

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 158.000: LICENSURE OF ADULT DAY HEALTH PROGRAMS

Section

- 158.001: Purpose and Scope
- 158.002: Authority
- 158.003: Citation
- 158.004: Definitions
- 158.005: Requirement for a License
- 158.006: Application for a License
- 158.007: Other Licensing Requirements
- 158.008: Ownership Interest of Applicant or Licensee
- 158.009: Acceptance of Application
- 158.010: Evaluation of Application
- 158.011: Right to Visit and Inspect
- 158.012: Deficiency Statements
- 158.013: Plan of Correction
- 158.014: Updating of Information
- 158.015: Suitability and Responsibility of Applicant or Licensee
- 158.016: Grounds for Suspension of License to Operate an Adult Day Health Program
- 158.017: Grounds on which to Deny, Revoke, or Refuse to Renew a License to Operate an Adult Day Health Program
- 158.018: Limiting Enrollment
- 158.019: Procedure for the Suspension or Revocation of a License, Refusal to Renew a License, and Denial of a License
- 158.020: Participant Notification
- 158.021: Effect of Determination of Unsuitability and Effect of Refusal to Renew a License, Revocation of a License, and License Denial
- 158.022: Non-transferability of License
- 158.023: Transfer of Ownership
- 158.024: Voluntary Closure
- 158.025: Name of Program
- 158.026: Licensed Program Capacity
- 158.027: Posting of License, Certificate of Inspection, and Related Documents
- 158.028: Restrictions
- 158.029: Special Projects and Waivers
- 158.030: Administration
- 158.031: Administrative Records, Reporting Requirements, and Policies and Procedures
- 158.032: Adult Day Health Staffing Requirements
- 158.033: Staff Qualifications and Responsibilities
- 158.034: Enrollment, Emergency Transports, and Discharges
- 158.035: Primary Care Provider Services
- 158.036: Diagnostic Services
- 158.037: Assessment and Care Planning
- 158.038: Quality of Care and Services
- 158.039: Medication Management Services
- 158.040: Participant Health Records
- 158.041: Participant Rights
- 158.042: Participant Comfort, Safety, Accommodations, and Equipment
- 158.043: Environmental Health and Housekeeping
- 158.044: Infection Control
- 158.045: Physical Plant Requirements
- 158.046: Quality Assessment and Performance Improvement

158.001: Purpose and Scope

(A) The purpose of 105 CMR 158.000 is to set forth the licensure and suitability requirements and standards for maintenance and operation for Adult Day Health Programs.

(B) 105 CMR 158.000 applies to the licensure of all persons who seek to or who currently own and operate Adult Day Health Programs in the Commonwealth of Massachusetts.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

158.002: Authority

105 CMR 158.000 is adopted under the authority of M.G.L. c. 111, § 3 and St. 2011, c. 87 as amended by St. 2012, c. 239, § 21.

158.003: Citation

105 CMR 158.000 will be known, and may be cited as, 105 CMR 158.000: *Licensure of Adult Day Health Programs*.

158.004: Definitions

Activities of Daily Living (ADL) means personal care activities including but not limited to bathing, dressing, grooming, toileting, transfers, ambulation, personal hygiene, and eating.

Adult Day Health Program (Program) means any entity, however organized, whether conducted for profit or not for profit that:

- (1) Is community-based and non-residential;
- (2) Provides nursing care, supervision, and health related support services in a structured group setting to persons 18 years of age or older who have physical, cognitive, or behavioral health impairments; and
- (3) Supports families and other caregivers thereby enabling the participant to live in the community.

Adult Day Health Services (Services) means the services that a Program provides or performs for participants in accordance with 105 CMR 158.000.

Applicant means any person who applies to the Department for a license to operate a Program. In the case of an applicant which is not a natural person, the term Applicant shall also mean any shareholder owning 5% or more; any officer and any director of any corporate applicant; any limited partner owning 5% or more and any general partner of any partnership applicant; any trustees of any trust applicant; any sole proprietor of any applicant which is a sole proprietorship; any mortgagee in possession; and any executor or administrator of any applicant which is an estate. Applicant also means a person filing a Notice of Intent form.

Aversive Interventions means any intervention technique based upon behavior modification principles, which applies painful, seclusion or intrusive methods, stimuli, or punishments to a participant in order to correct, decrease, or eliminate any undesirable behaviors.

Chemical Restraints means a drug that is used for discipline or convenience and not required to treat medical symptoms.

Commissioner means the Commissioner of the Department of Public Health.

Convenience means any action taken by a Program staff to control or manage a participant's behavior that requires a lesser amount of effort by Program personnel and is not in the participant's best interest.

Department means the Department of Public Health of the Commonwealth of Massachusetts.

Direct Care Staff include nurses, program aides, social workers and any individual(s) supervised by a social worker in accordance with 258 CMR 12.00: *Scope of Practice*, and activities directors.

Discharge means the termination of enrollment at a Program without an intention or expectation that the participant will return to the Program.

Discipline means any action taken by a Program for the purpose of punishing or penalizing a participant.

Elopement means that a participant who requires supervision has left the Program premises or safe area without the necessary supervision to do so.

158.004: continued

Emergency means a situation or condition which presents imminent danger of death or serious physical harm to one or more individuals.

Felony means a crime which is deemed a felony in the state in which the crime was committed or by the federal government.

Health Record means the cumulative required documentation maintained at a Program regarding the delivery of care and services to a participant, as specified in 105 CMR 158.000.

Influenza Vaccine or Vaccination means immunization by either influenza vaccine, inactivated or live; attenuated influenza vaccine including seasonal influenza vaccine, and/or other influenza vaccine pursuant to 105 CMR 158.030(L).

Jeopardy means a situation or condition which the Commissioner or his or her designee has determined presents an imminent threat to the health or safety of participants.

Legally Authorized Representative means the person or agency authorized to make health care decisions for a participant pursuant to an executed health care proxy or pursuant to an order of a Massachusetts court.

License means any license to operate a Program, issued by the Department, including an original or a renewal license.

Licensed Practical Nurse means a nurse who is currently licensed by the Massachusetts Board of Registration in Nursing, pursuant to M.G.L. c. 112, § 74A, to practice as a licensed practical nurse in Massachusetts.

Licensed Prescriber means a health care provider who is legally authorized to prescribe medication pursuant to M.G.L. c. 94C and other state and federal laws.

Licensee means any person holding a license to operate a Program. In the case of a licensee which is not a natural person, the term Licensee shall also mean any shareholder owning 5% or more, any officer, and any director of any corporate licensee; any limited partner owning 5% or more and any general partner of a partnership licensee; any trustee of any trust licensee; any sole proprietor of any licensee which is a sole proprietorship; any mortgagee in possession and any executor or administrator of any licensee which is an estate.

Massachusetts Medical Orders for Life Sustaining Treatments (MOLST) means the Department sponsored program to improve the communication and adherence to participants' expressed preferences regarding life sustaining treatments, by providing a standardized, easily recognized MOLST form documenting the care planning conversations between a participant or, if incapacitated, the participant's authorized representative for MOLST and the physician, nurse practitioner, or authorized physician assistant.

Medical Symptom means an indication or characteristic of a physical or psychological condition.

Medication Error means a failure to administer a medication as prescribed, including the failure to administer the correct medication or the failure to administer the medication:

- (1) Within appropriate time frames;
- (2) In the correct dosage;
- (3) In accordance with accepted practice;
- (4) To the correct participant; or
- (5) In the correct route.

Notice of Intent means a form supplied by the Department through which an applicant notifies the Department of his or her intent to acquire a Program and/or to apply for a license to operate a Program.

158.004: continued

Nurse Practitioner means a registered nurse authorized to practice as a nurse practitioner by the Board of Registration in Nursing pursuant to M.G.L. c. 112, § 80B and 244 CMR 4.00: *The Practice of Nursing in the Expanded Role*.

Original License means the first license issued to a Program by the Department pursuant to 105 CMR 158.000.

Participant means any individual enrolled in a Program licensed by the Department.

Participant Area means the physical space within the Program used for provision of Services, therapeutic activities, and dining. The Participant Area does not include reception areas, storage areas, offices, restrooms, corridors, or services areas.

Person means any natural person, corporation, society, association, partnership, or other entity.

Personnel means an individual or individuals employed by or affiliated with a Program, whether directly, by contract with another entity, or as an independent contractor, paid or unpaid.

Pharmacist means a person licensed by the Board of Registration in Pharmacy in accordance with M.G.L. c. 112, § 24.

Physical Restraints means any manual method or physical or mechanical device, material, or equipment attached to or adjacent to a participant's body that the participant cannot remove, which restricts freedom of movement or normal access to one's body.

Physician means a doctor of medicine or doctor of osteopathy who is registered to practice medicine in Massachusetts pursuant to M.G.L. c. 112, § 2.

Physician Assistant means a physician assistant authorized to practice by the Board of Registration of Physician Assistants, pursuant to M.G.L. c. 112, § 9I.

Primary Care Provider means a health care professional qualified to provide general medical care for common health care problems, who supervises, coordinates, prescribes or otherwise provides or proposes health care services, initiates referrals for specialist care and maintains continuity of care within the scope of practice.

Program Aide means any individual who meets the following criteria:

- (1) Is 18 years of age or older and has at least a high school diploma or its equivalent;
- (2) Meets the requirements stated in 105 CMR 158.033(F); and
- (3) Provides delegated nursing or nursing related services to participants in a Program as described at 105 CMR 158.033(F).

Program Capacity means the maximum number of participants that may be in the care of the Program at any one time based on the square footage specified in 105 CMR 158.026.

Program Director means a person responsible for general administration of daily operations of a Program, as specified at 105 CMR 158.030(K).

Qualified Cook means an individual who:

- (1) As described in 105 CMR 590.000: *State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments*, has passed a certified food protection manager test that is part of an accredited program recognized by the Department;
- (2) Has been issued a Massachusetts certificate of allergen awareness training by an allergen awareness training verification program recognized by the Department; and
- (3) Has a minimum of six months of supervisory experience in the planning, preparation, and service of food, including therapeutic diets.

158.004: continued

Registered Dietitian means a registered dietitian licensed under M.G.L. c. 112, §§ 201 through 210.

Registered Nurse means a nurse who is currently registered pursuant to M.G.L. c. 112, § 74 to practice as a registered nurse in Massachusetts.

Rehabilitation Services means services provided by physical therapists, occupational therapists, and speech, hearing and language therapists for the purpose of maximum reduction of physical or mental disability and restoration of the participant to maximum functional level.

Renewal License means any license issued after an original license to a Program by the Department pursuant to 105 CMR 158.000.

Restorative Nursing means the process of providing, in a coordinated manner, comprehensive services deemed appropriate to the needs of an individual with a disability, to achieve objectives of improved health and welfare with the realization of his or her maximum physical, psychological, and functional potential.

Self-administration means a participant taking or applying his or her medication in the manner directed by the prescribing provider, with no more than minimal assistance or direction from nursing staff, in accordance with Program policies and procedures.

Service Coordination means an interdisciplinary, collaborative process to assess, plan, implement, coordinate, monitor, and evaluate the services required to meet a participant's needs, including the medically-related physical, mental, behavioral, environmental, and other service needs of a participant at the time of enrollment, during treatment and care in the Program, or at the time of discharge.

Significant Change means a major decline or improvement in the participant's health status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status, and requires review or revision of the plan of care, or both.

Social Worker means an individual who meets the qualifications set forth in M.G.L. c. 112, § 131, and 258 CMR 9.00: *Licensure Requirements and Procedures* and who is licensed by the Board of Social Workers to perform or provide social work services in accordance with 258 CMR 12.01: *Scope of Professional Practice - Licensed Independent Clinical Social Worker (LICSW)*, 12.02: *Scope of Professional Practice - Licensed Certified Social Worker (LCSW)*, or 12.03: *Scope of Professional Practice - Licensed Social Worker (LSW)*.

Transfer of Ownership means a transfer of a majority interest in the ownership of a Program. In the case of a corporation, transfer of ownership includes the transfer of a majority of the stock thereof. In the case of a partnership, transfer of ownership includes the transfer of a majority of the partnership interest. In the case of a trust, transfer of ownership includes change of the trustee, or majority of trustees. In the case of a non-profit corporation, such changes in the corporate membership or directors as the Department determines to constitute a shift of 5% or more in control of the Program. A transfer of ownership shall also be deemed to have occurred where foreclosure proceedings have been instituted by a mortgagee in possession.

158.005: Requirement for a License

(A) No person shall establish or maintain a Program without having obtained an original license from the Department, except in accordance with 105 CMR 158.005(B).

(B) A Program operating prior to January 2, 2015 shall:

(1) Submit an application for an original license in accordance with 105 CMR 158.000 on or before May 1, 2015; and

158.005: continued

- (2) Comply with all requirements of 105 CMR 158.000 on or before May 1, 2015, except:
 - (a) requirements specifically waived in accordance with 105 CMR 158.029(B); and
 - (b) requirements that the Program specifically identifies in an attestation filed in accordance with 105 CMR 158.005(D).

(C) An application for an original license for a Program operating prior to January 2, 2015 shall have the effect of a license until such time as the Department takes action on the application.

(D) A Program operating prior to January 2, 2015 shall submit an attestation of compliance to the Department on or before May 1, 2015, as specified in guidelines of the Department. The attestation shall identify the Program's areas of compliance and areas of non-compliance and shall describe the Program's plan of action to achieve full compliance by one year after January 2, 2015 or to seek waivers in accordance with 105 CMR 158.029(B) by one year after January 2, 2015.

(E) A license shall pertain to only one Program site. Licensees or applicants that wish to operate, or operate more than one Program or program site shall apply for and obtain a separate license for each.

158.006: Application for a License

(A) Applications for licensure shall be made on forms prescribed by, and available from, the Department. The term Application as used in 105 CMR 158.000 shall include original and renewal applications. Every original application shall be signed under the pain and penalty of perjury either by each applicant as defined in 105 CMR 158.004, or by an applicant(s) who certifies that all other applicants have received copies of the application.

- (B) In support of an application for an original or renewal license, each applicant shall submit:
- (1) Any information concerning ownership or control, as the Department may require; and
 - (2) Any information required by the Department as part of the application package.

(C) Applications for renewal licenses must be filed on or before the expiration date of the previous license.

158.007: Other Licensing Requirements

As a prerequisite for a license, an applicant or licensee shall obtain current local board of health certificate(s), as applicable, a current occupancy permit, and a current local fire inspection certificate.

158.008: Ownership Interest of Applicant or Licensee

An applicant or licensee shall be the owner of the premises on which the Program is operated, or at least, as a lessee of the premises, have such rights and duties over the premises as the Commissioner or his or her designee finds necessary for the operation of a Program.

158.009: Acceptance of Application

- (A) The Department shall not accept an application for an original or renewal license unless:
- (1) The application includes all information required by the Department;
 - (2) The application, all required attachments and statements, and a Notice of Intent, if applicable, submitted by the applicant meet the requirements of 105 CMR 158.000; and
 - (3) The applicant has paid all required fees.

158.010: Evaluation of Application

The Department shall not approve an application for an original license, a renewal license, or a license due to transfer of ownership unless the Commissioner or his or her designee has conducted an inspection or other investigation and has determined that the applicant complies with 105 CMR 158.000, except in accordance with 105 CMR 158.005(B), and is suitable and responsible to establish or maintain a Program.

