

115 CMR 5.00: STANDARDS TO PROMOTE DIGNITY

Section

- 5.01: Scope and Enabling Authority
- 5.02: Definitions
- 5.03: General Principles
- 5.04: Other Rights of Individuals
- 5.05: Mistreatment
- 5.06: Special Sanctions for Violation of Rights of Individuals
- 5.07: Legal Competency, Guardianship and Conservatorship
- 5.08: Informed Consent
- 5.09: Labor
- 5.10: Possessions (and Funds)
- 5.11: Crisis Prevention, Response, and Restraint
- 5.12: Health-related Supports and Protective Equipment
- 5.13: Transportation Safety Devices
- 5.14: Positive Behavior Supports (PBS)
- 5.14A: Level III Interventions
- 5.15: Medication
- 5.16: Rights and Responsibilities of Service Providers

5.01: Scope and Enabling Authority

(1) Scope. 115 CMR 5.00 applies to all providers and to all services or supports operated, certified, licensed, or contracted for or otherwise funded by the Department.

(2) Enabling Authority. The Department is directed by M.G.L. c. 123B, § 2 to adopt regulations that establish procedures and the highest practicable professional standards for the reception, examination, treatment, restraint, transfer and discharge of persons with intellectual disability in public or private facilities for the care and treatment of such persons and for community services for persons with developmental disabilities (autism spectrum disorder and Prader-Willi and Smith-Magenis syndromes). 115 CMR is subject to appropriation.

5.02: Definitions

For purposes of 115 CMR 5.00, the following terms shall have the following meanings:

Behavior Safety Plan. A document, prepared by a Positive Behavior Support (PBS) Qualified Clinician, describing the plan for a rapid response to the challenging behavior of an individual. The Behavior Safety Plan must be a separate document from the Intensive Positive Behavior Support Plan (PBSP) document.

Chemical Restraint. The non-consensual use of medication, not for treatment, but for the purpose of impairing the individual's freedom of movement. Chemical restraint does not include medication administered subject to the provisions of 115 CMR 5.15.

Corporal Punishment. The application of painful stimuli to the body as a punishment for certain behavior and includes, but is not limited to, hitting, pinching, the use of electric contingent skin shock or infliction of other pain.

Crisis Prevention, Response and Restraint (CPRR) Curriculum. A standard, Department approved curriculum which includes training on de-escalation using Positive Behavior Supports, debriefing requirements and the monitoring of persons subject to a restraint. Each Department vendor may select from the list of Department qualified CPRR Curriculum providers and shall only use the procedures contained in the specific selected curriculum.

5.02: continued

Crisis Prevention, Response and Restraint Individual Modification Plan (CPRR Individual Modification Plan). A document providers must use to modify a restraint technique contained in a Department approved CPRR curriculum, where use is contraindicated due to a medical or psychological condition of an individual. A CPRR Individual Modification Plan must describe the reason the approved restraint is contraindicated, including the specific condition and how the modification will address the condition. A CPRR Individual Modification Plan developed due to a medical condition must be supported by an order from a physician, dentist, physician's assistant or nurse practitioner. A CPRR Individual Modification Plan developed in response to a psychological condition must be supported by an order from a PBS Qualified Clinician. Individual modifications of restraint techniques must be approved by the Department CPRR Curriculum Review Committee prior to implementation. The Department CPRR Curriculum Review Committee shall not approve any modification which is identified at 115 CMR 5.14(15) including, but not limited to, physical restraint in a prone position.

Emergency:

- (a) the occurrence of serious self-injurious behavior.
- (b) the occurrence of serious physical assault;
- (c) the substantial risk of serious self-injurious behavior; or
- (d) the substantial risk of serious physical assault.

Environmental Modification. Alterations or changes to the physical environment, such as altering lighting, sound, colors, or temperatures, to lessen an individual's responsiveness which may trigger challenging behavior.

Evidence-based Practice. Strategies based on procedures, assessments and interventions validated through peer-reviewed research.

Informed Consent. The knowing consent voluntarily given by an individual (or by the individual's guardian, if applicable) who can understand and weigh the risks and benefits involved in the particular decision or matter.

Mechanical Restraint. Any limitation of movement achieved by means of a physical device. Mechanical restraint does not include devices utilized in accordance with 115 CMR 5.12 or 5.13.

Positive Behavior Support (PBS). A systematic, person centered approach to understanding the reasons for behavior and applying evidence-based practices for prevention, proactive intervention, teaching and responding to behavior, with the goal of achieving meaningful social outcomes, increasing learning and enhancing the quality of life across the lifespan. PBS is a three-tiered system that includes Universal Supports, Targeted Supports, and Intensive Supports, as defined in 115 CMR 5.14(5).

Response Blocking. A procedure in which staff physically intervene as soon as the individual begins to emit a challenging behavior in order to prevent the completion of the targeted behavior. Response blocking is used mostly as a treatment to manage self-injurious behavior; however, it also is used as a defensive procedure when an individual is aggressing toward a staff person. Response blocking as described in CPRR-approved curricula (used defensively or to block self-injury) is not a restrictive procedure.

Restraint. Any method used to limit an individual's freedom of movement over the individual's active resistance. Restraint of individuals with intellectual or developmental disability may only be used in cases of emergency. Restraint does not include hand-over-hand assistance with activities of daily living or skill acquisition.

5.02: continued

Restrictive Procedure. A procedure that restricts an individual's freedom of movement or requires an individual, through coercion, to perform a task which is non-scheduled, not essential for acquiring a skill or learned task, or not essential for his or her health and well-being, or removes something an individual owns or has earned. Restrictive procedures do not include hand-over-hand assistance with activities of daily living or skill acquisition.

Seclusion. Any act which involuntarily places an individual alone in a locked room or other area from which there is no egress.

Substantial Risk. A serious, imminent threat of bodily harm, where this is the present ability to enact such harm.

Time Out from Positive Reinforcement. The contingent withdrawal of the opportunity to earn positive reinforcement or the loss of access to a form of positive reinforcement for a specified time. Time out from positive reinforcement is limited to a period not to exceed 15 minutes. Physical removal over active resistance to a time out is a restraint.

