds of which are to be used solely to the purposes of implementing the provisions of the Act. Staff anticipates that there will be a minimal cost to the Department for the creation of the staff positions necessary to implement the provisions of the Act, however, these costs will be funded from the licensing fees paid by the licensees, in accordance with the regulation and as allowed by the Act. Additional costs to State government are not anticipated.

External Costs: There will be a cost to the licensees of in-home care providers as allowed by, and in accordance with the Act. Fees established by the regulation include initial licensing fees, annual fees, reinstatement fees, and amended license fees. Fees are set out in Sections 103.F, G, H, and I. There will be no cost to the public for implementation of the regulation.

External benefits: Consumers of the services furnished by in-home care providers can be reasonably certain that the caregivers have been screened for criminal backgrounds and substance abuse. The consumer can be reasonably certain that the caregivers have been trained to provide the care for which the consumer contracted with the in-home care provider. This regulation will provide in-home care providers with licensing requirements that set standards for the in-home care industry across South Carolina.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

There will be no effect on the environment.

The regulation will provide minimum standards for a growing in-home care industry in South Carolina. The public will benefit from caregivers that have met minimum training requirements, passed a criminal background check and are subject to random drug screening. The public will receive appropriate care from appropriate sources.

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

There would not be a detrimental effect on the environment.

However, if the regulation is not implemented, consumers of services from in-home care providers would not have reasonable assurances that the caregivers have completed a minimum amount of training to provide the proper care for the consumer. The consumers would not have a reasonable assurance that the caregivers do not have a record of criminal convictions or are free from drug abuse. The consumers would have no assurance that the provider they contract to provide care meets minimum licensing standards.

**Statement of Rationale:**

The Department promulgated this regulation to implement the provisions of the Licensure of In-Home Care Providers Act codified at Sections 44-70-10 et seq., S.C. Code of Laws, 1976, as amended.