158.011: Right to Visit and Inspect

- (A) The Department or its agents may visit and inspect a Program or applicant at any time without prior notice in order to determine the Program's or applicant's compliance with state law and 105 CMR 158.000. A Program shall provide the Department with access to all parts of the Program facility and shall make all staff and all records available to the Department. Application for licensure shall constitute permission for such visit and inspection. The form on which such application is made shall contain a statement which advises any person seeking a license of such effect of an application.
- (B) A Program shall make available to the Department all information that may be relevant to a Department investigation of any incident or complaint.
- (C) A Program shall facilitate, and shall cooperate with, the Department's inspection of the Program, the Department's investigation of any incident or complaint, and the Department's interview of Program personnel and other witnesses.

158.012: Deficiency Statements

After every inspection in which any violation of 105 CMR 158.000 is observed, the Commissioner or his or her designee shall prepare a deficiency statement citing every violation observed, a copy of which shall be provided to the Program.

158.013: Plan of Correction

- (A) A Program shall submit to the Department a written plan of correction of any violations cited in a deficiency statement prepared pursuant to 105 CMR 158.012 within ten business days after receipt of the deficiency statement.
- (B) Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with 105 CMR 158.000 will be achieved, as specified in guidelines of the Department. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.
- (C) The Commissioner or his or her designee shall review the plan of correction for compliance with the requirements of 105 CMR 158.000 and shall notify the Program of either the acceptance or rejection of the plan. An unacceptable plan must be amended and resubmitted within five business days of the date of notice.

158.014: Updating of Information

A licensee shall keep all information required by 105 CMR 158.000 or otherwise required by the Commissioner or his or her designee current. A licensee shall report any changes in or additions to the content of the information contained in any document required to be filed to the Department within 30 days of such change or addition.

158.015: Suitability and Responsibility of Applicant or Licensee

- (A) Each of the following, in and of itself and as determined by the Department, constitutes full and adequate ground for deeming an applicant or licensee neither suitable nor responsible to establish or maintain a Program:
- (1) The applicant or licensee failed to demonstrate legal capacity as demonstrated by such documents as articles of incorporation, to provide the services for which a license is sought.
 - (2) The applicant or licensee has acted in a manner resulting in jeopardy to the health, safety, or welfare of any individual.
 - (3) The applicant or licensee has prevented or attempted to impede the work of any duly authorized representative of the Department or the lawful enforcement of any provision of M.G.L. c. 111, M.G.L. c. 112, or regulations promulgated thereunder.
 - (4) The applicant or licensee plans to assume or has assumed ownership of a Program in an effort to circumvent the effect and purpose of 105 CMR 158.000.

158.015: continued

(5) The financial management of one or more Programs for which an applicant or licensee was licensed has resulted in the filing of a petition for bankruptcy or receivership related to the financial solvency of the Program.

(6) The financial management of one or more Programs, in Massachusetts or another jurisdiction, for which an applicant or licensee was licensed has resulted in a lack of sufficient financial resources, as determined by the Department, to provide services required by state and federal laws and regulations.

(7) A Program owned or operated by the applicant or licensee has been the subject of proceedings which resulted in the suspension, denial, or revocation of the license of that Program or has been the subject of proceedings which resulted in the termination of the Program's participation in MassHealth.

(8) The applicant or licensee has failed to maintain a substantially consistent and adequate level of care, as measured by compliance with applicable licensing regulations in Massachusetts or elsewhere, with applicable federal and state regulations under the Medicaid or Medicare programs, and other pertinent evidence, in any institution for which the applicant or licensee has been a licensee in Massachusetts or elsewhere.

(a) The serious violation of applicable regulations shall constitute the failure to maintain a substantially consistent and adequate level of care.

(b) For purposes of 105 CMR 158.015(A)(8)(a), the following factors will be considered in determining whether a violation of applicable regulations is "serious".

1. The extent of any violation, including but not limited to:

- a. The number of participants affected;
- b. The length of time the violation persists;
- c. The frequency of the violation.

2. The actual or potential impact of any violation on participants of the Program. Violation of regulations in the following areas will be presumed to have an adverse impact upon participants:

- a. Participant rights;
- b. Adequate nursing services;
- c. Total nursing needs met;
- d. Receipt of proper medication and diet;
- e. Participant comfort;
- f. Participant cleanliness and grooming;
- g. Participant safety;
- h. Proper use of restraints;
- i. Proper sanitation;
- j. Infection control;
- k. Adequate equipment, supply, and storage;
- l. Therapeutic activities;
- m. Rehabilitation services;
- n. Service coordination; and
- o. Confidentiality of participant medical and personal information.

(9) The applicant or licensee has been the subject of specific documented findings by the Department of abuse, mistreatment, or neglect or misappropriation of property, made in accordance with M.G.L. c. 111, § 72J.

(B) Factors which have a significant bearing on the suitability and responsibility of an applicant or licensee include, but are not limited to:

(1) The applicant or licensee has failed to demonstrate that he or she has competence and experience in operating a Program.

(2) The applicant or licensee has failed to report participant abuse, mistreatment, neglect, or misappropriation to the Department.

(3) The applicant or licensee has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he or she is guilty of, any felony.

(4) The Attorney General has filed an action in any court concerning conditions in any health care facility for which the applicant or licensee was licensed, if that lawsuit resulted in an order or judgment against the applicant or licensee granting damages or any form of equitable relief, including an injunction.

158.015: continued

- (5) A Program owned or operated by the applicant or licensee, in Massachusetts or elsewhere, has been the subject of proceedings which were ultimately resolved by settlement agreement but which were initiated to suspend, deny, or revoke the license or renewal license or to terminate the Program's participation in MassHealth.
- (6) The applicant or licensee has obtained or attempted to obtain a license by fraud or misrepresentation or by submitting false information.
- (7) The applicant or licensee has employed in a management or supervisory position a person whom a hearing officer has determined pursuant to 105 CMR 158.015 to be unsuitable or not responsible to establish or maintain a Program.

158.016: Grounds for Suspension of License to Operate an Adult Day Health Program

The Commissioner may summarily suspend a license pending further proceedings for revocation of or refusal to renew a license whenever the Commissioner finds that there is jeopardy at a Program.

158.017: Grounds on which to Deny, Revoke, or Refuse to Renew a License to Operate an Adult Day Health Program

- (A) Each of the following, in and of itself, shall constitute full and adequate grounds on which to deny, revoke, or refuse to renew a license to operate a Program:
 - (1) The applicant or licensee is not suitable or responsible to operate a Program.
 - (2) The applicant or licensee has failed to remedy or correct a cited violation by the date specified in a written notice from the Department, or by the date specified in the plan of correction accepted or modified by the Department, unless the applicant or licensee demonstrates to the satisfaction of the Department that such failure was not due to any neglect of duty and occurred despite his or her good faith attempt to make correction by the specified time.
 - (3) There are deficiencies in the Program which jeopardize the health or safety of participants.
 - (4) There are deficiencies in the Program which seriously limit the capacity of the Program to provide adequate care.
 - (5) The Program has been found in violation of the same or a similar regulation twice or more within a 12 month period.
 - (6) The Program has been denied, or does not maintain, a local board of health certificate, occupancy permit, or local fire inspection certificate.
 - (7) The Program has failed to comply with the requirements of 105 CMR 158.000.
 - (8) The applicant or licensee has been convicted of, pleaded guilty or *nolo contendere* to, or has, in a judicial proceeding, admitted facts sufficient to find that he or she is guilty of:
 - (a) Abuse, mistreatment or neglect of any person;
 - (b) Rape, felonious assault, or any other felony against a person; or
 - (c) A felony involving the misuse of funds in connection with the Medicaid or Medicare program, including but not limited to, those offenses set forth in M.G.L. c. 118E, §§ 39 and 40 and the misuse of participant funds.
 - (9) The licensee has changed the location of a Program without prior approval of the Department.

158.018: Limiting Enrollment

- (A) If the Commissioner or his or her designee determines that a Program does not substantially comply with applicable licensure regulations, the Commissioner or his or her designee, in lieu of revoking or refusing renewal of the Program's license, may provide that the Program shall not enroll any participants after a date specified by the Commissioner or his or her designee.
- (B) The Commissioner or his or her designee shall not make a decision to limit enrollment until the licensee, or the applicant who signed the licensure application, has been notified that the Program does not substantially meet the provisions of applicable licensure regulations and that a decision to limit enrollments is contemplated, and the licensee or applicant has had a reasonable opportunity to correct the deficiencies.

158.018: continued

(C) A decision that a Program shall not enroll any participants after a date specified by the Commissioner or his or her designee shall be rescinded when the Commissioner or his or her designee finds that the Program is in substantial compliance with the provisions of applicable licensure regulations.

(D) Procedure for Limiting Enrollment.

(1) If the Commissioner or his or her designee determines the licensee should limit or cease all further enrollment to the Program, pursuant to 105 CMR 158.018, the Commissioner or his or her designee shall issue an Agency Notice of Action pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*.

(2) Upon written request, the licensee shall be afforded an opportunity to be heard concerning the order to limit or cease enrollment. Such a hearing, if requested, shall be initiated by filing a Claim for Adjudicatory Proceeding pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure* within 14 calendar days of receipt of notice of the decision to limit enrollment.

(3) Enrollment shall remain limited pending the hearing officer's decision on the appeal which shall be made within 21 calendar days of the close of the hearing.

(4) If the hearing officer finds that the Department has proved by preponderance of the evidence that the subject Program was not in substantial compliance with applicable licensure regulations at the time the determination was made, the hearing officer shall uphold the decision of the Commissioner or his or her designee to limit enrollment.

158.019: Procedure for the Suspension or Revocation of a License, Refusal to Renew a License, and Denial of a License

(A) If the Commissioner or his or her designee determines that a licensee is not suitable or responsible or that a license should be suspended, revoked, or refused renewal pursuant to 105 CMR 158.000, the Commissioner or his or her designee shall issue an Agency Notice of Action, pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*.

(B) Upon written request, the licensee shall be afforded an opportunity to be heard concerning the suspension, revocation, or refused renewal of a license by the Commissioner or his or her designee. Such a hearing, if requested, shall be initiated by filing a Claim for Adjudicatory Proceeding pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure* no later than 21 calendar days after the effective date of the suspension, revocation, or refused renewal.

(C) In cases of suspension of a license, the hearing officer shall determine whether the Department has proved by a preponderance of the evidence that jeopardy existed immediately prior to or at the time of the suspension.

(D) In cases of revocation of or refusal to renew a license, the hearing officer shall determine whether the Department has proved by a preponderance of the evidence that the license should be revoked or refused renewal, based on relevant facts as they existed at or prior to the time the Commissioner or his or her designee issued the Agency Notice of Action.

(E) License Denial.

(1) Upon receipt of notice that an application for licensure hereunder has been denied, an applicant may appeal to a hearing officer by filing a Claim for Adjudicatory Proceeding in accordance with 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*.

(2) In cases of denial of an original license, the hearing officer shall determine whether the applicant has proved by preponderance of the evidence that he or she is suitable and responsible for licensure under 105 CMR 158.000.

158.020: Participant Notification

(A) At the direction of the Department, whenever it appears likely that a renewal license denial or revocation action commenced pursuant to 105 CMR 158.000 will result in the discharge of participants, the Program shall provide a written notice, in accordance with guidelines of the Department, to inform each participant of:

158.020: continued

- (1) The status of the action;
- (2) The timetable and procedures for the discharge process; and
- (3) The Department representative to contact with respect to the discharge process.

(B) Whenever the Department initiates an action to summarily suspend a license, the Program shall immediately notify participants orally and in writing of the proposed suspension, and of the need for the Program to discharge its participants if its license is suspended.

(C) In those cases where a participant is not competent to understand the notices, the Program shall immediately forward the notice to the participant's next of kin or legally authorized representative.

158.021: Effect of Determination of Unsuitability and Effect of Refusal to Renew a License, Revocation of a License, and License Denial

Whenever an applicant or licensee has been determined after hearing to be unsuitable or not responsible to establish or maintain any Program licensed by the Department, or whenever the license of any applicant or licensee has been revoked or denied or refused, the applicant or licensee may not establish or maintain any Program subject to licensure by the Department for a period of time to be determined by the Department. An applicant or licensee may establish or maintain a Program thereafter only if he or she demonstrates to the Department that his or her circumstances have significantly changed such that he or she has become suitable and responsible to establish or maintain a Program.

158.022: Non-transferability of License

(A) Each license shall be valid only in the possession of the licensee to whom it is issued and shall not be subject to sale, assignment, or other transfer, voluntary or involuntary.

(B) The licensee shall notify the Department at least 90 days in advance of any change in location of the Program. A licensee may not change the location of a Program without prior approval of the Department.

(C) The license shall be returned by registered mail to the Department immediately upon:

- (1) Receipt of a renewal license;
- (2) Revocation of or refusal to renew the license;
- (3) Change of location;
- (4) Transfer of ownership;
- (5) Change of name;
- (6) Closure or other termination of the licensee's existence or authority to operate; or
- (7) Change in Program capacity.

158.023: Transfer of Ownership

(A) At least 90 calendar days in advance of any transfer of ownership, any applicant who intends to acquire a Program shall submit a Notice of Intent to the Department on a form supplied by the Department.

(B) Any applicant for a license as a result of any transfer of ownership shall file an application for licensure at least 45 days before the transfer.

(C) A license application filed as a result of a transfer of ownership, if timely filed and complete, shall have the effect of a license from the date of transfer or until such time as the Department takes action on the application. If not timely filed or complete, such an application shall not have such effect.

(D) The applicant shall submit proof of transfer to the Department within 48 hours of the transfer of ownership of a Program.

158.023: continued

(E) Any notice of hearing, order, or decision which the Department or the Commissioner or his or her designee issues for a Program prior to a transfer of ownership shall be effective against the former owner prior to such transfer and, where appropriate, the new owner, following such transfer unless said notice, order, or decision is modified or dismissed by the Department or by the Commissioner or his or her designee.

(F) A transfer of ownership shall not be recognized and the new owner shall not be considered suitable for licensure when the transfer is proposed or made to circumvent the effect and purpose of 105 CMR 158.000, as determined by the Department. The Department shall consider the following factors in determining whether a transfer has been proposed or made to circumvent the regulations:

- (1) The transferor's record of compliance with Department licensure laws and regulations;
- (2) The transferor's current licensure status;
- (3) The transferor's familial, business, and/or financial relation to the transferee;
- (4) The terms of the transfer; and
- (5) The consequences of the transfer.

158.024: Voluntary Closure

(A) The licensee or his or her designee shall notify the Department of its intent to close a Program and file a closure plan at least 70 days in advance of a proposed closure date. Notice to the Department and the closure plan shall be subject to the Department's approval, and shall be in addition to notification requirements established pursuant to 130 CMR 404.000: *Adult Day Health Services* and 450.00: *Administrative and Billing Regulations* and Massachusetts General Laws regarding withdrawal from participation in the MassHealth plan.

(B) In the event of a voluntary closure, a Program shall comply with requirements stated in 105 CMR 158.034(F)(4). Any notice to participants required by 105 CMR 158.034(F)(4) shall be provided at least 60 days prior to closure.

(C) The Program shall provide copies of all appropriate medical records to participants upon discharge.

(D) The Program's failure to comply with the notice provisions or to implement an approved closure plan prior to the 60 day notice period as specified in 105 CMR 158.024(B), may result in a finding that an emergency exists. Furthermore, failure to assure appropriate notice to and referral and transfer of all participants may result in a finding of neglect.