5.03: General Principles

To further the Department's goal of promoting the welfare and dignity of all persons with intellectual disability and developmental disabilities, the Department hereby establishes the following principles:

- (1) Services and supports are to be designed to provide meaningful assistance to the individual in acquiring and maintaining those physical, mental, and social skills which enable the individual to cope most effectively with the demands of his or her own person and environment.
- (2) Residential and day or employment settings are integrated in and support full access of individuals to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as other individuals.
- (3) Services and supports are to be provided in a manner that promotes:
 - (a) Human dignity;
 - (b) Humane and adequate care and treatment;
 - (c) Self determination and freedom of choice to the individual's fullest capability;
 - (d) The opportunity to live and receive services or supports in the least restrictive and most typical setting possible;
 - (e) The opportunity to undergo typical developmental experiences, even though such experiences may entail an element of risk; provided however, that the individual's safety and well-being shall not be unreasonably jeopardized; and
 - (f) The opportunity to engage in activities and styles of living which encourage and maintain the integration of the individual in the community including:
 1. Social interactions in integrated settings typical of the community which maximize the individual's contact with other citizens who live or work in that community;
 2. Activities, routines, and patterns of living which are appropriate to the individual's age and the practices of the surrounding community, and which are consistent with his or her interests and capabilities;
 3. Communication by staff in a manner appropriate to the individual's age and the practices of the surrounding community;
 4. Recreation and leisure time activities appropriate to the individual's age and the practices of the surrounding community and which are consistent with the individual's interests and capabilities;
 5. A home with a design which takes into consideration numbers of individuals present, physical comfort, style of decor, opportunities for privacy, external appearance, type of neighborhood where the home is located, and access to the community;

5.03: continued

6. Possessions which are appropriate to the individual's age and the practices of the local community and consistent with the individual's interests;
7. Privacy, including the opportunity wherever possible, to be provided clearly defined private living, sleeping and personal care spaces; and
8. Freedom from discomfort, distress, and deprivation which arise from an unresponsive and inhumane environment.

5.04: Other Rights of Individuals

Individuals served by providers subject to 115 CMR 5.00 shall have, in addition to the rights specified elsewhere in 115 CMR or in applicable state or federal laws or judicial decrees, the following rights:

- (1) The right to communicate, including:
 - (a) The right to have reasonable access to a telephone, the internet, email, social media and other web-based communication applications and the opportunity to make and receive confidential communications, and to have assistance when desired and necessary to implement this right; and
 - (b) The right to unrestricted mailing privileges, to have access to stationery and postage, and to assistance when desired and necessary to implement this right.
 - (c) Any restriction of telephone or internet use must be based upon a demonstrable risk, documented in the individual's record, and promptly provided to the provider's human rights committee.
 - (d) Such restriction shall be accompanied by a training plan to eliminate the need for the restriction, documented in the individual's Individual Support Plan (ISP), and should be included in a PBSP, if clinically required.
- (2) The right to be protected from private and commercial exploitation including: the right not to be exposed to public view by photograph, film, video, interview, or other means unless prior written consent of the individual or guardian is obtained for such release; and the right not to be identified publicly by name or address without the prior written consent of the individual or guardian.
- (3) The right to be visited and to visit others under circumstances that are conducive to friendships and relationships, in accordance with the following requirements:
 - (a) An individual shall be permitted to receive visitors, unless ill or incapacitated to the degree that a visit would cause serious physical or emotional harm; provided that the individual's attorney, guardian, legal or designated representative, personal physician, clergy, or family members shall be permitted to visit at all times, unless the individual objects, and shall be provided with a suitable place to confer on a confidential basis;
 - (b) Reasonable restrictions may be placed on the time and place of the visit in order to protect the welfare of the individual or the privacy of other individuals and to avoid serious disruptions in the normal functioning of the provider. Arrangements shall be made for private visitation to the maximum extent possible; and
 - (c) Denial of visitation or restrictions for any reason other than those stated in 115 CMR 5.04(3)(b), shall be treated as a modification of the ISP, and requires compliance with the regulations governing ISP modifications. The human rights committee shall be notified of the intention to deny or restrict visitation no later than the next meeting following the ISP modification meeting or, in the case of the waiver of an ISP modification meeting, at the next meeting following the implementation of the ISP modification.

5.04: continued

- (4) The right to enjoy basic goods and services without threat of denial or delay for any purpose by providers subject to 115 CMR 5.00. Basic goods and services include at least the following:
- (a) A nutritionally sound diet of wholesome and appetizing food served at appropriate times and in as normative a manner as possible;
 - (b) Opportunities for daily recreational activity and physical exercise, as appropriate to the age and interests of the individual;
 - (c) Unrestricted access to drinking water and bathrooms;
 - (d) Arrangement for or provision of an adequate allowance of neat, clean, appropriate and seasonable clothing;
 - (e) Opportunities for social contact in the individual's home, work, or community environments;
 - (f) Opportunities to keep and use personal possessions; and
 - (g) Access to individual storage space for personal use.
- (5) The right to a reasonable expectation of privacy. In connection with hygiene and medication administration by non-licensed staff, such an expectation includes assistance by same gender staff for hygiene and medication administration when the partial or complete disrobing of the individual is required.
- (6) The right to decline any service or support.

5.05: Mistreatment

No provider subject to 115 CMR 5.00 shall mistreat an individual or permit the mistreatment of an individual by persons in its employ or subject to its direction. Mistreatment includes any intentional or negligent action or omission which exposes an individual to a serious risk of physical or emotional harm. Mistreatment includes, but is not limited to:

- (a) Corporal punishment or any other unreasonable use or degree of force or threat of force not necessary to protect the individual or another person from bodily harm;
- (b) Infliction of mental or verbal abuse, such as screaming, name calling, or any other activity damaging to the individual's self respect;
- (c) Incitement or encouragement of individuals or others to mistreat an individual;
- (d) Transfer or the threat of transfer of an individual for punitive reasons;
- (e) Termination of services or supports or threat of termination of services or supports for punitive reasons;
- (f) Any act in retaliation against an individual for reporting any violation of the Department's regulations;
- (g) The use of any restraint as punishment, for the convenience of staff, or otherwise in violation of 115 CMR 5.11 and 5.14;
- (h) Sexual abuse of an individual;
- (i) Intentional failure to obtain or render medical services;
- (j) Misappropriation of an individual's funds; and
- (k) Any act in violation of 115 CMR 5.00.

5.06: Special Sanctions for Violations of Rights of Individuals

The following special sanctions shall be available to the Department, in addition to those set forth in 115 CMR 8.00: *Certification, Licensing, and Enforcement*, when deemed necessary by the Department to protect the interest of the individual involved as well as other individuals who currently or may in the future receive services or supports from the provider:

- (1) Mistreatment of an individual by a person in the employ or subject to the direction of a provider shall be grounds for suspension or revocation of the certification and license of the provider by the Department.
- (2) Department and provider employees are mandated reporters under M.G.L. c. 19C and shall comply with reporting requirements in M.G.L. c. 19C, and 118 CMR: *Disabled Persons Protection Commission*.

5.06: continued

(3) Failure of the head of the provider to report any allegation or instance of mistreatment to the Department in accordance with 115 CMR 5.00 and 115 CMR 9.00: *Investigations and Reporting Responsibilities* shall be grounds for action by the Department including revocation or suspension of the certification and license of the provider under 115 CMR 8.00: *Certification, Licensing and Enforcement* and, if the provider is the Department, grounds for disciplinary action against the head of the provider (as defined at 115 CMR 2.01: *Definitions*), including dismissal.