(E) If a Program intends to cease operation for any period of time, the Program shall obtain written approval from the Commissioner or his or her designee for a specified period at least 30 days prior to closure. If emergency circumstances are such that it is not possible to obtain approval from the Commissioner prior to closing, such approval shall be obtained within 72 hours of closing. Failure to obtain approval and closure of the program for more than seven days shall constitute abandonment of license.

158.025: Name of Program

(A) A Program shall be designated by a distinctive name which shall appear on the Program's application and license. To avoid public confusion or misrepresentation, this name shall not be changed without the prior approval of the Commissioner or his or her designee. Such name shall appear on all listings, advertisements, and stationery.

(B) The name of a Program shall not tend in any way to mislead the public as to the type or extent of care provided by the Program.

158.026: Licensed Program Capacity

(A) The Department shall determine the licensed program capacity for a Program based on the square footage of the participant area as specified in 105 CMR 158.045(B). As used in 105 CMR 158.026, licensed program capacity is not a form of a license within the meaning of M.G.L. c. 30A, § 13.

(B) In cases where a permanent reduction or a temporary reduction of the square footage of the participant area is necessary for any reason:

(1) A Program shall notify the Department in writing of the reduction in square footage, the reason for the reduction in square footage, and the estimated length of time of the reduction in square footage; and

(2) On receipt of this notification the Department will establish a revised licensed program capacity or take other such actions as the Department determines appropriate.

158.027: Posting of License, Certificate of Inspection, and Related Documents

A Program shall maintain a board suitable for posting notices and other written materials in an area of the premises accessible to participants, employees, and visitors. Such notices and materials as may be required by the Commissioner or his or her designee shall be conspicuously posted thereon and include, but are not limited to, the following:

(A) A framed, current license, or if the Program is operating under an application, the most recent license and a copy of such application;

(B) Any notices, orders, statements of deficiencies, plans of corrections, or decisions issued by the Department or other federal, state, and local authority within two years that pertain to the Program;

(C) Participants rights;

(D) Names, addresses, and telephone numbers of all pertinent State advocacy groups including:

(1) The Department's licensure office complaint unit;

(2) Elder abuse hotline;

(3) Disabled Person Protection Commission;

(4) Attorney General's Medicaid fraud complaint line;

(5) Department of Elder Affairs Community Care Ombudsman Program; and

(6) Local Aging Services Access.

(E) Written information regarding application for MassHealth benefits;

(F) Disaster dietary plan;

(G) Emergency evacuation plan; and

(H) Staffing schedules.

158.028: Restrictions

(A) A Program may not utilize any portion of its participant area for any purpose other than providing Services during the Program hours of operation.

(B) A Program may not utilize any portion of its participant area for the purpose of running a business other than the business of providing Services.

158.029: Special Projects and Waivers

(A) A Program may submit a proposal for a special project for innovative delivery of Services related to the Program. However, no such proposal shall be implemented without prior written approval of the Department. Such proposals shall be approved only on an experimental basis and subject to renewal of approval by the Department at such time periods as the Department shall determine.

158.029: continued

(B) The Commissioner or his or her designee may, to the extent allowable by state or federal law, waive the applicability to a particular Program of one or more of the requirements imposed by 105 CMR 158.000 upon finding that:

- (1) The Program's non-compliance does not jeopardize the health or safety of its participants and does not limit the Program's capacity to provide adequate care;
- (2) The Program has instituted compensating features or has undertaken a special project under 105 CMR 158.029(A) acceptable to the Department;
- (3) Compliance would cause undue hardship to the Program; and
- (4) The Program provides to the Commissioner or his or her designee written documentation supporting its request for a waiver.

158.030: Administration

(A) The licensee shall be responsible for compliance with all applicable laws and regulations.

(B) Each licensee shall establish by-laws or policies which describe the organizational structure, establish authority and responsibility of the Program, and identify the goals and service components of the Program.

(C) The licensee shall appoint a qualified Program Director who is responsible for establishing and implementing policies and procedures regarding the management and operation of the Program.

(D) The licensee shall ensure the Program is open at least Monday through Friday and is non-residential.

(E) The licensee shall ensure that all required records, reports, and other materials required by 105 CMR 158.000 are complete, accurate, current, and available within the Program.

(F) The licensee shall ensure the Program is administered in a manner that uses its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each participant.

(G) The licensee shall make participant records and copies of participant records available to the Commissioner or his or her designee upon request.

(H) Personnel.

(1) The licensee shall be responsible for procurement of competent personnel. The licensee and the Program Director shall each be responsible for the direction and supervision of personnel.

(2) The licensee and Program Director shall establish and maintain written policies and procedures regarding personnel that promote quality care of participants.

(3) The licensee shall:

- (a) Maintain accurate time records for all personnel;
- (b) Maintain payroll records, timesheets, and staffing schedules for at least seven years;
- (c) Post, and make accessible to participants and their families, staffing schedules; and
- (d) Maintain a written job description for each position that includes title, reporting authority, qualifications, duties, and responsibilities.

(4) The licensee shall maintain a personnel record for each employee and volunteer that is current, accurate, and available on the premises for seven years. Personnel records shall contain:

- (a) Pertinent information regarding identification, including maiden name, if applicable;
- (b) Social Security number, photo copy of a government issued photo identification, professional registration number or competency determination (if applicable), and year of original licensure, registration, or competency determination;
- (c) Cardiopulmonary resuscitation and first aid certifications;
- (d) Names and addresses of educational institutions attended, dates of graduation, degrees or certificates conferred, and name at the time of graduation;
- (e) Employment history including experience, training, names and addresses of previous employers, dates of employment, and reasons for terminating previous employment;

158.030: continued

- (f) Completed and signed job application forms;
 - (g) Job descriptions;
 - (h) Performance evaluations;
 - (i) A pre-employment physical examination completed within 12 months of employment and a physical examination completed at least once every two years during the period of employment;
 - (j) A pre-employment Tuberculosis (TB) history and risk assessment with additional screening as indicated within three months prior to employment in accordance with Department Bureau of Infectious Disease guidelines;
 - (k) An annual TB risk assessment, symptom review, and education with additional screening as indicated in accordance with Department Bureau of Infectious Disease guidelines;
 - (l) For food service personnel, any documentation required by 105 CMR 590.000: *State Sanitary Code Chapter X - Minimum Sanitation Standards for Food Establishments*;
 - (m) Training attendance records; and
 - (n) Records of illnesses, incidents, and complaints involving personnel while on duty.
- (5) Prior to hiring staff or approving volunteers, a Program shall perform a background check that includes the candidate's references, job history, Criminal Offender Records Information (CORI), and the Nurse Aide Registry, established under M.G.L. c. 111, § 72J.
- (6) A Program shall conduct an annual performance evaluation for each employee which includes a face-to-face meeting.
- (7) A Program shall have an organized orientation program for all new employees that explains job responsibilities, duties, conditions of employment, and relevant participant care policies. All new personnel shall attend orientation training.
- (8) A Program shall provide a minimum of 12 hours of relevant in service training per year for personnel who interact with participants. The in-service training shall be relevant to the participant population and to the services provided by the Program.
- (9) A Program shall ensure that all personnel are knowledgeable about the types of medical and behavioral conditions of participants and their cultural diversity, including, but not limited to, race, ethnicity, sexual orientation and gender identity, such that personnel are able to provide care that is appropriate to participants' needs.
- (10) A Program shall ensure that all personnel are adequately trained to understand, respond to, and address the needs of participants with Alzheimer's disease and related disorders. Training regarding Alzheimer's disease and related disorders shall include:
- (a) Knowledge about Alzheimer's disease and related disorders;
 - (b) Behavior management skills necessary to respond appropriately to participant behaviors and non-verbal communications; and
 - (c) Group process skills in working with special need populations.
- (11) No individual may be employed, allowed to work, or allowed to volunteer, if he or she is infected with a contagious disease that might endanger the health of participants or personnel.
- (12) The Department shall be notified in writing within two business days of the resignation or dismissal of the Program Director and the name and qualifications of the new Program Director or interim Program Director.
- (13) A Program shall require all persons, including students, who examine, observe, or treat a participant to wear an identification badge that readily discloses the first name, licensure status, if any, and staff position of the person so examining, observing, or treating a participant.
- (I) In order to promote appropriate placements, a Program shall exchange information regarding resources and services with other agencies and institutions that provide health care or community care in the geographic area of the Program.
- (J) Participant and Family Advisory Council.
- (1) A Program shall establish a Participant and Family Advisory Council to advise the Program on matters including, but not limited to, participant and provider relationships, community services and needs, quality improvement initiatives, and participant education related to safety and quality.
 - (2) A Program operating prior to January 2, 2015 shall establish a Participant and Family Advisory Council on or before May 1, 2015.

158.030: continued

(3) Membership of the Participant and Family Advisory Council shall, to the extent possible, reflect the cultural diversity of the community served, and at least 50% of the Council members shall be current or former participants and their family members, legal representatives or caregivers; at least one member shall be the Program Director or designee; members may include health care professionals from outside the Program who work with the target population.

(4) A Program shall develop and implement written policies and procedures for the Participant and Family Advisory Council, which shall include:

- (a) The Council's purposes and goals;
- (b) Membership of the Council including qualifications, selection, retention, and term of service;
- (c) Orientation, training, and continuing education for members of the Council on topics related to Council membership and community health care services; and
- (d) Responsibilities of members of the Council.

(5) The Participant and Family Advisory Council shall:

- (a) Advise on participant quality of life, quality of care, safety issues and, if the participant or participant's family and/or legally authorized representative seeks the Council's advice, specific grievances;
- (b) Advise the Program Director on physical plant and program related matters;
- (c) Review and advise on the Program's QAPI semi-annual report and make recommendations as applicable;
- (d) Review and advise on the Program's written policies and procedures;
- (e) Convene meetings at least one time every four months;
- (f) Maintain minutes of Council meetings and accomplishments for at least five years; and
- (g) Submit Council meeting minutes to the licensee and Program Director.

(6) Reporting Requirements.

- (a) At least one time per year, a Program shall prepare a written report documenting the Program's compliance with 105 CMR 158.030(J) and describing the Participant and Family Advisory Council's accomplishments during the preceding year.
- (b) A Program shall make the written reports required by 105 CMR 158.030(J) available to the Department within seven days upon request.

(7) In the event a Program's bylaws or organizational structure require it to be overseen by a Board of Directors, the Board of Directors may assume the roles and responsibilities of the Participant and Family Advisory Council and may operate in *lieu* of such a Council, provided that the Board of Directors otherwise complies with all requirements specified in 105 CMR 158.030(J). The composition of the Board of Directors need not be reconfigured to comply with 105 CMR 158.030(J)(3) if the Board has participant, family, or caregiver representation on the Board; otherwise, in *lieu* of reconfiguration, the Board may establish a Participant and Family Advisory subcommittee to the Board.

(K) Program Director.

(1) A Program with a licensed program capacity of 35 or fewer participants shall employ a qualified Program Director for at least ten hours per week to manage the Program.

(2) A Program with a licensed program capacity of 36 to 72 participants shall employ a qualified Program Director for at least 20 hours per week to manage the Program.

(3) A Program with a licensed program capacity of 73 or more participants shall employ a qualified Program Director for at least 35 hours per week.

(4) The Program Director shall be on-site and available to staff, participants, and legally authorized representatives for at least a portion of each week during the hours of operation. A senior staff person may be designated to assume temporary responsibility for a Program Director in the event that the Program Director requires an absence longer than a full week. If the Program Director also serves the Program as a registered nurse, then the temporary designee may only act in the capacity of a Program Director, and may not act in the capacity as a registered nurse, unless the temporary designee is also a registered nurse, or licensed nurse acting as a relief nurse pursuant to 105 CMR 158.032(B)(2).

(5) A Program Director shall be a suitable and responsible person, 21 years of age or older, who has:

- (a) A high school diploma or its equivalent;
- (b) At least two years' experience working with adults in a health care setting in a professional or volunteer position; and

158.030: continued

- (c) At least two years of related managerial experience.
- (6) A licensed nurse may not simultaneously serve in the capacity of the Program Director and as a nurse required to satisfy minimum staffing requirements in 105 CMR 158.032.
- (7) A Program shall post, and make available to staff, the name and telephone numbers of the Program Director.
- (8) The Program Director shall be responsible to the licensee and shall operate the Program to ensure that services required by participants are available and are provided in accordance with professional standards of care, the Program's written policies and procedures, and 105 CMR 158.000.
- (9) The responsibilities of a Program Director shall include:
 - (a) Direction and supervision of all aspects of the Program;
 - (b) Management of personnel;
 - (c) Ensuring appropriate supervision and evaluation of all personnel;
 - (d) Overseeing Program safety and emergency evacuation plans;
 - (e) Managing the fiscal administration of the Program;
 - (f) Establishing collaborative relationships with community services to ensure that necessary support services are available to participants and their families;
 - (g) Notifying the participant or his or her legally authorized representative in the event of change in a participant's charges, billings, benefit status, or other administrative matters;
 - (h) Delegating responsibility for managing the day-to-day operations of the Program during any short term absence of the Program Director;
 - (i) Overseeing the quality assessment and performance improvement program, as described at 105 CMR 158.046; and
 - (j) Immediately informing the participant, consulting with the participant's primary care provider, and immediately notifying the participant's legally authorized representative or contact person in the following circumstances:
 - 1. An emergency, serious incident, or fire;
 - 2. Severe illness involving the participant;
 - 3. An incident involving the participant which resulted in injury or which required medical intervention;
 - 4. A significant change in the participant's status;
 - 5. A need to alter the participant's treatment significantly;
 - 6. A significant revision of the participant's plan of care; or
 - 7. A decision to transfer the participant from the Program.
 - (k) Immediately notifying the participant, the participant's primary care provider, and the participant's legally authorized representative or contact person, upon a decision to discharge the participant from the Program as specified in 105 CMR 158.034.
- (L) Requirement for Personnel to Be Vaccinated against Influenza Virus.
 - (1) Definitions.
 - (a) For purposes of 105 CMR 158.030(L), personnel means an individual or individuals who either work at or come to the licensed program site and who are employed by or affiliated with the program, whether directly, by contract with another entity, or as an independent contractor, paid or unpaid including, but not limited to, employees, members of the medical staff, contract employees or staff, students, and volunteers, whether or not such individual(s) provide direct care.
 - (b) For purposes of 105 CMR 158.030(L), the requirement for influenza vaccine or vaccination means immunization by either influenza vaccine, inactivated or live; attenuated influenza vaccine including seasonal influenza vaccine pursuant to 105 CMR 158.030(L).
 - (c) For purposes of 105 CMR 158.030, mitigation measures mean measures that personnel who are exempt from vaccination take to prevent viral infection and transmission.
 - (2) Each program shall ensure all personnel are vaccinated annually with seasonal influenza vaccine, consistent with any guidelines of the Commissioner, unless an individual is exempt from vaccination in accordance with 105 CMR 158.030(L)(6).
 - (3) Each program also shall ensure all personnel are vaccinated against other pandemic or novel influenza virus(es) as specified in guidelines of the Commissioner, unless an individual is exempt from vaccination in accordance with 105 CMR 158.030(L)(6). Such guidelines may specify:

158.030: continued

- (a) The categories of personnel to be vaccinated and the order of priority of vaccination of personnel, with priority for personnel with responsibility for direct care;
 - (b) The influenza vaccine(s) to be administered;
 - (c) The dates by which personnel must be vaccinated; and
 - (d) Any required reporting and data collection relating to the personnel vaccination requirement of 105 CMR 158.030(L)(3).
- (4) Each program shall provide all personnel with information about the risks and benefits of influenza vaccine.
- (5) Each program shall notify all personnel of the influenza vaccination requirements of 105 CMR 158.030(L) and shall, at no cost to any personnel, provide or arrange for vaccination of all personnel who cannot provide proof of current immunization against influenza unless an individual is exempt from vaccination in accordance with 105 CMR 158.030(L)(6).
- (6) Exemptions.
- (a) Subject to the provisions set forth in 105 CMR 158.030(L)(6)(b), a program shall not require an individual to receive an influenza vaccine pursuant to 105 CMR 158.030(L)(2) or (3) if the individual declines the vaccine.
 - (b) For any individual subject to the exemption, a program may require such individual take mitigation measures, consistent with guidance from the Department.
 - (c) An individual who is exempt from vaccination shall sign a statement certifying that they are exempt from vaccination and they received information about the risks and benefits of influenza vaccine.
- (7) Unavailability of Vaccine. A program shall not be required to provide or arrange for influenza vaccination during such times the vaccine is unavailable for purchase, shipment, distribution or administration by a third-party or when complying with an order of the Commissioner restricting the use of the vaccine. A program shall obtain and administer influenza vaccine in accordance with 105 CMR 158.030(L) as soon as vaccine becomes available.
- (8) Documentation.
- (a) A program shall require and maintain for each individual proof of current vaccination against influenza virus pursuant to 105 CMR 158.030(L)(2) and (3), or the individual's exemption statement pursuant to 105 CMR 158.030(L)(6).
 - (b) Each program shall maintain a central system to track the vaccination status of all personnel.
 - (c) If a program is unable to provide or arrange for influenza vaccination for any individual, it shall document the reasons such vaccination could not be provided or arranged for.
- (9) Reporting and Data Collection. Each program shall report information to the Department documenting the facility's compliance with the personnel vaccination requirements of 105 CMR 158.030(L), in accordance with reporting and data collection guidelines of the Commissioner.
- (10) 105 CMR 158.030(L) establishes requirements for influenza vaccination of adult day health program personnel. Nothing in 105 CMR 158.000 shall be read to prohibit programs from establishing policies and procedures for influenza vaccination of personnel that exceed the requirements set forth in 105 CMR 158.030(L).
- (M) Requirement for Personnel to Be Vaccinated against Coronavirus Disease 2019 (COVID-19) Caused by the Virus SARS-CoV-2.
- (1) Definitions.
- (a) For purposes of 105 CMR 158.030(M), personnel means an individual or individuals who either work at or come to the licensed program site and who are employed by or affiliated with the program, whether directly, by contract with another entity, or as an independent contractor, paid or unpaid including, but not limited to, employees, members of the medical staff, contract employees or staff, students, and volunteers, whether or not such individual(s) provide direct care.
 - (b) For purposes of 105 CMR 158.030(M), COVID-19 vaccination means being up to date with COVID-19 vaccines as recommended by the Centers for Disease Control and Prevention (CDC).
 - (c) For purposes of 105 CMR 158.030(M), mitigation measures mean measures that personnel who are exempt from vaccination take to prevent viral infection and transmission.

158.030: continued

- (2) Each program shall ensure all personnel have received COVID-19 vaccination in the timeframe specified in Department guidelines, unless an individual is exempt from vaccination in accordance with 105 CMR 158.030(M)(5).
- (3) Each program shall provide all personnel with information about the risks and benefits of COVID-19 vaccination.
- (4) Each program shall notify all personnel of the COVID-19 vaccination requirements of 105 CMR 158.030(M) and shall, at no cost to any personnel, provide or arrange for vaccination of all personnel who cannot provide proof of current vaccination against COVID-19 unless an individual is exempt from vaccination in accordance with 105 CMR 158.030(M)(5).
- (5) Exemptions.
 - (a) Subject to the provisions set forth in 105 CMR 158.030(M)(5)(b), a program shall not require an individual to receive a COVID-19 vaccine pursuant to 105 CMR 158.030(M)(2) if the individual declines the vaccine.
 - (b) For any individual subject to the exemption, a program may require such individual take mitigation measures, consistent with guidance from the Department.
 - (c) An individual who is exempt from vaccination shall sign a statement certifying that they are exempt from vaccination and they received information about the risks and benefits of COVID-19 vaccine.
- (6) Unavailability of Vaccine. A program shall not be required to provide or arrange for COVID-19 vaccination during such times the vaccine is unavailable for purchase, shipment, distribution, or administration by a third-party or when complying with an order of the Commissioner restricting the use of the vaccine. A program shall obtain and administer COVID-19 vaccine in accordance with 105 CMR 158.030 (M) as soon as vaccine becomes available.
- (7) Documentation.
 - (a) A program shall require and maintain for each individual proof of current vaccination against COVID-19 virus pursuant to 105 CMR 158.030(M)(2), or the individual's exemption statement pursuant to 105 CMR 158.030(M)(5).
 - (b) Each program shall maintain a central system to track the vaccination status of all personnel.
 - (c) If a program is unable to provide or arrange for COVID-19 vaccination for any individual, it shall document the reasons such vaccination could not be provided or arranged for.
- (8) Reporting and Data Collection. Each program shall report information to the Department documenting the program's compliance with the personnel vaccination requirements of 105 CMR 158.030(M) in accordance with reporting and data collection guidelines of the Commissioner.
- (9) 105 CMR 158.030(M) establishes requirements for COVID-19 vaccination of adult day health program personnel. Nothing in 105 CMR 158.000 shall be read to prohibit programs from establishing policies and procedures for COVID-19 vaccination of personnel that exceed the requirements set forth in 105 CMR 158.030(M).

158.031: Administrative Records, Reporting Requirements, and Policies and Procedures

- (A) A Program shall maintain administrative records including the following:
 - (1) The names and number of participants enrolled;
 - (2) The names and number of participants waiting for service commencement;
 - (3) The names and number of personnel;
 - (4) Incident reports;
 - (5) Complaint and grievance reports;
 - (6) A personnel file on each staff person and volunteer, as specified under 105 CMR 158.000;
 - (7) Contracts for therapy, nutritional, and other services;
 - (8) Daily attendance records; and
 - (9) Other records as may be required by the Department.
- (B) A Program shall submit records, reports, and other documentation to the Department within seven days upon request.

158.031: continued

(C) Serious Incident and Accident Reports.

(1) Each Program shall immediately report to the Department any of the following which occurs on premises covered by its license:

- (a) Death that is unanticipated, not related to the natural course of the participant's illness or underlying condition, or that is the result of an error or other incident as specified in guidelines of the Department;
- (b) Full or partial evacuation of the facility for any reason;
- (c) Fire;
- (d) Suicide;
- (e) Serious criminal acts;

158.031: continued

- (f) Pending or actual strike action by its employees, and contingency plans for operation of the Program;
 - (g) Illness including:
 - 1. Illness believed to be part of a suspected or confirmed cluster or outbreak of any illness;
 - 2. Illness believed to be unusual; or
 - 3. Illness related to food consumption or believed to be transmissible through food.
 - (h) Other serious incidents or accidents as specified in guidelines of the Department.
 - (2) A Program shall immediately report to the Department any suspected instance(s) of participant abuse, neglect, mistreatment, or misappropriation of a participant's personal property.
 - (3) A Program shall report to the Department any other serious incident or accident occurring on premises covered by the Program's license that seriously affects the health or safety of a participant(s) or that causes serious physical injury to a participant(s), within seven days of the date of occurrence of the event.
- (D) The Department shall establish guidelines for the reporting of serious incidents and accidents, including the means of reporting.
- (E) In accordance with guidelines established by the Department, a Program shall:
- (1) Ensure a reliable means for sending information to the Department regarding incidents at the Program;
 - (2) Ensure a reliable means for receiving information from the Department and from state and local authorities in the event of an emergency; and
 - (3) Ensure all staff are trained to send and receive information regarding incidents and emergencies.
- (F) Policies and Procedures.
- (1) A Program shall develop and implement written policies and procedures, consistent with professional standards of care and 105 CMR 158.000, regarding the following:
 - (a) Enrollment, emergency transport, and discharge;
 - (b) Diagnostic services, including laboratory services;
 - (c) Nursing services;
 - (d) Medication management;
 - (e) Dietary services;
 - (f) Rehabilitation services;
 - (g) Service Coordination;
 - (h) Therapeutic activities;
 - (i) Other professional services;
 - (j) Medical emergencies, including criteria for calling emergency telephone access number 911;
 - (k) Disaster and emergency plans, including evacuation and transfer plans;
 - (l) Participant elopement;
 - (m) Health records;
 - (n) Participant rights and grievances;
 - (o) Abuse, mistreatment, neglect, and misappropriation;
 - (p) Quality assessment and performance improvement;
 - (q) Infection control;
 - (r) Personnel policies;
 - (s) Research;
 - (t) Safekeeping of participant items, funds, and other property, as appropriate; and
 - (u) Compliance with antidiscrimination provisions of 105 CMR 158.034(B) and 158.041(A).
 - (2) The Program Director and licensee shall be responsible for the development and review of the policies and procedures stated in 105 CMR 158.031(F)(1). The Program Director shall consult with the Participant and Family Advisory Council, professionals who may include primary care providers, pharmacists, nursing staff, and representatives from other disciplines in the development of these policies.
 - (3) The Program Director shall ensure the policies and procedures shall be reviewed at least annually and revised as needed.

158.031: continued

(G) Disaster Plan.

- (1) A Program shall establish written emergency policies and procedures to be followed in case of fire, or other emergency, developed with the assistance of local and state fire and safety experts, and posted at all nurses' stations and in conspicuous locations throughout the Program.
- (2) Written emergency policies and procedures shall include the following:
 - (a) An emergency evacuation plan that is in compliance with and coordinated with local fire department requirements;
 - (b) A procedure to be followed in the event a participant is missing or lost;
 - (c) Procedures for handling medical emergencies at the Program;
 - (d) Persons to be notified in case of an emergency;
 - (e) Locations of alarm signals and fire extinguishers; and
 - (f) Assignment of specific tasks and responsibilities to the personnel. All personnel shall be trained to perform an assigned task.
- (3) A Program shall maintain an emergency fact sheet on each participant that contains the following information:
 - (a) The name and telephone number of the participant's primary care provider;
 - (b) The participant's diagnosis;
 - (c) Any special treatments or medications the participant may need;
 - (d) Insurance information; and
 - (e) The name and telephone number of the identified contact person and, if applicable, the legally authorized representative to be notified in case of emergency.
- (4) A Program shall conduct quarterly fire and evacuation drills. All staff shall participate in these drills. Documentation of evacuation drills shall be kept on file.
- (5) A Program shall ensure staff are trained to respond to emergencies in accordance with written policies and procedures.
- (6) A Program shall ensure staff are trained to send and receive reports to the Department, and respond to reports in an appropriate manner for the safety of participants as specified at 105 CMR 158.031.

158.032: Adult Day Health Staffing Requirements

(A) A Program shall ensure adequate staff are on duty at all times so that the health, safety, and care needs of each participant are met.

(B) Licensed Nursing Staff.

- (1) All Programs shall provide sufficient, licensed nursing staff to ensure that preventive measures, treatments, medications, nutritional care, rehabilitation services, therapeutic activities, and related services are carried out, recorded, and reviewed, in accordance with participant assessments and plans of care.
 - (a) A Program must ensure licensed nursing staff are on-site for a minimum of eight hours per day, four of which must be provided by a registered nurse. The balance of the coverage may be provided by a licensed practical nurse.
 - (b) When the census reaches 35 members or more, the Program must provide nursing coverage on-site for a minimum of 12 hours per day, four hours of which must be provided by a registered nurse.
 - (c) When the census reaches 50 members or more, the Program must provide nursing coverage on-site for a minimum of 16 hours per day, eight hours of which must be provided by a registered nurse.
 - (d) When the census reaches over 75 members, the Program must increase the nursing coverage in proportion to the requirements listed in 105 CMR 158.032(B)(1)(a) through (d).
- (2) When a registered nurse is absent from the Program due to vacation or other temporary circumstances, the Program shall designate a licensed nurse to fulfill the nursing duties within the designee's scope of practice to act as a relief nurse in accordance with Department guidance.

(C) Program Aide Staff.

- (1) A Program shall provide at least one qualified Program Aide per 12 participants attending the Program.
- (2) A Program shall ensure a sufficient number of qualified Program Aide staff are available at all times to provide necessary supervision and assistance for each participant in accordance with participant needs and plans of care, written policies and procedures, and 105 CMR 158.000.

158.032: continued

(3) Licensed nursing staff shall supervise Program Aides.

(D) Service Coordination Staff. A Program with a licensed program capacity of 24 or more participants shall provide a social worker or other staff person who is appropriately licensed or supervised pursuant to 258 CMR 12.00: *Scope of Practice* for at least 20 hours per week.

(E) Therapeutic Activity Director. A Program shall provide a therapeutic activity director who is on-site at least four hours per day.

(F) Dietary Staff.

(1) Registered Dietitian. A Program shall provide a registered dietitian to monitor dietary services. A registered dietitian shall be on-site for a minimum of four hours every six months.

(2) Qualified Cook. A Program that prepares meals on-site shall employ a qualified cook. A Program shall ensure the qualified cook is available on-site for a sufficient number of hours to effectively manage all aspects of the meal service and kitchen functions.

(3) A Program shall provide sufficient numbers of adequately trained personnel to plan, prepare, and serve the proper diets to participants. All dietary staff shall be 18 years of age or older.

(G) Direct Care Staff.

(1) A Program shall provide at least one direct care staff person per six participants attending the Program.

(2) A Program shall ensure a sufficient number of qualified direct care staff are available at all times to provide necessary care, supervision, and assistance for each participant in accordance with participant assessed needs, plans of care, written policies and procedures, and 105 CMR 158.000.

158.033: Staff Qualifications and Responsibilities

(A) All personnel shall be currently licensed, registered, or deemed competent in accordance with applicable laws, licensure, registration, or competency requirements, and 105 CMR 158.000.

(B) All Program personnel in direct contact with participants shall be trained in emergency procedures and licensed nurses and Program Aides shall be certified in cardiopulmonary resuscitation (CPR) and basic first aid by an approved instructor.

(C) All personnel shall be assigned duties that are consistent with their training, experience, and written job description, and within their scope of practice.

(D) Registered Nurse.

(1) A Program's registered nurse(s) shall have at least two years of recent experience in the direct care of adults or chronically disabled persons.

(2) The minimum responsibilities of the Program's registered nurse(s) include:

(a) Provision and supervision of all nursing services;

(b) Supervision of staff;

(c) Coordinating the completion of, and ensuring the accuracy of, each participant's assessment;

(d) Coordinating the development, ongoing review, and revision of each participant's plan of care;

(e) Ensuring that nursing notes are written at least one time per month or more often as necessary to reflect each participant's health care status;

(f) Responding appropriately to any acute changes in a participant's health or functioning;

(g) Providing appropriate health care education for each participant and legally authorized representative;

(h) Assisting as necessary in the delivery of other Services;

(i) Ensuring ongoing education, training, and professional development of all Program staff that is relevant to care of participants;

158.033: continued

- (j) Obtaining, reviewing, and implementing primary care provider orders;
- (k) Coordinating the participant's care with the primary care provider and, if applicable, community service providers;
- (l) Supervising medication management services; and
- (m) Developing medication policies and procedures, in accordance with 105 CMR 158.039.

(E) Licensed Practical Nurse.