5.07: Legal Competency, Guardianship, and Conservatorship

(1) All Adults Presumed Competent Absent Court Determination to Contrary. An individual who has reached 18 years of age shall be presumed to be competent to manage his or her affairs, including to contract, to hold a professional, occupational, or vehicle operator's license; to make a will, or to vote and no individual shall be presumed incompetent solely by reason of receiving services or supports from any provider, or services or support operated, certified, licensed or contracted for by the Department, unless otherwise determined by a court in a guardianship or conservatorship proceeding.

(2) Safeguarding the Rights of Individuals to Make Financial and Health Care Decisions.

(a) Competent Individual.

1. Health Care Proxy. Every competent adult shall have the right to appoint a health care agent by executing a health care proxy in accordance with M.G.L. c. 201D. The standard to show competence to name a health care agent, includes:

- a. individual is a competent adult 18 years of age or older;
- b. of sound mind; and
- c. under no constraint or duress.

2. Power of Attorney. Every competent adult shall have the right to appoint a durable power of attorney in accordance with M.G.L. c. 190B, § 5-501. A durable power of attorney is a power of attorney by which a principal designates another his attorney effective upon the disability or incapacity of the principal.

(b) Notification of Possible Need for Assistance with Decision-making: Guardianship.

1. Financial Affairs: Notification If Capacity Is in Doubt and Preference for Least Restrictive Response. If an individual's ISP team has reason to believe that he or she lacks capacity to make informed decisions with regard to financial affairs, the Department or the head of the provider shall notify the individual's nearest living relative(s) in writing, with an accompanying recommendation that steps to protect the individual's finances be taken. Such steps may include the appointment of a representative payee, co-signatory bank account, a shared or delegated money-management plan or the appointment of a conservator. The appointment of a conservator shall be recommended only if:

- a. the Department or head of the provider has reason to believe that alternatives such as a representative payee, co signatory bank account, or a shared or delegated money management plan, are inadequate to protect the individual from a substantial and unreasonable risk to his or her property; or
- b. the individual has cash or assets easily converted into cash in excess of \$10,000.

2. Guardianship of the Person: Least Restrictive Form of Guardianship. If an individual's ISP team has reason to believe an individual lacks capacity to make informed decisions with regard to personal affairs, the Department or the head of the provider shall notify the individual's nearest living relative in writing, with an accompanying recommendation for supports necessary to assist the individual in decision-making. A guardian shall be recommended only if:

- a. the Department or head of the provider has reason to believe that the less restrictive alternatives or other supports are inadequate to protect the individual from unreasonable risk to his or her health and welfare; and
- b. the type of guardianship recommended shall be the narrowest and least restrictive necessary in order to protect the individual from unreasonable risk to his or her health and welfare.

5.07: continued

(3) Actions Taken Where Appropriate Nominee for Guardian Does Not Exist. Where the nearest living relative cannot be found, is incapable of, unsuited for, or not interested in making decisions on behalf of the individual, and the head of the provider has reason to believe that less restrictive alternatives are inadequate to protect the individual's health, welfare or property, or the individual has more than \$10,000 in cash or assets easily converted to cash, then the Department and the provider shall devise procedures to recruit a conservator, or guardian, as appropriate. These procedures shall attempt to ensure that:

- (a) temporary guardians are available to meet emergency situations;
- (b) individuals requiring conservators or guardians are identified and the appropriate relatives contacted;
- (c) suspected improprieties of a trustee, conservator, guardian, representative payee, or other fiduciary are reported to the court, the Department, and other appropriate authorities; and
- (d) individuals are provided with an explanation of conservatorship and guardianship, and, if requested or needed, referred to appropriate legal assistance.

5.08: Informed Consent

(1) The informed and voluntary consent of the individual or of a guardian if the individual is incapacitated or is not capable of providing informed consent shall be required in the following circumstances:

- (a) Prior to admission to a facility;
- (b) Prior to medical or other treatment and, with respect to medication, in accordance with 115 CMR 5.15;
- (c) Prior to involvement of the individual in research activities, in accordance with 115 CMR 10.00: *Research*;
- (d) Prior to the initiation of a Targeted or Intensive PBSP, in accordance with 115 CMR 5.14;
- (e) Prior to the initiation of level III interventions, in accordance with 115 CMR 5.14A; and
- (f) Prior to the release of personal information to other agencies, providers, or persons, unless there exists one of the situations specified in 115 CMR 4.06: *Access to Records and Record Privacy*, permitting release without the individual's consent.

(2) Whenever the informed consent of the individual or guardian is required, the following criteria shall apply:

- (a) The consent of the individual or guardian shall be in writing and filed in the individual's record;
- (b) The written consent shall be dated and shall expire as expressly stated or upon completion of the specific procedure for which it applies; in any event an informed consent shall expire one year after it is signed.
- (c) No coercion or overbearing inducement shall be utilized to obtain consent;
- (d) A written record shall be made:
 - 1. identifying the name, position, and affiliation of the individual securing the consent; and
 - 2. summarizing the information provided to the individual from whom consent is secured, in accordance with 115 CMR 5.08(2)(d) and (e).
- (e) The person securing the consent shall:
 - 1. explain the intended outcome and nature of, and the procedures involved in, the proposed treatment or activity;
 - 2. explain the benefits and the risks, including side effects, of the proposed treatment or activity, as well as the risks of not proceeding;
 - 3. explain the alternatives to the proposed treatment or activity, particularly alternatives offering less risk or other adverse effects;

5.08: continued

4. explain that consent may be withheld or withdrawn at any time, with no punitive action taken against the individual;
 5. present the foregoing information in a manner which can be understood by the individual, or guardian if any; and
 6. offer to answer questions that the individual or guardian may have regarding the matter for which consent is being sought.
- (f) The appropriateness of the consent shall be reviewed as part of the annual review of the individual's ISP.

5.09: Labor

- (1) No individual shall be required to perform labor which involves the essential operation and maintenance of the provider or the regular care, treatment, or supervision of other individuals; provided however, that:
- (a) Individuals may be expected to perform labor involving normal housekeeping and light home maintenance functions in their own home; and
 - (b) Individuals may be required to perform labor in accordance with a supervised plan of vocational or habilitation training that is included in their ISP. Such labor shall be compensated to the extent of its economic value, in accordance with applicable state and federal laws regarding wages and hours.
- (2) Any individual may voluntarily perform any labor available, provided that all federal and state legal requirements are met.