- (1) The minimum responsibilities of a Program's licensed practical nurse(s) include:
 - (a) Provision of nursing services and treatments to participants;
 - (b) Supervision of the care and services provided to participants by Program Aides, volunteers, and other personnel, as applicable;
 - (c) Participating in the completion of participants' comprehensive assessments and plans of care;
 - (d) Writing nursing notes at least one time per month or more often as necessary to address significant changes and health care teaching in each participant's health record;
 - (e) Responding appropriately to any acute changes in a participant's health or functioning;
 - (f) Providing appropriate health care education for each participant and legally authorized representative;
 - (g) Obtaining, reviewing, and implementing primary care provider orders; and
 - (h) Coordinating the participant's care with the primary care provider and, if applicable, community service providers.

(F) Program Aide.

- (1) On and after May 1, 2015 a Program may not employ any individual for more than four months as an aide at a Program unless the individual has been determined competent, pursuant to one of the following criteria:
 - (a) Has demonstrated competence through satisfactory participation in a relevant health care training or competency evaluation program. Said training or competency evaluation program must teach students nursing and nursing related skills including, at minimum, the skills identified at 105 CMR 158.033(F)(1)(b); or
 - (b) A registered nurse employed by the Program or under contract with the Program has determined the individual is competent to provide direct care to participants based on the individual's demonstration of competency in basic nursing and nursing related skills and techniques. The Program shall provide at least 40 hours of a combination of classroom and experiential training regarding the skills identified at 105 CMR 158.033(F)(1)(b) prior to determining the individual is competent to be a Program Aide. In order to be deemed competent, the individual must demonstrate competency in the following skill areas:
 - 1. Communication and interpersonal skill;
 - 2. Observation, reporting, and documentation of participant status and the care or service furnished;
 - 3. Basic infection control procedures;
 - 4. Basic delegated nursing and nursing related skills including:
 - a. Basic elements of body functioning and changes in body function that must be reported to the aide's supervisor;
 - b. Obtaining and recording vital signs;
 - c. Personal care skills including appropriate and safe participant personal hygiene and grooming techniques;
 - d. Assisting participants at various levels of functioning with ADL;
 - e. Basic restorative nursing; and
 - f. Safety and emergency procedures, including the Heimlich Maneuver.
 - 5. Maintenance of a clean, safe, and healthy environment;
 - 6. Recognizing, responding to, and reporting emergencies and knowledge of emergency procedures;
 - 7. Recognizing the physical, emotional, and developmental needs of participants and working in a manner that respects participants, their privacy, and their property;
 - 8. Prevention of, and reporting, participant abuse, neglect, mistreatment and misappropriation; and

158.033: continued

9. Caring for participants enrolled at the Program and participants with Alzheimer's Disease and related disorders.

(2) A Program shall provide each individual who has not been determined competent pursuant to 105 CMR 158.033(F)(1)(a) with at least eight hours of orientation training regarding the skills identified at 105 CMR 158.033(F)(1)(b)1. through 9. before that individual may provide any direct care to participants.

(3) The Program shall maintain documentation of each Program Aide's training and competency determination in his or her personnel file.

(4) The responsibilities of the Program Aide include assisting the nursing staff and the therapeutic activities director as required, and in accordance with participant plans of care, written policies and procedures, and 105 CMR 158.000, in order to meet the needs of individual participants.

(5) A Program Aide may not simultaneously perform maintenance, food preparation, or extensive housekeeping tasks during Program hours of operation and serve as a Program Aide necessary to satisfy minimum staffing requirements in 105 CMR 158.032(C).

(G) Service Coordination Staff.

(1) The responsibilities of the Program's social worker(s) or other staff person(s) who is appropriately licensed or supervised pursuant to 258 CMR 12.00: *Scope of Practice* shall include:

- (a) Informing participants of and referring participants to available community services;
- (b) Participating in the completion of comprehensive assessments and plans of care;
- (c) Writing service coordination notes in the participant's health record upon service commencement, when significant changes occur, and at least one time every 90 days or more often as necessary to ensure the health record reflects the current clinical needs of the participant;
- (d) Providing, as appropriate, coordination of the medically-related physical, mental, and behavioral, service needs of a participant at the time of enrollment, during treatment and care in the Program, or at the time of discharge;
- (e) Assisting with any personal, social, family, or adjustment problems the participant may experience at the Program;
- (f) Referring the participant or family to the appropriate community resources if the participant or the participant's family requires specialized counseling; and
- (g) Coordinating services if a participant needs services from other community agencies, and no agency is acting as coordinator of services for that participant.
- (h) Assessing, planning, implementing, coordinating, monitoring, and evaluating the services required to meet a participant's needs.

(2) Any staff person who performs service coordination shall have a minimum of a bachelor's degree in human services or a related field from an accredited college or university and at least one year of relevant and recent experience working with adults in a professional capacity.

(H) Therapeutic Activity Director.

(1) The therapeutic activity director shall be a therapeutic recreation specialist or an activities professional who:

- (a) Is certified as a therapeutic recreation specialist or an activities professional by an accrediting body recognized by the Department; or
- (b) Is a qualified occupational therapist; or
- (c) Is an occupational therapy assistant; or
- (d) Has at least two years of experience working in a social or recreational program within the last five years, one of which was full-time in an activities program in a health care setting.

(2) If the activity director is not certified as a therapeutic recreation specialist or an activities professional by an accrediting body recognized by the Department, or is not a qualified occupational therapist, the activity director and the Program shall:

- (a) consult with an occupational therapist in the development of a therapeutic activities program that meets the individual needs of each participant; or
- (b) adopt a model therapeutic activities program, provided that the model activities program is developed in consultation with an occupational therapist, and implement such activities program in a manner that meets the individual needs of each participant.

158.033: continued

- (3) The responsibilities of the therapeutic activity director shall include:
- (a) Developing and implementing the therapeutic activity program for each participant;
 - (b) Supervising the program aides who assist with therapeutic activities;
 - (c) Planning and scheduling activities and events;
 - (d) Posting in a conspicuous place a monthly calendar of activities and events;
 - (e) Contributing to each participant's comprehensive assessment and plan of care;
 - (f) Writing a therapeutic activity note at least one time every 90 days or more often as necessary in each participant's health record that documents the participant's therapeutic activity needs, participation in, reaction to, and current preference for activities; and
 - (g) Assisting as necessary with other Services.

(I) Rehabilitation Services. Rehabilitation services shall be provided by licensed physical therapists, occupational therapists, and speech, hearing, and language therapists.

(J) Registered Dietitian.

- (1) The responsibilities of the registered dietitian shall include:
- (a) Ensuring dietary services are provided and the nutritional needs of participants are met;
 - (b) Providing, as applicable, consultation and training to the qualified cook regarding dietary personnel, food production, service procedures, maintenance of records, training programs, and sanitation;
 - (c) Providing consultation and education to staff regarding the nutritional requirements of participants, meal service, distribution, sanitation, and disaster dietary plans; and
 - (d) Evaluating and approving the nutritional adequacy of the menus as planned.

(K) Qualified Cook. The qualified cook shall be responsible for the following:

- (1) Managing all aspects of the meal service and kitchen;
- (2) Preparing menus;
- (3) Procuring food from approved sources; and
- (4) Storing, preparing, distributing, and serving food under sanitary conditions.

(L) Volunteers.

- (1) The Program Director shall determine the duties and responsibilities of volunteers.
- (2) If a volunteer provides direct participant care, the volunteer shall, at minimum, meet the qualifications of program aide staff specified at 105 CMR 158.033(F).
- (3) A volunteer may not be counted as a licensed nurse, Program Aide, social worker or any individual(s) supervised by a social worker in accordance with 258 CMR 12.00: *Scope of Practice*, or activity director for the purpose of satisfying the minimum staffing requirements specified in 105 CMR 158.032.

158.034: Enrollment, Emergency Transports, and Discharges

(A) The enrollment and discharge of participants shall be in accordance with written policies and procedures developed by each Program and acceptable to the Department.

(B) A Program shall not discriminate against any participant on the basis of source of referral, source of payment, race, religion, ethnic origin, gender, sexual orientation, age, or disability. A Program shall comply with all state and federal antidiscrimination laws.

(C) A Program shall designate a member of the staff to be responsible for enrollment and discharge planning.

(D) Enrollment.

- (1) A Program shall enroll and care for only those participants in need of Services and for whom it can provide care and services appropriate to the participant's physical, cognitive, psychosocial, and behavioral needs.
- (2) A Program may not enroll a participant without a written order for Services from a primary care provider who determined that Program care is appropriate to meet the participant's needs.

158.034: continued

(3) A Program may not enroll a participant without the written consent of the participant or his or her legally authorized representative, if he or she is not competent.

(4) A participant shall be screened for TB prior to enrollment in a Program. The participant's health record at the Program shall contain evidence of initial health screening for TB, including the following:

NON-TEXT PAGE

158.034: continued

- (a) A pre-enrollment TB history and risk assessment with additional screening as indicated within three months prior to enrollment in accordance with Department Bureau of Infectious Disease guidelines.
 - (b) An annual TB risk assessment, symptom review, and education with additional screening as indicated in accordance with Department Bureau of Infectious Disease guidelines.
- (5) Participant Enrollment Agreement. A Program shall provide a written agreement to the participant and, if appropriate, to the participant's legally authorized representative. The participant enrollment agreement shall specify:
- (a) The services offered to the participant by the Program and the costs of those services;
 - (b) The responsibilities of the participant and his or her legally authorized representative to the Program;
 - (c) The days and hours of Program operation;
 - (d) The schedule of holidays when the Program is closed;
 - (e) The days per week the participant will attend;
 - (f) Procedures for notifying the participant of any unexpected closing of the Program due to disaster or inclement weather;
 - (g) Arrangements for transporting the participant to and from the Program, if applicable;
 - (h) Emergency procedures; and
 - (i) Reasons the Program may initiate discharge, as specified at 105 CMR 158.034(F)(3).
- (E) Emergency Transportation to an Acute Care Hospital.
- (1) In the event of a medical emergency, a Program shall call the emergency access number 911 and arrange for the transport of a participant to an acute care hospital for emergency medical care.
 - (2) The Program shall provide all pertinent health information to the emergency medical technician(s) and to any hospital to which any participant is transported, including the participant's Comfort Care/Do Not Resuscitate Verification Form, MOLST Form, or other advance directive on file at the Program, as applicable.
 - (3) The Program shall contact the participant's primary care provider and legally authorized representative at the time of the emergency or immediately thereafter to advise of the emergency and all actions taken in response to the emergency.
 - (4) The Program shall, immediately after such medical emergency, document in the participant's health record the following:
 - (a) The nature of the emergency and actions taken in response to the emergency;
 - (b) The reason for the participant's emergency transport to an acute care hospital, if applicable; and
 - (c) The name of the participant's legally authorized representative who was notified of the medical emergency, and the date and time the participant's legally authorized representative was notified.
- (F) Discharges.
- (1) Discharge from a Program may be initiated by the Program or by the participant.
 - (2) A participant may choose to discontinue enrollment at a Program at any time.
 - (3) A Program may not discharge a participant unless one or more of the following conditions has been met:
 - (a) The discharge is necessary for the participant's welfare or the participant's needs can no longer be met by the Program;
 - (b) The participant's health has improved and he or she no longer requires Services;
 - (c) The safety of other participants in the Program is endangered;
 - (d) The health of other participants in the Program is endangered;
 - (e) The participant has failed, after reasonable and appropriate notice, to pay for services at the Program or to have services paid by any public or private insurer; or
 - (f) The Program ceases to operate.
 - (4) When a discharge is initiated by the Program, it shall:
 - (a) Arrange for the participant to be discharged to other appropriate services.

158.034: continued

- (b) Develop a discharge plan, in consultation with the participant and his or her legally authorized representative that will assist the participant in adjusting to his or her new environment and will coordinate the transition to appropriate and available services. The discharge plan shall include the provision of counseling and services to the participant in order to prepare the participant for discharge.
- (c) Develop a written discharge plan that includes the following:
 1. Recommendations for continuing care;
 2. The setting to which the participant is to be discharged; and
 3. Referrals to community services.
- (d) Prepare a written discharge summary which includes a synopsis of the participant's participation in the program, his or her health status at the time of discharge, arranged services, and discharge location.
- (e) Notify the local Aging Service Access Point, if applicable, 30 days prior to discharge, in cases where a participant will be referred for alternative community services.
- (f) At least 30 days prior to the date of discharge, provide written notice containing sufficient explanation of reasons for discharge, discharge procedure, and discharge plan to the participant or his or her legally authorized representative and the participant's primary care provider.
- (5) When the participant discontinues his or her enrollment, the Program shall be responsible for discharge service planning to facilitate a safe referral to alternate services to the extent possible.
- (6) When the participant is discharged on an emergency or unplanned basis, the Program shall be responsible for discharge service planning to facilitate a safe referral to alternate services to the extent possible.
- (7) A Program shall communicate with the participant or the participant's legally authorized representative at least one time within 25 business days following discharge. The Program shall document its findings regarding the participant's post-discharge status and condition in the participant's health record.
- (8) A Program shall complete discharge related documentation in the participant's health record within two weeks of discharge, including documenting the reason for discharge.

158.035: Primary Care Provider Services

- (A) A Program shall only provide Services to a participant in accordance with current treatment orders from that participant's primary care provider.
- (B) A Program shall maintain the business addresses, telephone number(s), and emergency contact information of each participant's primary care provider in each participant's health record. Emergency contact information shall be readily accessible to personnel on duty in case of emergencies.
- (C) A Program may not enroll a participant unless said participant has had a physical examination within 12 months prior to enrollment which documents the following:
 - (1) Diagnoses and associated conditions;
 - (2) Known allergies;
 - (3) Pertinent findings of physical exam;
 - (4) Significant medical history;
 - (5) Assessment of physical capability, including ADL;
 - (6) Assessment of cognitive status; and
 - (7) TB screening.
- (D) A Program shall obtain initial treatment orders or prescriptions from the participant's primary care provider that include the following:
 - (1) Medications;
 - (2) Special treatments or procedures;
 - (3) Rehabilitation services;
 - (4) Dietary needs;
 - (5) Assistance required with ADL; and
 - (6) Special requirements necessary for the participant's health or safety.

158.035: continued

(E) A Program shall record the primary care provider's initial treatment orders in the participant's health record prior to enrollment.

(F) A Program shall maintain a record of all orders and prescriptions from primary care providers and other physicians in the participant's health record that pertain to services at the Program.

158.036: Diagnostic Services

(A) A Program shall comply with 105 CMR 180.000: *The Operation, Approval and Licensing of Clinical Laboratories* and 42 CFR Part 493.

(B) A Program may not perform clinical laboratory tests for participants except waived urine tests, glucose testing, and PT/INR tests, as ordered by a primary care provider. A Program may not perform tuberculin skin tests except as ordered by a primary care provider.

(C) A Program may not perform any diagnostic service unless it is ordered by a participant's primary care provider.

(D) A Program shall record all findings, reports, and results of any diagnostic test in the participant's health record and shall report results to the participant's primary care provider as appropriate.

158.037: Assessment and Care Planning(A) Assessment.

(1) A Program shall conduct and document in writing a participant-specific, interdisciplinary, accurate, comprehensive assessment, as specified in 105 CMR 158.037 and in guidelines of the Department.

(2) A Program shall:

(a) Complete an initial comprehensive assessment within 14 days of enrollment.

(b) Complete a revised comprehensive assessment within 14 days of any significant change.

(c) Review and revise, as necessary, the comprehensive assessment at least once every six months.

(d) Complete a new comprehensive assessment within 365 days of the completion of the most recent comprehensive assessment.

(e) Assess participants' health status and evolving needs on an ongoing basis.

(3) The comprehensive assessment shall include an assessment of the participant's health status and care requirements, as well as the participant's and his or her family's goals and desires, and shall be conducted in conformance with guidelines of the Department and 105 CMR 158.037. The comprehensive assessment shall include, at minimum, the following areas:

(a) Identification and demographic information;

(b) Customary routine and support services;

(c) Cognitive patterns;

(d) Communication;

(e) Vision;

(f) Mood and behavior patterns;

(g) Psychological well-being;

(h) Physical functioning and structural problems;

(i) Continence;

(j) Disease diagnoses and health conditions;

(k) Dental and nutritional status;

(l) Skin conditions;

(m) Activity pursuits;

(n) Medications, including a review of all of the participant's prescription and over-the-counter drugs, herbal remedies, and other alternative treatments that could affect drug therapy;

(o) Special treatments and procedures;

158.037: continued

- (p) The need for referrals and further evaluation by appropriate health professionals;
- (q) Discharge potential;
- (r) Complications and risk factors that affect care planning;
- (s) A comprehensive summary of the participant's health status; and
- (t) Name and credentials of those who participated in the comprehensive assessment.

(B) Interim Plan of Care. An interim plan of care shall be developed upon enrollment in order to meet a participant's immediate care needs until the comprehensive plan of care is developed.

(C) Comprehensive Plan of Care.

(1) The comprehensive plan of care shall be based on the comprehensive assessment and shall specify the type, amount, frequency, and duration of services to be provided to each participant and shall include the following:

- (a) Required medical services;
- (b) Required nursing services;
- (c) Required service coordination;
- (d) Required dietary services;
- (e) Required rehabilitation services;
- (f) Required therapeutic activity services;
- (g) Any other service required to meet the participant's needs;
- (h) Information regarding the coordination of the participant's care with primary care providers, caregivers, and community services (including homemaker, home health, personal care, or therapy services) that the participant is receiving outside the Program; and
- (i) Measurable goals, objectives, and timetables to meet a participant's needs as identified in the comprehensive assessment.

(2) A Program shall complete the comprehensive plan of care within seven days of completion of the comprehensive assessment.

(3) A Program shall review and revise each participant's comprehensive plan of care after each comprehensive assessment and at least once every six months or more often as necessary.

(4) Each participant's comprehensive plan of care shall be developed by the registered nurse in conjunction with other care team members and the participant or his or her legally authorized representative.

(5) The registered nurse shall consult with and shall notify the primary care provider of the participant's plan of care after each assessment and at least once every six months, or more often in the event of a significant change.

158.038: Quality of Care and Services

(A) All services provided by a Program shall meet professional standards of care and shall be provided by qualified persons.

(B) A Program shall provide services in accordance with each participant's comprehensive assessment and plan of care that support each participant's highest level of functioning, and that support the participant's and caregiver's goals to maintain the participant in the community.

(C) A Program shall provide all services, including those identified in 105 CMR 158.038(D), in accordance with the Program's written policies and procedures and in accordance with 105 CMR 158.000.

(D) A Program shall provide the following services:

- (1) Nursing care;
- (2) Service coordination;
- (3) Therapeutic activities;
- (4) Dietary services; and
- (5) Medication management services.

158.038: continued

(E) Nursing Care. Nursing care shall be an integral part of the health care provided at a Program and shall emphasize the promotion and maintenance of health and the education, counseling, and emotional support of participants and caregivers. Nursing care includes coordination and collaboration with other professions and organizations within the community.

(F) Service Coordination.

(1) A Program shall provide sufficient service coordination to coordinate care and ensure participants attain or maintain their highest practicable physical, behavioral, and psychosocial well-being in accordance with the participants' plans of care, the written policies and procedures, and 105 CMR 158.000.

(2) Service coordination shall be coordinated with the nursing care, therapeutic activities, and other Program services.

(3) Service coordination shall include educational programs for Program personnel in order to promote the development of a therapeutic community, a congenial atmosphere, and healthy interpersonal relationships in the Program.

(G) Therapeutic Activities.

(1) A Program shall provide an on-going, regularly scheduled, organized program of meaningful and purposeful therapeutic activities for at least four hours per eight hour time period, exclusive of meal time and snack time.

(2) Therapeutic activities shall be individualized and designed to improve or maintain participants' self-awareness and level of functioning and shall be reasonably suited to the needs and interests of participants. Therapeutic activities shall be provided in a congenial environment on an individual and group basis.

(3) Program personnel shall seek ways to engage participants in therapeutic activities.

(4) The therapeutic activities program may utilize community resources to enhance participant-community interactions.

(5) A Program shall provide, maintain, and store basic supplies and equipment for therapeutic activities.

(6) A Program shall provide sufficient space for therapeutic activities.

(7) A Program that serves both participants with and without Alzheimer's disease and related disorders shall provide a separate space, as necessary, for therapeutic activities for participants with advanced dementia.

(8) Therapeutic activities shall be:

(a) Based on an assessment of each participant's gross motor, self-care, sensory, cognitive, and memory skills;

(b) Structured and planned to maximize the functional independence of each participant;

(c) Purposeful and meaningfully designed to assist participants in self-help and functional skills necessary to reside successfully in home and community based settings;

(d) Cognitively stimulating;

(e) Designed to enhance memory, to the extent practicable;

(f) Designed to promote physical fitness;

(g) Opportunities for self-expression;

(h) Coordinated with community service providers for necessary therapies; and

(i) Implemented in accordance with standards of practice for specific populations, including participants with Alzheimer's and related disorders, and appropriate to the stage of disease of the participants.

(H) Dietary Service.

(1) A Program shall provide adequate dietary services for participants in accordance with participants' nutritional needs.

(2) A Program may provide dietary services directly or may contract for the procurement of prepared meals provided the contracted service complies with 105 CMR 158.038(H).

(3) A Program shall maintain a written record of dates, times, services rendered, and recommendations made by the registered dietitian.

(4) Nutrition.

(a) A Program shall provide at least one third of the daily nutritional and dietary needs of each participant, as specified in guidelines of the Department.

(b) A Program shall provide each participant with a minimum of one nourishing and palatable hot mid-day meal. Occasional seasonal variations to the hot meal may be made as appropriate.

158.034: continued

- (c) Menus shall be planned and food supplies maintained so that a nutritionally adequate equivalent alternate meal can be provided at all times. Alternate meals shall be planned.
- (d) An alternate meal reference book approved by the registered dietitian shall be maintained at the Program for reference.
- (e) A Program shall provide morning and afternoon snacks that are appropriate to participants' dietary needs.
- (f) A Program shall maintain records of menus as served for at least 30 days.
- (5) Therapeutic Diets.
 - (a) A Program that has participants in need of therapeutic diets shall plan, prepare, and serve therapeutic diets as prescribed by primary care providers.
 - (b) A current diet manual shall be readily available to personnel.
- (6) Food and Equipment.
 - (a) A Program shall provide convenient and suitable utensils such as forks, knives, tongs, spoons, or scoops, in order to minimize direct handling of food at all points where food is prepared or served.
 - (b) Single service items shall be discarded after one use.
 - (c) A Program shall establish procedures and provide equipment to maintain food at a proper temperature during service and transportation.
 - (d) Hot food shall be hot, and cold food shall be cold, when it reaches the participant.
 - (e) A Program shall serve food in a home-like, pleasant, clean, relaxing, and quiet atmosphere.
 - (f) Meals may not be served and activities may not occur simultaneously at the same table. Meals shall be served only after activities have been discontinued at the table, the area cleared of such supplies, and the area cleaned and prepared for meal service.
 - (g) A Program shall establish a written Disaster Dietary Plan and staff shall be familiar with it. The dietary disaster plan shall include, but not be limited to, alternate methods for preparing and serving food, including proper sanitation of dishes and utensils, in the event of an emergency or loss of electrical power, and a supply of food and water sufficient to provide for the dietary needs of the participants in the event that it becomes advisable to shelter in place.
- (7) Sanitation.
 - (a) Sanitary conditions shall be maintained in all aspects of the storage, preparation, and distribution of food.
 - (b) Written reports of inspections by state and local health authorities shall be kept on file and posted in the Program with the notations made of action taken by the Program to comply with any recommendations.
 - (c) All food shall be maintained at safe temperatures and in accordance with 105 CMR 590.000: *State Sanitary Code Chapter X - Minimum Sanitation Standards for Food Establishments.*
 - (d) All food service personnel shall wear clean, washable garments, closed toe shoes, and hairnets or clean caps, and shall keep their hands and fingernails clean at all times.
 - (e) All food service personnel shall be in good health, shall practice hygienic food handling techniques, and shall conform to 105 CMR 590.000: *State Sanitary Code Chapter X - Minimum Sanitation Standards for Food Establishments.*
 - (f) A Program shall maintain an inventory of food and related supplies.
 - (g) A Program shall establish and follow written policies and procedures for cleaning, disinfecting, and sanitizing all equipment and work areas.
 - (h) Poisonous and toxic materials shall be stored in locked cabinets that are not used for any other purpose, and in a place that is separate from all food storage areas, food preparation areas, and clean equipment and utensils.
- (I) Rehabilitation Services.
 - (1) A Program shall arrange for or coordinate rehabilitation services by licensed physical, occupational, and speech, hearing and language therapists for participants in need of these rehabilitation services.
 - (2) Rehabilitation services shall be coordinated with the nursing, dietary, service coordination, therapeutic activity, and other services provided to participants in order to promote restoration or maintenance of the participant to his or her maximum potential.

158.038: continued

(J) Interpreter Services. A Program shall provide interpreter services, as necessary, that are appropriate to the population served. Interpreter services may be provided by a telephone interpreter service where appropriate.

158.039: Medication Management Services

(A) A Program shall:

- (1) in consultation with a registered nurse, physician, and pharmacist, develop and implement written policies and procedures governing medications, including the receipt, storage, and administration of all drugs and biologicals; or
- (2) adopt model written policies and procedures governing medications, including the receipt, storage, and administration of all drugs and biologicals, provided that such model policies and procedures are developed in consultation with a registered nurse, physician, and pharmacist.

(B) A Program shall designate a registered nurse as supervisor of medication management services.

(C) Medication policies and procedures shall address:

- (1) Receipt of medications;
- (2) Documentation of the administration of all medications;
- (3) Response to medication emergencies;
- (4) Storage of medications;
- (5) Wasting and disposal of unused medications;
- (6) Inventorying and auditing controlled substances in accordance with state and federal laws and regulations;
- (7) Reporting and documentation of medication errors;
- (8) Reporting theft or loss of medications including controlled substances; and
- (9) Procedures for resolving concerns raised by the Program or the participant or legally authorized representative regarding administration of medications. Such procedures shall provide for and encourage the participation of the participant or legally authorized representative.

(D) A Program shall provide a copy of its written medication policies and procedures to each participant or his or her legally authorized representative upon enrollment.

(E) Medication Orders.

- (1) The licensed nurse shall ensure that there is a complete and current medication order from a licensed prescriber in the participant's health record for each medication that has been prescribed and dispensed to the participant.
- (2) An order for any change in prescription medication that has already been dispensed to the participant, may only be received by the nurse. Any verbal order must be followed by a signed written order within seven business days. The medication order shall be obtained and documented and the medication administration plan updated.
- (3) A Program may not administer a non-prescription medication, or a prescription medication that has been prescribed and dispensed to the participant, without a medication order from a licensed prescriber that contains the following information:
 - (a) Participant's name;
 - (b) Name and signature of the licensed prescriber;
 - (c) Name, route, and dosage of medication;
 - (d) Frequency and duration of medication administration;
 - (e) Date of the prescription; and
 - (f) Any specific directions for administration.

(F) Any research or investigational drug studies conducted at a Program must be in compliance with state and federal laws and regulations. Medication research projects governed by M.G.L. c. 94C, § 8 shall be conducted in accordance with 105 CMR 700.009: *Research Involving Controlled Substances*.

(G) Only Program personnel who are legally authorized in accordance with current state and federal laws and regulations may administer medications.

158.039: continued

(H) Medications prescribed for a specific participant may not be administered to any other participant.

(I) Administration of Medications.

(1) The legally authorized individual administering medications shall:

- (a) Positively identify the participant who receives the medication;
- (b) Document assessments of the participant and communicate significant information relating to prescription medication effectiveness, adverse reactions, or other harmful effects to the participant or legally authorized representative and licensed prescriber;
- (c) Respond to medication emergencies; and
- (d) Have a current pharmaceutical reference available for his or her use.

(2) Medication Errors.

- (a) Medication errors shall be documented by the nurse on an incident report form. Medication error incident report forms shall be retained by the Program and shall be made available to the Department upon request.
- (b) The participant or legally authorized representative shall be notified of all medication errors.
- (c) The primary care provider and prescriber shall be notified immediately of all medication errors with the potential for adverse participant consequences.

(3) A Program may not add any medication to any food or beverage without the participant's or his or her legally authorized representative's knowledge or consent.

(J) Participants may self-administer medications provided that the following requirements are met:

- (1) The nurse evaluated the participant's health status and abilities and deemed self-administration safe and appropriate;
- (2) The primary care provider's order or prescription indicates that self-administration is appropriate;
- (3) A nurse and the participant or legally authorized representative, where appropriate, entered into a written agreement which specifies the conditions under which prescription medication may be self-administered;
- (4) Self-administration is included in the plan of care;
- (5) The self-administered medications are stored in the medication cabinet; and
- (6) A nurse monitors the participant's self-administration.

(K) A Program shall report all suspected drug diversion and drug tampering to the Division of Health Care Facilities Licensure and Certification and all appropriate local, state, and federal authorities.

(L) Medication Administration Record.

(1) A Program shall maintain a monthly medication administration record for each participant who receives medications at the Program.

(2) All medications shall be accurately recorded and accounted for at all times.

(3) Each dose of prescription and over-the-counter medication administered shall be recorded in the medication administration record.

(4) A medication administration record shall include the following information:

- (a) The participant's name;
- (b) The current month and year;
- (c) The primary care provider's name;
- (d) Known allergies;
- (e) Medication prescriptions;
- (f) Contraindications;
- (g) Documentation of side effects, adverse reactions, and effectiveness of PRN medications;
- (h) The dose or amount of medication administered;
- (i) The name of the medication and the date and time of administration or omission of administration, including the reason for omission; and
- (j) The full signature of the nurse administering the medication. If the medication is given more than once by the same person, he or she may initial the record, subsequent to signing a full signature.

(5) All documentation regarding medication administration shall be recorded in a permanent format that is not able to be altered.

158.039: continued

(M) Handling and Storage of Medications.