5.10: Possessions (and Funds)

- (1) No provider subject to 115 CMR 5.00 shall interfere with the right of an individual to acquire, retain, and dispose of personal possessions unless authorized by a guardian, conservator, or representative payee; the interference or restriction is part of a duly developed and reviewed ISP; ordered by the court; or possession poses an immediate threat of serious physical harm to the individual or other persons. In the event of restriction of possession by the provider on the grounds of imminent and serious physical harm, the provider shall be authorized to place the object in custodial safekeeping for the individual.
- (a) Any restriction on personal possessions or funds shall be accompanied by a training plan to eliminate the need for the restriction, documented in the individual's Individual Support Plan (ISP), and should be included in a PBSP, if clinically required.
 - (b) Such restriction shall be accompanied by a training plan to eliminate the need for the restriction, as appropriate, and documented in the individual's record.
- (2) Where an individual seeks or requires assistance in the management or expenditure of funds, the provider shall establish, or assist the individual to establish, an individual interest-bearing bank account under the individual's name.
- (a) All principal and interest shall be the property of the individual.
 - (b) If the provider is a facility, it shall establish individual accounts in accordance with 115 CMR 3.08: *Funds Belonging to Residents*.
- (3) Unless a guardian, conservator, or representative payee has been appointed, the individual shall have an unrestricted right to manage and spend his or her funds; provided however, that if a determination is made pursuant to the development or review of the individual's ISP or, for the facilities, pursuant to an evaluation required by 115 CMR 3.08(5) that the individual lacks capacity to manage and spend all or a portion of his or her funds, the provider shall develop and implement a written plan to advise and assist the individual to manage and spend that portion of the individual's funds, in accordance with his or her needs, capabilities, interests, and desires. This written plan shall be a part of the individual's record and incorporated into the ISP.
- (a) The plan shall be the least restrictive possible to meet the individual's needs for assistance. The plan may include advice and training in the management and expenditure of funds, two-signature accounts, and representative payee accounts.

5.10: continued

(b) The provider shall obtain the agreement of the individual, if not under guardianship or conservatorship, or the guardian or conservator, if any, for shared or delegated management responsibilities. Where the individual is not under guardianship or conservatorship and is not capable of such agreement, the head of the provider may authorize a plan involving shared or delegated management responsibilities, where necessary and as appropriate. This provision shall not apply, however, where the head of the provider has reason to believe that shared or delegated management is not sufficient to protect the individual's assets or where the individual has cash or assets easily converted into cash in excess of \$10,000. In such instances, the provisions of 115 CMR 5.07 shall apply.

(c) Where the provider has shared or delegated management responsibilities, it shall meet the following requirements:

1. Individuals' funds shall not be applied to goods or services the provider is obligated by law or funded by contract to provide;
2. The provider or provider staff may not expend or borrow the funds of any individual for the use of anyone other than that individual;
3. The provider or provider staff shall have no direct or indirect ownership or survivorship interest in the funds;
4. A plan for shared or delegated management responsibilities shall be accompanied by a training plan, documented in the individual's record (and ISP), to eliminate the need for such assistance, unless it is established by clinical evaluation that the individual cannot learn how to manage or spend any portion of his or her funds, even with supports.
5. Provider staff shall not participate in arrangements for shared or delegated management of the individual's funds except as representatives of the provider;
6. A record shall be kept of every transaction, including the date, amount received or disbursed, the manner in which such funds were managed or expended, identification of involved parties, and receipts for expenditures exceeding \$25;
7. The individual, guardian, other legal representative, or the Department may inspect such records and may demand an accounting at any time;
8. Funds held by the provider pursuant to a shared or delegated money management plan shall be treated as the property of the individual for the purpose of collecting charges for care. The individual and guardian (or conservator or trustee), if any, shall be informed of any possible charges for care before services begin and following any change in the cost of services. These charges shall be treated as any other significant debt of the individual, to be collected only after an appropriate explanation and written billing, including notice of means available to contest the charges for care. A copy of this billing shall be entered into the individual's record;
9. Any arrangements made to transfer an individual from one provider or location to another shall include provisions for transferring shared or delegated financial management responsibilities to the receiving provider or location.
10. The provider shall consider, as part of the ISP process, alternatives to involvement by persons affiliated with the provider. Such alternatives may include outside representative payees, trustees, conservators, and guardians;
11. The individual shall be informed of all proposed expenditures, and any expression of preference shall be honored if possible; and
12. Expenditures shall be made only for purposes which directly benefit the individual, in accordance with his or her interests and desires.

(4) With the assistance of the Department, every provider subject to 115 CMR 5.00 shall develop procedures to assist individuals, guardians, trustees, and conservators in determining eligibility and applying for financial benefits.

(5) Where a provider has shared or delegated money management responsibilities, it is required to have written procedures for implementing the Department's regulations and policies regarding individual funds and for maintaining accurate financial accounts of such funds.

(6) In addition to 115 CMR 5.10, facilities shall be governed by 115 CMR 3.08: *Funds Belonging to Residents*, and to the extent that any conflict exists between the provisions of 115 CMR 5.10 and 115 CMR 3.08, the requirements of the latter shall apply.

5.11: Crisis Prevention, Response, and Restraint(1) Crisis Prevention, Response, and Restraint (CPRR).(a) Restrictive Procedures: Restraint.

1. Requirements For Use. The use of restraints must conform to the requirements set forth in 115 CMR 5.11.

a. Use Permitted Only in Emergency. Restraint of an individual with intellectual or developmental disability may be used only in cases of emergency as defined in 115 CMR 5.02.

b. Acceptable Restraint Techniques. Restraint techniques are limited to those contained in the Department approved CPRR curricula and administered by persons trained in the specific restraint(s) that is utilized.

c. Restraint Debriefing. Debriefings are required following a restraint for:

i. Persons administering a restraint shall debrief with a staff person identified by the PBS Leadership Team. The debriefing shall include:

- (i) review of the technique utilized;
- (ii) antecedents to the restraint;
- (iii) duration of the restraint; and
- (iv) alternative de-escalation strategies that may be employed in the future.

ii. Individuals who are subject to a restraint shall participate in a separate debriefing with trained staff persons who did not participate in administering the restraint in order to support the individual and to mitigate distress that may result after experiencing a restraint. In the event the debriefing is clinically contraindicated, the PBS qualified clinician shall document the reason why the debriefing cannot take place in the restraint form.

iii. Restraint debriefings described in 115 CMR 5.11(1)(a)1.c.i. shall be completed within three business days after the time the restraint occurred. The restraint debriefing described in 115 CMR 5.11(1)(a)1.c.ii shall be completed within 24 hours after the time the restraint occurred.

2. Least Restrictive Alternative. In an emergency, restraint may be used only after the failure of less restrictive alternatives or there is not sufficient time to de-escalate the individual and maintain a safe environment.

3. Duration of Restraint. Restraint may be used only for the period of time necessary for the individual to regain control, but in no event may the duration of a restraint exceed 60 minutes.

(b) Staff Training.

1. Restraint Curriculum. Providers utilizing CPRR shall ensure all direct care staff providing supports to an individual who has a Behavior Safety Plan are trained in the Department approved CPRR curriculum adopted for use by the Provider's PBS Leadership Team described at 115 CMR 5.14(5).