- (1) A participant, legally authorized representative, or delegated responsible adult shall deliver all medications to be administered by Program personnel or to be taken by self-administering participants to the nurse. Medications shall be delivered as follows:
 - (a) Prescription medication must be in a pharmacy labeled container.
 - (b) Over the counter medications must be in a manufacturer labeled container.
 - (c) The nurse receiving the medication shall document the name, strength, and quantity of the medication delivered, and the date of delivery, in the participant's Medication Administration Record.
 - (d) In extenuating circumstances, as determined by the nurse, the medication may be delivered by other persons; provided, however, that the nurse is notified in advance by the participant or legally authorized representative of the arrangement and the quantity of medication being delivered to the Program.
- (2) All medications shall be maintained and stored in original pharmacy or manufacturer labeled containers and in such manner as to maintain the integrity of the medications. Transfer to other containers is forbidden.
- (3) Security.
 - (a) All medications shall be kept in a securely locked cabinet or closet used exclusively for medications. The medication cabinet(s) or closet(s) shall be locked except when opened to obtain medications. If a cabinet is used to store medications, it shall be substantially constructed and anchored securely to a solid surface.
 - (b) Medications requiring refrigeration shall be stored in a permanently affixed locked box in a refrigerator or in a locked refrigerator used exclusively for medications. The refrigerator shall be maintained at temperatures of 38°F to 42°F.
 - (c) The medication cabinet or closet shall be located in or near the nursing office and in a location that is not frequented by participants or visitors.
 - (d) The medication cabinet or closet shall be well-lighted, locked at all times with a suitable lock, and maintained in a clean and sanitary manner. It shall be sufficient in size to permit storage without crowding.
 - (e) The medication cabinet or closet shall be located near a sink for handwashing.
 - (f) There shall be a separately locked, securely fastened compartment within the locked medicine cabinet or closet for the proper storage of prescribed controlled substances.
 - (g) Medications for "external use only" shall be kept in a locked cabinet or compartment that is separate and apart from internal use medications.
- (4) Access to medications shall be limited to staff authorized to administer medications at the Program.
- (5) Participants or legally authorized representatives may retrieve medications from the Program at any time.
- (6) No more than a 30 day supply of any prescription medication may be stored at the Program.
- (7) All unused, discontinued, or outdated medications and medications with defaced labels shall be returned to the participants or legally authorized representatives and the return documented in the Medication Administration Record.
- (8) If unable to comply with 105 CMR 158.039(M)(7), unused, discontinued, or outdated prescription medications may be destroyed by two staff members, one of which must be a nurse, in accordance with guidelines of the Department.

158.040: Participant Health Records

- (A) All Programs shall provide conveniently located and suitably equipped areas for the recording and storage of health records.
- (B) All Programs shall maintain on the premises, in accordance with acceptable professional standards of practice, a separate, complete, accurate, systematically organized, and current health record for each participant from the time of admission to the time of discharge. All entries shall be dated and signed. The participant health record shall be kept at the nursing station.
- (C) The participant health record shall, at minimum, include:
 - (1) Participant information including the participant's name, social security number, date of birth, gender, marital status, religion, home address, any public and private insurance information, and date and time of enrollment.

158.040: continued

- (2) The name, address, and phone number of the participant's identified contact person and legally authorized representative.
 - (3) Documentation from primary care providers including orders or prescriptions for Services, physical examinations, and initial treatment orders, as described at 105 CMR 158.035.
 - (4) The participant enrollment agreement.
 - (5) Participant clinical information, including:
 - (a) A copy of the most recent physical examination;
 - (b) The primary care provider orders;
 - (c) Medical history;
 - (d) TB screening;
 - (e) A list of known allergies;
 - (f) Information concerning participant's dietary requirements;
 - (g) The medication administration record;
 - (h) The results of all assessments;
 - (i) Correspondence with family, therapists, primary care providers, physicians, health care consultants, or others pertaining to the health care of the participant;
 - (j) Consultation notes from any health care provider who visits or examines the participant at the Program.
 - (k) The participant's attendance record;
 - (l) Relevant legal documentation that may include signed authorizations for release of information, advanced directives, or health care proxy;
 - (m) Plans of care;
 - (n) An inventory of participant's personal belongings maintained at the program; and
 - (o) Documentation regarding transfers and discharges, as required in 105 CMR 158.034.
 - (6) Any notification provided by Program Director pursuant to 105 CMR 158.030(K) shall be recorded in writing in the participant's health record.
 - (7) Professional documentation as applicable, including but not limited to the following:
 - (a) Nursing notes and assessments;
 - (b) Rehabilitation services notes and assessments;
 - (c) Therapeutic activity notes and assessments;
 - (d) Service coordination notes and assessments;
 - (e) Dietary notes and assessments; and
 - (f) Assistance provided with ADL or a staff log of care provided to participant.
- (D) Participant health records shall be:
- (1) Readily accessible to clinical personnel;
 - (2) Readily accessible to the Department upon request and in the manner in which it is requested;
 - (3) Safeguarded against loss, destruction, or unauthorized use;
 - (4) Maintained in compliance with state and federal privacy and security laws and regulations, including HIPAA; and
 - (5) Maintained on-site for at least the most recent 24 months.
- (E) A Program shall maintain participant health records for at least seven years. In the event a Program discontinues operations, the Program shall make arrangements for storage of all health records for at least seven years, and shall notify the Department as to the location of the records and the person responsible for their maintenance.
- (F) A Program may implement and use electronic health records. A Program that implements and uses electronic health records shall:
- (1) Comply with all requirements of 105 CMR 158.000;
 - (2) Establish, follow, and make accessible to all users written policies and procedures for the use of electronic health records;
 - (3) Adequately train all personnel in the use of the electronic health records in order to ensure safe and quality participant care and to ensure the privacy and security of participants' health information;

158.040: continued

- (4) Ensure security of records by implementing password protections and audit trails to verify entries and access and by maintaining up-to-date antivirus software and appropriate network security. Any data on a portable storage device, mobile computing device, or wireless transmission shall be adequately encrypted;
- (5) Establish and follow written policies and procedures regarding electronic signatures. Electronic health records must be designed to ensure integrity, authenticity, and non-repudiation of data entered;
- (6) Ensure a minimum of two participant identity checks prior to data entry;
- (7) Ensure the system includes redundancy and other protections against possible loss, deletion, or destruction of information;
- (8) Ensure the required health record and pharmaceutical information is and will be available at all times including during emergencies such as flooding or loss of electrical power; and
- (9) Report any breach of confidential information to the Department, state, and federal authorities as required.

158.041: Participant Rights(A) Exercise of Rights.

- (1) A participant has the right to be free from interference, coercion, and reprisal from the Program in exercising his or her rights.
- (2) A participant has the right to be free from discrimination on the grounds of source of referral, source of payment, race, religion, national origin, sex, sexual orientation, age, or disability.
- (3) In the case of a participant adjudged incompetent under the state law by a court, the rights of the participant are exercised by the person appointed under state law to act on the participant's behalf. In the case of a participant who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with state law may exercise the participant's rights to the extent provided by state law.
- (4) A participant or his or her legally authorized representative, upon request, has the right:
 - (a) To access all of his or her records within 24 hours; and
 - (b) To purchase, at a cost not to exceed the community standard, photocopies of the records within two business days.
 - (c) To receive upon request the name and specialty of the person(s) responsible for his or her care and the coordination of his or her care; and
 - (d) To receive an explanation as to the relationship, if any, of the Program to any other health care program or educational institution insofar as said relationship relates to his or her care or treatment.

(B) Notice of Rights and Services.

- (1) A participant has the right to be fully informed, both orally and in writing, in a language that the participant understands, as documented by the participant's written acknowledgment, of all participant rights.
- (2) A participant has the right to receive a copy of participant rights stated in 105 CMR 158.041 upon request.
- (3) A participant has the right to be notified whenever there is a change in participant rights.

(C) Free Choice.

- (1) A participant has the right to informed consent.
- (2) A participant has the right to refuse treatment and medication.
- (3) A participant has the right to make advanced directives about his or her medical care.
- (4) A participant has the right to be fully informed in a language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.
- (5) A participant has the right to refuse to be examined, observed, or treated by students or any other Program personnel.
- (6) A participant has the right to refuse to serve as a research subject and to refuse any care or examination when the primary purpose is educational or informational rather than therapeutic.
- (7) A participant has the right to refuse to perform services for the Program.

158.041: continued

(D) Privacy and Confidentiality.

(1) A participant has the right to refuse the release of, and the Program must keep confidential, all information contained in the participant's records, regardless of the form or storage method of the records, except when release is required by:

- (a) Transfer to another health care institution;
- (b) Law;
- (c) Third party payment contract; or
- (d) The participant.

(2) A participant has the right to privacy during personal treatment and care.

(E) Grievances.

(1) A participant has the right to voice grievances without discrimination or reprisal. Grievances include those with respect to treatment which has been furnished as well as that which has not been furnished.

(2) A participant has the right to prompt efforts by the Program to resolve grievances the participant may have, including those with respect to the behavior of other participants. Such grievances and the action taken by the Program shall be documented in the participant's health record.

(F) A participant has the right to examine the state license inspection reports for the Program. The Program must make the results available for examination in a place readily accessible to participants without the need to request access.

(G) A participant has the right to private, unrestricted, communication with persons of his or her choice while at the Program, including privacy for telephone calls and meetings.

(H) Quality of Life and Care.

(1) A participant has the right to be free from isolation, aversive interventions, unnecessary medication, and mental and physical abuse, mistreatment, and neglect.

(2) A participant has the right to be free from chemical and physical restraints imposed for purposes of discipline or convenience and not required to treat any medical symptom.

(3) A participant has the right to prompt life saving treatment in an emergency.

(4) A participant has the right to receive adequate and appropriate health care.

(5) A participant has the right to be treated with consideration, respect, and dignity.

(6) A participant has the right to have all reasonable requests, within the capacity of the Program, responded to promptly and adequately.

(I) The enrollment of a participant in a Program and his or her presence therein shall not confer on the Program or its licensee, Program Director, personnel, or representatives the authority to manage, use, or dispose of any property of a participant without a written authorization from the participant or his or her legally authorized representative, except in accordance with 105 CMR 158.039(M)(8). The Program Director may require that valuables be excluded or removed from the premises, when necessary, for the protection of those valuables and to avoid unreasonable responsibility.

158.042: Participant Comfort, Safety, Accommodations, and Equipment(A) Participant Comfort and Accommodations.

(1) A Program shall provide for the comfort, safety, and mental and physical well-being of participants.

(2) Program personnel shall be familiar with each participant's plan of care and need for assistance with ADL and supervision.

(3) Program personnel shall treat participants' personal effects with respect and care.

(4) A Program shall reasonably accommodate participant needs and preferences, except when the health or safety of the participant or other participants would be endangered.

(5) All participant areas shall be arranged and decorated to provide for a cheerful and homelike milieu which is pleasant, clean, well-kept, in good repair, and free from unpleasant odors, sights, and sounds.

158.042: continued

(B) Participant Safety and Protection.

- (1) At all times a professional or qualified staff member shall be on duty and immediately accessible to participants for the following purposes:
 - (a) Responding to reports of injuries, symptoms of illness, emergencies, and any other discomfort or complaint of a participant; and
 - (b) Ensuring that prompt, appropriate action is taken in response to reports of injuries, symptoms of illness, emergencies, and any other discomfort or complaint of a participant.
- (2) Restraints.
 - (a) Chemical or physical restraints may only be imposed to ensure the immediate physical safety of the participant, personnel, or others and must be discontinued at the earliest possible time.
 - (b) Chemical or physical restraints shall be used only in accordance with a primary care provider's order, and the type of restraint shall be specified by the primary care provider.
- (3) A Program may not apply any aversive intervention to any participant.
- (4) A Program shall maintain a check-in and check-out system that records participant names, dates, times of arrival and departure, and destination.

(C) Equipment and Supplies.

- (1) A Program shall provide all equipment and supplies necessary for the comfort and care of participants.
- (2) A Program shall maintain equipment and supplies in good working condition and in a clean and sanitary manner.
- (3) A Program shall establish and enforce a preventive maintenance program to ensure all equipment is in safe working order.
- (4) A Program shall perform regular maintenance checks, in accordance with manufacturer's instructions, on all mechanical and electronic medical equipment to ensure that it is properly functioning, grounded, and calibrated.
- (5) A Program shall follow manufacturer's instructions to sterilize, disinfect, or dispose of equipment and supplies.
- (6) All equipment used for personal care shall be thoroughly cleaned and sanitized after each use.
- (7) Disposable single use items shall not be reused.
- (8) A Program shall maintain the following basic equipment and supplies:
 - (a) One bed, cot, or recliner for every 20 participants;
 - (b) A supply of clean dry linens as needed to service participants;
 - (c) A sufficient number of tables and chairs including easy chairs or comfortable padded or upholstered straight back chairs with arms, suited to individual participant needs;
 - (d) Readily accessible storage space for participants' personal belongings;
 - (e) Washable portable screens, if needed, to ensure participant privacy during treatments; and
 - (f) Medical equipment and supplies, including but not limited to:
 1. A stethoscope;
 2. A scale;
 3. A blood-pressure apparatus;
 4. Foot basins;
 5. Thermometers; and
 6. An emergency first-aid kit that is visible and accessible to personnel.

158.043: Environmental Health and Housekeeping(A) Water Supply.

- (1) Water used for the care or treatment of participants, drinking, domestic, or culinary purpose shall be pure, fit for such use, and consistent with established standards of sanitation.
- (2) Ice that comes in contact with food or drink shall be made from potable water and shall be stored, handled, and dispensed in a sanitary manner.
- (3) Domestic hot water heating equipment shall have adequate capacity to maintain safe and sanitizing temperatures to supply participant and food preparation areas.
- (4) Drinking water shall be readily available and easily accessible to all participants.

158.043: continued

(B) Waste Disposal and Garbage Disposal.

- (1) Suitable sanitary procedures and equipment shall be provided for the collection, storage, and disposal of all wastes and garbage.
- (2) Wastes and garbage shall be disposed of at proper intervals and in a sanitary manner.
- (3) A Program shall comply with the requirements governing the disposal of infectious waste specified in 105 CMR 480.000: *State Sanitary Code, Chapter VIII.*

(C) Housekeeping and Maintenance.

- (1) A Program shall provide sufficient housekeeping and maintenance services to maintain the interior of the Program in good repair and in a safe, clean, orderly, attractive, and sanitary manner. A Program site shall be free from accumulation of dirt, rubbish, and objectionable odors.
- (2) Licensed nurses and personnel who provide direct participant care may not be assigned housekeeping duties during Program hours.
- (3) Deodorizers may not be used to cover up odors caused by unsanitary conditions or poor housekeeping.
- (4) A pest control program shall be provided as needed.
- (5) Windows and doors shall be properly screened during the insect season, and harborage and entrances for insects shall be eliminated.

158.044: Infection Control

(A) A Program shall establish and maintain infection control practices designed to prevent the development and transmission of disease and infection.

(B) A Program shall prohibit employees with a communicable disease or infected skin lesion from direct contact with participants or participants' food, if direct contact will transmit the disease.

(C) A Program shall require staff to wash their hands after each direct participant contact for which handwashing is indicated by accepted professional practice.

(D) Personnel shall handle, store, process, and transport linens so as to prevent the spread of infection.

(E) All accumulated soiled dressings that meet the definition of infectious waste shall be handled in accordance with 105 CMR 480.000: *State Sanitary Code, Chapter VIII.*

158.045: Physical Plant Requirements

(A) General Requirements.

- (1) The Program site shall be designed with adequate space for the provision of all Services.
- (2) When located in a facility housing other services, the Program shall operate solely within the Program's licensed space.
- (3) A Program shall be located in a site that complies with the Americans with Disability Act (ADA) and ADA Standards for Accessible Design, including, but not limited to, the following features:
 - (a) On ground level with at least two means of egress;
 - (b) Free of architectural barriers;
 - (c) Designed to meet the needs of disabled persons; and
 - (d) In compliance with local health, fire, and safety codes.
- (4) Each site shall include adequate outdoor space for participants to safely arrive at and depart from the Program site.
- (5) Each site shall provide a protected and secure environment for participants, including participants who wander or require increased supervision and security.
- (6) The Program shall provide sufficient parking capacity to satisfy the needs of participants, personnel, and the public.
- (7) Separate and additional space shall be provided for service delivery vehicles and vehicles used for participants' transfer.