2. Monitoring and Examination of Individuals in Restraint.

a. Staff persons shall observe and monitor an individual in a restraint in accordance with the CPRR curriculum adopted by the provider's PBS Leadership Team. The staff person(s) observing an individual in a restraint shall be situated so the staff person is able to communicate with and see the individual at all times.

b. In the event an individual in restraint is observed to be in distress or injured, the restraint shall be terminated and staff persons shall seek medical attention for the individual.

c. One staff person may be in attendance for more than one individual at the same time provided that the monitoring, examination, release, and documentation requirements of the CPRR curriculum are met for each individual who is in a restraint.

(c) Frequent Restraints. An individual subject to a restraint more than one time within a week or more than two times within a month shall be referred to a PBS Qualified Clinician for the development of a Behavior Safety Plan and an Intensive PBSP.

1. A Behavior Safety Plan is only available with an Intensive PBSP: 115 CMR 5.14(5)(c) and (8).

5.11: continued

2. The Behavior Safety Plan should specify:
 - a. observable criteria for severe, unsafe behavior (circumstances under which restraints may be used to ensure safety);
 - b. termination criteria;
 - c. maximum duration;
 - d. the type of restraint as contained in the Department approved CPRR curriculum used by the organization;
 - e. data collection; and
 - f. additional safeguards.
 3. The PBS Qualified Clinician shall notify the PBS Leadership Team of the development of a Behavior Safety Plan and Intensive PBSP.
- (d) Documentation Requirements.
1. Restraint Form. Each provider shall ensure a restraint form is completed on each occasion when an individual is placed in a restraint. Restraint forms shall be completed on the Department's electronic incident tracking database, Home and Community Services Information System (HCSIS), if available.
 - a. The restraint form must be in a form approved by the Commissioner;
 - b. The restraint form shall be retained in the Department electronic tracking database (HCSIS);
 - c. Restraint forms shall be reviewed by the:
 - i. head of provider or designee;
 - ii. Commissioner's designee;
 - iii. the area office director or designee; and
 - iv. the provider's human rights committee.
 - d. All fields contained in the restraint form must be completed.
 - e. Individual's Comments. Individual participation in a restraint debriefing, including the individual's comments, shall be documented by the provider in the restraint form.
 - (e) Commissioner's Review. The commissioner or designee shall review restraint forms in accordance with M.G.L. c. 123B, § 8. All restraints will be reviewed by a provider's human rights committee in accordance with 115 CMR 3.09: *Protection of Human Rights/Human Rights Committees.*
- (2) Statistical Records. Statistical records of restraints shall be made available to the general public in accordance with M.G.L. c. 123B, § 8.

5.12: Health-related Supports and Protective Equipment

- (1) Supports Needed for an Individual to Achieve Proper Body Position, Balance, or Alignment and Health-related Protective Equipment.
- (a) Health-related supports may be used only to achieve proper body position and balance, to permit the individual to actively participate in ongoing activities without the risk of physical harm from those activities, to prevent re-injury during the time that an injury is healing or to prevent infection of a condition for which the individual is being treated, or to enable provider staff to evacuate an individual who is not capable of evacuation. Devices providing such support include, but are not limited to, orthopedically prescribed appliances, surgical dressings and bandages, protective helmets, and supportive body bands.
 - (b) Health-related Protective Equipment.
 1. Health-related protective equipment used during a specific medical or dental procedure for the individual's protection during the time the individual is undergoing treatment or to prevent injury for an ongoing medical condition. For example, the use of a helmet for drop seizures, may only be used when ordered by a physician, dentist, physician assistant, or a nurse practitioner.
 2. Health related protective equipment used to prevent risk of harm during challenging self-injurious behavior, for example, a helmet or arm splints, may only be used when authorized by a PBS Qualified Clinician. Protective equipment used to prevent risk of harm during self-injurious behavior may only be used as part of an Intensive PBSP, and is subject to human rights committee review.

5.12: continued

- (c) Providers must assure all health related supports and protective equipment are:
 - 1. described with specificity in the licensed medical professional's order for health related protective equipment identified in 115 CMR 5.12(1)(b)1. or an Intensive PBSP for health related protective equipment identified in 115 CMR 5.12(1)(b)2. by a qualified clinician; and
 - 2. are in good repair and properly applied.
- (d) Health-related supports and protective equipment do not constitute an emergency restraint and shall not be used for the convenience of staff.

(2) Further Limitations on the Use of Health-related Supports and Protective Equipment. Health-related supports and protective equipment permitted under 115 CMR 5.12 shall be designed and applied:

- (a) In accordance with principles of good body alignment, concern for circulation, and allowance for change of position;
- (b) In accordance with safety checks and opportunities for exercise as specified in the licensed medical professional's order for health related protective equipment identified in 115 CMR 5.12(1)(b)1. or an Intensive PBSP by a qualified clinician for health related protective equipment identified in 115 CMR 5.12(1)(b)2. and, if applicable, set forth in the individual's ISP; and
- (c) With documentation as to the frequency and duration of use.

5.13: Transportation Safety Devices

- (1) A transportation safety device necessary for the safety of the individual during transportation shall not be deemed a restraint, or a health-related support or protective equipment for purposes of 115 CMR 5.11 and 5.12.
- (2) Transportation safety devices are permitted during and limited to transportation of the individual. For purposes of 115 CMR 5.13, "transportation" includes temporary stops during transportation where the individual remains in or near the transporting vehicle.
- (3) Use of a transportation safety device, other than the use of standard passenger safety devices (for example, seat belts), shall be the least restrictive method of ensuring passenger safety during transportation, and shall not be used for staff convenience. The specific method of transportation safety device shall be determined on an individualized basis and shall be included in the individual's ISP. Any use of a transportation safety device not approved as part of an ISP shall be reported in accordance with 115 CMR 13.00: *Incident Reporting*, and with 115 CMR 9.00: *Investigation and Reporting Responsibilities*, if the reporter has reasonable cause to believe such use meets a criterion identified in 115 CMR 9.05(1) through (3).

5.14: Positive Behavior Supports

- (1) Policy. It is the purpose of the Department, reflected in M.G.L. c. 123B, § 2, and 115 CMR 5.14, "to establish procedures and the highest practicable professional standards" for the treatment of persons with intellectual and developmental disability, and to assure the dignity, health, safety, of its clients. System-wide PBS is a widely accepted and utilized framework for both systems change and individual treatment which supports individuals to grow and reach their maximum potential. PBS emerged from three major sources:
 - (a) applied behavior analysis;
 - (b) the normalization/inclusion movement; and
 - (c) person-centered values.

Journal of Positive Behavior Interventions, Positive Behavior Support: Evolution of an Applied Science," (Carr, Edward, Dunlap, Glen, Horner, Robert, *et al.*) Vol. 4, No. 1 (2002). PBS provides a means for selecting, organizing and implementing evidenced-based practices in the treatment of individuals. It focuses on clearly defined outcomes, data-based decision making and problem-solving processes that support practices with fidelity and durability. PBS emphasizes the use of positive behavior approaches and recognizes that behavior is often an individual's response or reaction to the environment and the need to communicate his or her preferences and wants to others. Therefore, PBS focuses on environmental modifications and antecedents. The strategies used to modify the behavior of individuals should involve PBS,

5.14: continued

which promote the dignity and respect of individuals, and should not be unduly restrictive or intrusive. It is both sound law and policy to use only procedures which have been determined to be the least restrictive or least intrusive alternatives.

(2) Required Elements of Positive Behavior Support for All Providers. All programs services or supports operated, certified, licensed, contracted for or otherwise funded by the Department, shall have the following elements to support the implementation of PBS: a PBS Leadership Team; a PBS Action Plan; Universal Supports, as defined in 115 CMR 5.14(3); and a system of data-based decision making for both individual treatment decisions and for system decisions.

(3) Required Elements of Positive Behavior Supports for Providers with Individuals Needing Targeted or Intensive Supports. All programs providing supports to individuals needing Targeted or Intensive Supports shall have the following elements, in addition to those described in 115 CMR 5.14(2), to support the implementation of PBS: a referral plan for additional PBS support; a system to conduct functional behavior assessment, as described at 115 CMR 5.14(7), for each individual requiring Targeted or Intensive Supports; Targeted or Intensive Supports, based on individual needs; a PBSP for each individual requiring such supports; a PBS Qualified Clinician(s) to develop, implement, and monitor the PBSP; a system of coaching; and a systemic process for monitoring and quality improvement.

(4) PBS Leadership Team. The PBS Leadership Team is the organizational entity providing governance for all PBS activities. All providers are required to have a PBS Leadership Team.

(a) Membership of the PBS Leadership Team must include: an individual in an executive leadership position with authority to implement changes in management, content, resources and/or training, a Senior PBS qualified clinician, and other agency personnel representing different functional units within the organization, such as human rights, quality assurance or clinical staff.

(b) In accordance with their organization's practices with regard to stakeholder participation, providers should invite one or more representatives of stakeholders, including individuals served by the organization, and or family members of individuals served, to participate and/or provide advice on PBS.

(c) The responsibilities of the PBS Leadership Team shall include:

1. developing a written organization-wide PBS Action Plan;
2. determining the configuration and number of PBS tiers based on population served and agency organizational structure, including Targeted or Intensive Team(s), as necessary;
3. ensuring that the Universal Tier of PBS is implemented, and strategies have been identified to implement the Targeted or Intensive Tiers if they are needed by specific individuals;
4. developing agency PBS goals and metrics to assess progress toward the goals;
5. using ongoing data based decision making to:
 - a. assess the implementation of the PBS Action Plan(s) on an ongoing basis,
 - b. assess the treatment integrity of PBS across all three tiers, and
 - c. assess the effectiveness of implementation of PBS plans across all three tiers;
6. providing PBS training, coaching and oversight to staff within the organization.

(5) Tiers of Support. All providers must maintain such systems of support as are necessary to meet the needs of the individuals they serve. These must include a Universal tier team, Universal tier of supports, and may include one or more tiers of support.

(a) Universal Tier of Supports. Universal Supports are practices in place at all times supporting all individuals. Universal Supports ensure appropriate expectations are developed in all settings, socially appropriate behavior is reliably encouraged, and individuals are given choices and have opportunity to engage in preferred activities. Universal Supports include teaching individuals replacement skills and/or modifying physical or social environments to prevent challenging behavior.

1. For individuals requiring interventions in addition to Universal Supports, providers must implement a standardized identification and referral process to refer an individual for Targeted or Intensive Supports.
2. For individuals requiring additional support at the Targeted or Intensive Supports level, Universal Supports shall be maintained.

5.14: continued

3. Universal Supports include, but are not limited to, evidence-based practices such as praise, redirection, or use of schedules to provide structure to the environment.

(b) Targeted Tier of Support.

1. All Targeted PBSPs must be in compliance with 115 CMR 5.14(8).

2. Targeted Supports are practices implemented fairly rapidly on an "as needed" basis for an individual or group of individuals at risk for developing challenging behavior and needing interventions in addition to Universal Supports. The initiation of Targeted Supports is a means to avoid serious challenging behavior. Targeted Supports are intended to support an individual(s) who is at risk for reduced quality of life due to his or her actions or the actions of another person. Reasons for initiating Targeted Supports may include responding to stressful life events or to address behaviors that are not immediately high risk.

3. The Targeted Supports available for inclusion in a PBSP are determined by a provider's PBS Leadership Team.

4. Targeted Supports include, but are not limited to, the least restrictive, evidence-based practices such as "check-in, check-out," self-monitoring, relaxation training, individualized schedule(s), positive-only token economies, or minimally intrusive decelerative consequences such as "planned ignoring" or voluntary time-out.

5. Notwithstanding anything contained in 115 CMR 5.14(5), providers may develop individualized, targeted supports unique to an individual but that do not meet the criteria for the Targeted Tier of Support set forth in 115 CMR 5.14(5)(b)2. Such individualized or "targeted supports" must be expressed in written guidelines, but do not require an abbreviated or informal functional behavior assessment and do not require a PBSP. An example of an individualized or targeted support would be a unique approach to transitions to avoid the development of a challenging behavior.

(c) Intensive Tier of Support.

1. All Intensive Support Plans must be in compliance with 115 CMR 5.14(8).

2. Individuals are referred for Intensive Supports when there are concerns the health, safety, or emotional well-being of the individual, or others, is at risk, or the individual's quality of life is seriously impeded due to challenging behavior.

3. An Intensive PBSP may include, but are not limited, to restrictive procedures identified at 115 CMR 5.14(14). A PBSP containing a restrictive procedure(s) requires an Intensive PBSP and must meet the requirements for the same.

4. Intensive Supports typically are not implemented until Universal and Targeted Supports have been implemented with integrity and data have shown them to be insufficient to effect meaningful behavioral change. However, when there is danger of harm to an individual's self or others, Intensive Supports may be implemented immediately.

5. Intensive Supports may include the use of de-escalation techniques contained in the CPRR curriculum as defined in 115 CMR 5.02.

(6) General Principles of Positive Behavior Supports.

(a) PBS should avoid the use of intrusive or restrictive interventions. There should be a focus on developing a comprehensive understanding of the individual, his or her life, health, and challenging behaviors through assessments including functional behavior assessment.

(b) PBS require the use of evidence-based practices and peer-reviewed literature for interventions, the ongoing monitoring of individuals and ensuring treatment integrity, *i.e.* the use of practices that are effective and improve outcomes for individuals.

(c) Targeted and Intensive Supports require a statement of the areas of concern, a functional behavior assessment (abbreviated or informal for Targeted Supports and formal for Intensive Supports) and a written PBSP. However, a PBSP is not required for "targeted supports" described at 115 CMR 5.14(5)(b)5.

(7) Functional Behavior Assessment.

(a) Functional behavior assessment (FBA) is the process of gathering and analyzing information about an individual's behavior in order to determine the purpose or intent of the actions. FBA should include an assessment of the antecedents and consequences, and consider the individual's history, paying special attention to factors that may have contributed to the behavior(s). As part of the initial steps in FBA, consideration of explanations for the behavior(s), including medical, medication or psychiatric issues is required.