158.045: continued

(8) Each site shall include a clean and sanitary food preparation area equipped with a refrigerator, a sink, adequate counter space, and adequate storage space.

(9) If meals are cooked on-site, a Program shall have a full kitchen approved by the local Board of Health.

(10) Adequate artificial lighting shall be available in all rooms, stairways, hallways, corridors, toilet rooms, and offices.

(11) A Program with five or more unrelated participants shall comply with the Massachusetts State Building Code, 780 CMR 3.00: *Use and Occupancy Classification*.

(B) Participant Area.

(1) The Participant Area shall contain at least 50 square feet per participant.

(2) When a kitchen is used for activities other than meal preparation, 50% of the kitchen floor area shall be counted as Participant Area.

(3) All Participant Areas shall have hand sanitizer dispensers and access to at least one handwashing station. Hand sanitizer dispensers and handwashing stations shall be conveniently placed and accessible to staff. Hand sanitizer dispensers and handwashing stations shall be placed with consideration for participant safety.

(4) An ADH Program shall provide participant areas with access to natural light and outside views.

(5) Participant Areas shall have adequate lighting, heating, and ventilation so that participants are comfortable in all seasons of the year.

(C) Rest or Private Area. A Program shall provide a private, quiet rest area for participants who require rest or become ill. This area shall be considered part of the Participant Area. This area shall be located in a place that can be clearly monitored and that is near a toilet room.

(D) Outdoor Area.

(1) When space for outdoor activities is available, it shall be safe, accessible to the Program from indoors, and accessible to individuals with disabilities.

(2) Outdoor areas shall have a fence or landscaping to create a boundary that prevents participant elopement.

(E) Meeting Area. A Program shall provide a space for participants, family, and caregivers to have private meetings with staff. An administrative office may be used as a meeting area.

(F) Equipment and Supply Storage.

(1) Storage space shall be available for Program and operating supplies.

(2) Each site shall include a locked storage area not accessible to participants for the storage of toxic substances.

(G) Participant Toilet Rooms.

(1) A Program shall provide at least two toilet rooms, one of which is handicapped accessible. Each toilet room shall be equipped with at least one toilet and one lavatory.

(2) A Program with a licensed program capacity of 24 or more participants shall provide at least one toilet per 12 participants.

(3) At least 50% of the toilets shall be designed or adapted to provide access and maneuverability for individuals with disabilities or individuals in wheelchairs.

(4) Participant toilet rooms shall be located no more than 40 feet away from the Participant Area.

(5) Emergency call stations shall be provided in each toilet stall used by participants.

(H) Bathing Facilities.

(1) A Program shall provide at least one shower. Shower floors shall be flush and without curbs. The floor shall be sloped to the center of the shower stall. Mixing valves and controls shall be mounted outside the shower stall. Shower enclosure may not be less than 30 inches by 60 inches.

(2) Emergency call stations shall be provided in bathing facilities used by participants.

158.045: continued

(I) Areas for Staff.

- (1) A Program shall provide at least one dedicated staff toilet.
- (2) A staff break area shall be provided.

(J) Nursing Office.

- (1) The Program shall have a nursing office.
- (2) A Program shall provide a nursing office with a minimum clear floor area of 80 square feet.
- (3) The nursing office shall be equipped to accommodate nursing functions, which may include charting or providing counseling to participants, families, or caregivers.
- (4) If the nursing office is used for providing treatments, a handwashing station shall be provided in the office.

(K) Medical Equipment Storage. A Program shall provide for the secure storage of medical equipment and supplies.

(L) Janitor's Closet. A janitor's closet that contains a service sink shall be provided to store and secure housekeeping items.

(M) Telephone. A telephone shall be available for participants in an area that affords privacy during use.

(N) Architectural Details.

- (1) Any corridor used by participants shall have a minimum width of five feet. Staff-only corridors shall be at least three feet eight inches wide.
- (2) The minimum ceiling height shall be eight feet zero inches, with the following exceptions:
 - (a) Ceilings in storage rooms may not be less than seven feet eight inches;
 - (b) Ceilings in normally unoccupied spaces may not be less than seven feet;
 - (c) Architecturally framed and trimmed openings in corridors, doorways, and other openings may not be less than seven feet in height.
- (3) Doors and Door Hardware.
 - (a) Lever hardware shall be used on all doors for ease of use by participants with mobility limitations. Toilet doors used by participants shall be equipped with hardware that allows staff to manually unlock doors for emergency access.
 - (b) Exterior doors that may be left open shall have insect screens.
 - (c) All interior doors used by participants shall open with ease and little resistance.
 - (d) Operable windows or vents that open from the inside shall be restricted to inhibit participant elopement or suicide.
 - (e) Operable windows that may be left open shall have insect screens.

(O) Handwashing Stations.

- (1) Fittings.
 - (a) General handwashing stations used by staff and participants shall be trimmed with valves that can be operated without hands.
 - (b) If single-lever or wrist blade devices are used, blade handles shall be at least four inches in length. Care shall be taken in location and arrangement of fittings to provide the clearance required for operation of blade-type handles.
- (2) Handwashing stations shall include a hand-drying device that does not require hands to contact the dispenser.
- (3) Handwashing stations shall include liquid or foam soap dispensers.
- (4) Each participant handwashing station shall have a mirror. Mirror placement shall allow for convenient use by both wheelchair occupants and ambulatory persons.

(P) Grab Bars.

- (1) Grab bars shall be installed in all resident toilets and bathing areas.
- (2) For wall-mounted grab bars, a minimum clearance of 1½ inches from walls shall be provided.
- (3) Grab bars, including those which are part of fixtures such as soap dishes and toilet paper holders, shall have the strength to sustain a concentrated load of 250 pounds.

158.045: continued

(Q) Handrails. Handrails shall comply with the Americans with Disabilities Act (ADA) Standards for Accessible Design, and, with respect to corridors, shall comply with the Facilities Guidelines Institute guidelines for adult day health care facilities.

(R) Flooring.

- (1) Flooring surfaces shall be easily maintainable, readily cleanable, and appropriate for the location.
- (2) Flooring surfaces shall allow for ease of ambulation and self-propulsion.
- (3) Flooring surfaces shall provide smooth transitions between differing flooring materials.
- (4) Slip-resistant flooring products shall be used for flooring surfaces in wet areas, including the kitchen, shower(s), toilet rooms, ramps, and entries from exterior to interior space.

(S) Building Systems.

(1) Heating, Ventilation, and Air-conditioning Systems.

- (a) Ventilation by mechanical means shall be provided. Air conditioning and heating equipment shall be adequate and capable of maintaining the temperature in the participant area between 72°F and 78°F.
- (b) Continuous exhaust ventilation to outdoors shall be provided in toilet rooms, bathing rooms, kitchen, and janitor's closet.
- (2) Plumbing Systems. Hot and cold running water shall be available. Hot water at shower, bathing, and handwashing facilities shall not exceed 110°F.

(T) Fire Protection and Safety.

- (1) A Program shall have:
 - (a) Current local board of health certificate(s), as applicable;
 - (b) Current occupancy permit; and
 - (c) Current local fire inspection certificate.
- (2) All exits shall be clearly identified by exit signs, adequately lighted, and free from obstruction.
- (3) Clothes dryers shall have the lint filter cleaned after each use.
- (4) A Program shall have easily accessible fire extinguishers that are maintained in accordance with local fire department requirements.

(U) Storage and Use of Oxygen.

(1) Administration.

- (a) A Program shall have policies and procedures in place for the safe use and storage of oxygen.
- (b) Personnel responsible for the use and transport of equipment shall be trained in proper handling of cylinders, containers, hand trucks, supports, and valve protection caps.
- (c) Carts and hand trucks for cylinders and containers shall be constructed for the intended purpose and shall be provided with appropriate means to retain cylinders or containers in place.
- (2) Storage of 3000 Cubic Feet of Oxygen or More.
 - (a) Closets or rooms shall be provided for cylinder storage. Such closets or rooms shall be constructed of an assembly of building materials with a fire-resistive rating of at least one hour. Such enclosures shall serve no other purpose.
 - (b) Closets or rooms for oxygen storage shall be vented to the outside by a dedicated mechanical ventilation system or by natural venting. If natural venting is used, the vent opening or openings shall be at least 72 square inches total free area.
 - (c) Storage locations for oxygen shall be kept free of flammable materials. Flammable gases shall not be stored with oxidizing agents.
 - (d) Combustible materials, such as paper, cardboard, plastics, and fabrics, shall not be stored or kept near supply system cylinders or manifolds containing oxygen. Racks for cylinder storage shall be permitted to be of wooden construction.
 - (e) Storage of full or empty cylinders is permitted.
 - (f) Provisions shall be made for racks or fastenings (properly chained or supported in a proper cylinder stand or cart) to protect cylinders from accidental damage or dislocation. Oxygen cylinders shall be protected from abnormal mechanical shock, which is liable to damage the cylinder, valve, or safety device.

158.045: continued

- (g) Ordinary electric wall fixtures, switches, and receptacles shall be installed in fixed locations not less than five feet above the floor as a precaution against their physical damage.
 - (h) Sources of heat in storage locations shall be protected or located so that cylinders shall not be heated to the activation point of integral safety devices. Cylinders shall be kept away from radiators, steam piping, and like sources of heat. In no case shall the temperature of the cylinders exceed 130°F.
 - (i) Containers shall not be stored in a tightly closed space such as a closet.
 - (j) The door to the storage location shall be provided with a precautionary sign, readable from a distance of five feet, indicating "No Smoking, Oxygen Storage Area".
- (3) Storage for Less Than 3000 Cubic Feet of Oxygen.
- (a) Storage locations shall be in an enclosure or within an enclosed interior space of noncombustible or limited-combustible construction, with doors or outdoors.
 - (b) Oxygen shall not be stored with any flammable gas, liquid, or vapor.
 - (c) Oxygen shall be separated from combustibles or incompatible materials by either:
 1. A minimum distance of 20 feet;
 2. A minimum distance of five feet if the entire storage location is protected by an automatic sprinkler system; or
 3. An enclosed cabinet of noncombustible construction having a minimum fire protection rating of ½ hour for cylinder storage. An approved flammable liquid storage cabinet shall be permitted to be used for cylinder storage.
 - (d) Storage of full or empty cylinders is permitted.
 - (e) Provisions shall be made for racks or fastenings (properly chained or supported in a proper cylinder stand or cart) to protect cylinders from accidental damage or dislocation. Oxygen cylinders shall be protected from abnormal mechanical shock, which is liable to damage the cylinder, valve, or safety device.
 - (f) Ordinary electric wall fixtures, switches, and receptacles shall be installed in fixed locations not less than five feet above the floor as a precaution against their physical damage.
 - (g) Sources of heat in storage locations shall be protected or located so that cylinders shall not be heated to the activation point of integral safety devices. Cylinders shall be kept away from radiators, steam piping, and like sources of heat. In no case shall the temperature of the cylinders exceed 130°F.
 - (h) The door to the storage location shall be provided with a precautionary sign, readable from a distance of five feet, indicating "No Smoking, Oxygen Storage Area".
- (4) Storage for Less Than 300 Cubic Feet of Oxygen. Up to 300 cubic feet (12 "E" cylinders) of oxygen in cylinders may be accessible as operational supply located outside of a storage enclosure. Provisions shall be made for racks or fastenings (properly chained or supported in a proper cylinder stand or cart) to protect cylinders from accidental damage or dislocation. Oxygen cylinders shall be protected from abnormal mechanical shock, which is liable to damage the cylinder, valve, or safety device.
- (5) Liquefied Gas Container Storage. Containers of liquefied oxygen shall be stored in accordance with the storage requirements for the storage of more than 3000 cubic feet of oxygen.
- (6) Transferring of liquid oxygen from one container to another shall be done outside of the building or at a location specifically designated for the transferring that meets the following:
- (a) Separated from any portion of a facility wherein participants are housed, examined, or treated by a separation of a fire barrier of one-hour fire-resistive construction;
 - (b) The area is mechanically ventilated, has sprinklers, and has ceramic or concrete flooring; and
 - (c) The area is posted with signs indicating that transferring is occurring, and that smoking in the immediate area is not permitted.
- (7) Smoking shall be prohibited where flammable liquids, combustible gases, or where supplemental oxygen is used or stored. Such areas shall be posted with signs that read NO SMOKING or shall be posted with the international symbol for no smoking. Exception: In health care occupancies where smoking is prohibited and signs are prominently placed at all major entrances, secondary signs with language that prohibits smoking shall not be required.
- (8) The use of any type of oxygen dispensing system not outlined in 105 CMR 158.000 must be approved by the Department.

158.046: Quality Assessment and Performance Improvement

- (A) A Program shall develop and implement an ongoing, program-wide, data-driven Quality Assessment and Performance Improvement (QAPI) program.
- (B) A Program shall form a QAPI committee to implement the QAPI program.
- (1) The QAPI committee shall include at least the Program Director, a registered nurse employed by the program, and one or more individuals appointed by the Program Director.
 - (2) The QAPI committee shall meet at least two times per year and shall maintain minutes of all meetings.
- (C) The QAPI program shall measure, analyze, and track quality indicators, including adverse events and other aspects of performance that enable the Program to assess the quality of Program services and operations.
- (D) The QAPI program shall collect quality indicator data in order to:
- (1) Monitor the effectiveness of services;
 - (2) Monitor quality of care at the Program;
 - (3) Monitor safety at the Program; and
 - (4) Identify opportunities and priorities for improvement.
- (E) The QAPI program's activities shall:
- (1) Focus on high risk, high volume, or problem-prone areas;
 - (2) Consider incidence, prevalence, and severity of problems in those areas;
 - (3) Positively affect participant safety and quality of care;
 - (4) Track adverse participant events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the Program;
 - (5) Take actions aimed at performance improvement; and
 - (6) Measure success and track performance to ensure that improvements are sustained.
- (F) QAPI Projects.
- (1) QAPI programs must develop, implement, and evaluate performance improvement projects.
 - (2) The number of QAPI projects shall be based on the needs of the Program's population and internal organizational needs, and must reflect the scope, complexity, and past performance of the Program's services and operations.
 - (3) The QAPI program shall document the performance improvement projects it conducts, the reasons for conducting the projects, and the measurable progress achieved on the projects.
- (G) The Program Director shall be responsible for the following:
- (1) Ensuring that the QAPI program reflects the complexity of the Program's organization and services, involves all Program services, focuses on indicators related to improved outcomes, and exhibits improvement in Program performance;
 - (2) Approving the frequency and content of the data collection;
 - (3) Obtaining, reviewing, and acting upon the findings of the QAPI Committee;
 - (4) Ensuring that the QAPI program efforts address priorities for improved quality of care and participant safety, and that all improvement actions are evaluated for effectiveness;
 - (5) Preparing and submitting a report to the Participant and Family Advisory Council that details QAPI program activities and projects at least two times per year; and
 - (6) Responding to the Participant and Family Advisory Council feedback regarding the QAPI program.
- (H) The QAPI program must be capable of showing measurable improvement in indicators related to improved outcomes and Program services.

REGULATORY AUTHORITY

105 CMR 158.000: M.G.L. c. 111, § 3 and St. 2011, c. 87 as amended by St. 2012, c. 239, § 21.