5.14: continued

(b) FBA looks beyond the behavior itself for the cause of the behavior (the function). FBA seeks to understand what the individual is trying to communicate through his or her behavior, and what the function of the behavior is in the environmental context in which it occurs.

(c) An FBA should include the elements consistent with guidance provided by the Department.

(8) Positive Behavior Support Plans.

(a) A written PBSP is required for Targeted or Intensive Supports. The PBSP must be designed and written by a PBS qualified clinician. A PBSP should include the elements consistent with guidance provided by the Department. The PBSP should describe procedures for preventing a problem from occurring and ongoing monitoring of individuals to ensure treatment integrity.

(b) PBSPs may include other assessments as needed and will seek to identify the strengths, preferences and interests of the individual.

(c) PBSPs shall consist of the most efficient and the fewest interventions and support strategies coupled with reinforcement. Success will be measured by the increase of desired behaviors, a reduction of challenging behaviors, and improvements in quality of life.

(d) PBSPs should focus on alternative strategies that address people's needs and provide meaningful choices. PBSPs should document such strategies, including that consideration was given to eliminating, reducing or minimizing antecedents or environmental conditions causing or exacerbating challenging behavior by making environmental modifications; emphasizing teaching or strengthening effective replacement behaviors and reinforcing incompatible behaviors serving the same function as and replace the identified challenging behavior(s); implementing a formal skill acquisition plan and data collection procedure in order to assess the effectiveness of skill acquisition activities; increasing monitoring of all aspects of the plan; and initiating more frequent or external reviews of data to ensure treatment integrity.

(e) PBSPs that incorporate restrictive procedures must focus on alternative strategies contained in 115 CMR 5.14(8)(d).

(9) Crisis Prevention, Response and Restraint Procedures. Crisis, Prevention, Response and Restraint (CPRR) procedures may be utilized as provided in 115 CMR 5.11 and may not be included in a PBSP. The goal of CPRR procedures is to ensure the safety of the individual and/or others. CPRR should terminate as quickly as possible.

(10) PBS Qualified Clinician.

(a) A PBS qualified clinician shall:

1. be currently licensed in Massachusetts in accordance with applicable law as one of the following:
 - a. a psychologist;
 - b. an independent clinical social worker;
 - c. an applied behavior analyst;
 - d. a master's or doctorate level speech pathologist;
 - e. a physician;
 - f. a master's or doctorate level teacher with a certification in special education; or
 - g. a licensed mental health counselor (LMHC); or
 be a doctorate level special education teacher actively teaching the topics of positive behavior support or applied behavior analysis at the college or university level;
2. have at least three years of training, including post graduate class work or formal training, and/or experience in function based behavioral assessment and treatment; and
3. have at least three years of clinical experience in the treatment of individuals with developmental disabilities.

(b) A Senior PBS qualified clinician serving on a leadership team under 115 CMR 5.14(4) shall:

1. be a PBS Qualified Clinician as described at 115 CMR 5.14(10)(a);
2. have training in PBS, organizational strategies, and multi-tiered systems of support;
3. have at least five years of training, including post-graduate class work or formal training, and/or experience in function based behavioral assessment and treatment;

5.14: continued

4. have at least five years of clinical experience in the treatment of individuals with developmental disabilities; and
 5. be able to perform all duties of a PBS qualified clinician under 115 CMR 5.14(10)(c).
- (c) A PBS qualified clinician's duties include:
1. design and implementation of PBSPs, including making referrals to other clinicians;
 2. monitoring individuals and data to ensure treatment integrity and to determine effectiveness of the PBSP;
 3. making revisions to the PBSP as necessary; and
 4. providing supervision of:
 - a. clinicians who meet the criteria described in 115 CMR 5.14(10)(a)1. and 2. who do not have a minimum of three years of experience as described at 115 CMR 5.14(10)(a)3., and
 - b. personnel with a bachelor's degree in:
 - i. psychology;
 - ii. social work;
 - iii. applied behavior analysis;
 - iv. speech and language pathology; or
 - v. education (teacher) and at least one year of post graduate experience working with individuals with developmental disabilities.
- (11) Quality Review and Monitoring.
- (a) All programs shall be responsible for implementing an internal quality review and monitoring process.
 - (b) Quality review and monitoring processes should include the elements consistent with guidance provided by the Department.
 - (c) The Department may periodically review a sample of PBS Action Plans, PBSPs and PBS internal monitoring plans to improve quality of systems and individual PBSPs.
- (12) Peer Consultation and Peer Review.
- (a) Peer Consultation. Peer consultation is provided in order to improve the quality and skill of the qualified clinician or author of the activities associated with the provision of PBS. Peer consultation is a voluntary activity designed to offer consultation and support from a peer.
 - (b) Peer Review. Peer review is provided in order to ensure compliance with regulatory standards applicable to PBS contained in 115 CMR 5.14. A PBSP containing restrictive procedures shall, in addition to the other requirements set forth at 115 CMR 5.14, be reviewed by a Peer Review Committee appointed by the program head or designee or, at the election of the provider, by a Peer Review Committee convened by the Department. Except in an emergency, such review shall occur and the comments of the Peer Review Committee, if any, shall be addressed by the treating clinician(s) prior to the implementation of the PBSP.
 1. For each such review, the Peer Review Committee shall be composed of three or more PBS Qualified Clinicians with combined expertise in the care and treatment of individuals with needs similar to those served by the facility or program and in behavior analysis and behavioral treatment, at least one of whom shall be a licensed psychologist.
 2. The Peer Review Committee shall be specially constituted so as to exclude any clinician responsible for the development or implementation of the Intensive PBSP.
 3. The Peer Review Committee shall review an Intensive PBSP to determine if it conforms to the requirements for appropriate treatment established by 115 CMR 5.14.
 4. The Peer Review Committee's review of an Intensive PBSP may include such record reviews, interviews, inspections, and other activity as the Peer Review Committee may in its discretion deem necessary, and may include requests that the Intensive PBSP be resubmitted for such periodic review as the Peer Review Committee may deem appropriate.
 5. In the event that the Peer Review Committee concludes the Intensive PBSP or a part of the Intensive PBSP violates the requirements for appropriate treatment established by 115 CMR 5.14, the Intensive PBSP, or part thereof, shall not be implemented, unless the issue is resolved by the PBS qualified clinician responsible for the development or implementation of the Intensive PBSP.

5.14: continued

6. The provider, and the Peer Review Committee, shall maintain a written record of the Intensive PBSPs reviewed at each Peer Review Committee meeting, and the results of each individual review. The records of changes, if any, to the Individual PBSP shall be available to Peer Review Committee members at each meeting.

(13) Human Rights Committee Review.

(a) Positive Behavior Support Plan Review. New PBSPs containing restrictive procedures shall be submitted to the program's human rights committee established in accordance with 115 CMR 3.09: *Protection of Human Rights/Human Rights Committees*. The human rights committee shall monitor and review PBSPs containing restrictive procedures.

(b) Frequency of Review. The human rights committee review of a new PBSP shall occur no later than the next meeting following the meeting at which the PBSP was first presented to the committee. However, provided the committee shall further expedite such review on request of the program head or designee for cases where the program head or designee determines immediate consideration of the proposed PBSP is necessary to protect the individual's health and safety. Except in an emergency, such review shall occur and the comments (if any) of the human rights committee shall be addressed by the treating clinician(s) prior to implementation of the PBSP.

(c) PBSP Review. The human rights committee's review of an existing PBSP containing restrictive procedures shall occur:

1. upon the introduction of a new restrictive procedure; or
2. at least annually.

(14) Restrictive Procedures. PBSPs incorporating restrictive procedures must focus on alternative strategies and the elements contained in 115 CMR 5.14(8)(d). Restrictive procedures may be permitted only after positive approaches have been utilized and only in conjunction with an Intensive PBSP. Such restrictive procedures may include, but are not limited to:

- (a) "Time out" requiring physical removal over the individual's active resistance to the time out;
- (b) Overcorrection;
- (c) Response Cost;
- (d) Response blocking; and
- (e) Protective devices as described at 115 CMR 5.12(1)(b)2.

(15) Prohibited Practices.

(a) The following procedures are prohibited:

1. corporal punishment;
2. any noxious, unpleasant, uncomfortable or distasteful stimuli;
3. chemical restraint;
4. forced exercise;
5. seclusion;
6. the locking of exits from buildings, except in accordance with 115 CMR 5.04 and 42 CFR 441.301(c)(4);
7. prone restraint; and any physical restraint which causes pressure or weight on the lungs, diaphragm or sternum causing chest compression or restricting the airway, or basket hold in a seated position on the floor;
8. removing, withholding, or taking away money;
9. denial of a nutritionally sound diet including withholding of a meal;
10. denial of adequate bedding or clothing; and
11. mechanical restraint.

(b) A limited, short-term waiver of the prohibition on prone restraint for use in an emergency may be available from the Department Office of Policy and Planning on an individualized basis.

5.14: continued

(16) Emergency Procedures. Nothing in 115 CMR 5.14 prohibits the use of emergency restraint, confiscation of any item used in a threatening manner, or removal from the environment for the purpose of protecting the individual and others around him or her. This includes the use of restraint procedures in the course of an established program, when the individual becomes a danger to him or herself or others, prior to staff being able to implement a lesser restrictive hierarchy. However, it is emphasized that emergency procedures may not be used at frequent intervals, becoming a routine method of intervention. If emergency procedures are utilized three times in a six-month period, the PBS qualified clinician will conduct a FBA and develop an appropriate plan of action.

5.14A Level III Interventions.

(1) 115 CMR 5.14A applies only to Level III interventions permitted pursuant to 115 CMR 5.14A(4)(b)4. Level III interventions are allowed under 115 CMR 5.14A subject to the provisions herein. Providers utilizing Level III Interventions must comply with all other requirements of 115 CMR 5.00, including 115 CMR 5.11 and 115 CMR 5.14 with the exception of 115 CMR 5.14(15)(a)1. and 2. Notwithstanding any provision of 115 CMR 5.14A, nothing in 115 CMR 5.14A is intended to contravene the obligations of the parties set forth in the Settlement Agreement in *Behavior Research, Inc. v. Mary Kay Leonard*, Civ. Action No. 86-0018-GI (Rotenberg, J.) (Bristol County Probate Court) (filed Dec. 12, 1986), subject to any changes in said order or in applicable law.

(2) The following shall be deemed Level III Interventions for purposes of 115 CMR 5.14A, provided that no such Level III Intervention may be used except in accordance with the standards and procedures set forth in 115 CMR 5.14A(4) including, without limitation, the special certification requirement of 115 CMR 5.14A(4)(f) and the general requirement of 115 CMR 5.14A(4)(b) that a determination be made that the predictable risks, as weighed against the benefits of the procedure, would not pose an unreasonable degree of intrusion, restriction of movement, physical harm or psychological harm:

- (a) Any Intervention which involves the contingent application of physical contact aversive stimuli such as spanking, slapping, hitting or contingent skin shock.
- (b) Time Out wherein an individual is placed in a room alone for a period of time exceeding 15 minutes.
- (c) Any Intervention not listed in 115 CMR 5.14A which is highly intrusive and/or highly restrictive of freedom of movement.
- (d) Any Intervention which alone, in combination with other Interventions, or as a result of multiple applications of the same Intervention poses a significant risk of physical or psychological harm to the individual.

(3) Advisory Opinions. Any person may request the Commissioner or designee to provide an advisory opinion regarding the proper classification of particular Interventions not set forth in 115 CMR 5.14A(2), or for clarification of proper classification by Level in a particular instance involving a specific individual.

- (a) Upon receipt of any such request, the Commissioner or designee shall refer the request to the Advisory Panel.
- (b) The Commissioner or designee shall facilitate the Advisory Panel's review of the request and shall seek to obtain such additional information regarding the request as the Advisory Panel shall deem necessary.
- (c) Upon completing its review of the request, the Advisory Panel shall advise the Commissioner or designee regarding the matter and the Commissioner or designee shall thereupon issue an advisory opinion responding to the request and classifying the Intervention as appropriate.
- (d) The Commissioner or designee, and the Advisory panel, shall respond to each request as expeditiously as possible, and shall prioritize those requests that allege either that inappropriate treatment is resulting from an improper classification or that there is an urgent need for treatment that may be jeopardized if a prompt response is not received.

(4) Requirements for Level III Interventions.

- (a) Scope. 115 CMR 5.14A(4), establishes requirements for Level III Interventions that are used, or that are proposed for use, for behavior modification purposes.

5.14A: continued

1. Interventions that limit an individual's freedom of movement and that are consented to, approved, and implemented for treatment purposes as part of a behavior modification plan for an individual in accordance with the requirements of 115 CMR 5.14A(4), constitute reasonable limitations on freedom of movement. Such Interventions are not subject 115 CMR 5.11.
 2. Procedures that are used, or that are proposed for use, for the purpose of protecting an individual or others from harm and not for behavior modification purposes may be used subject to 115 CMR 5.11, and are not subject to the provisions of 115 CMR 5.14A.
 3. The prescription and administration of psychotropic medication are not subject to 115 CMR 5.14A.
- (b) General Requirements.
1. No behavior modification plan may provide for a program of treatment which denies the individual adequate sleep, a nutritionally sound diet, adequate bedding, adequate access to bathroom facilities, and adequate clothing.
 2. No Level III Interventions shall be approved in the absence of a determination, arrived at in accordance with all applicable requirements of 115 CMR 5.14A, that the behaviors sought to be addressed may not be effectively treated by any less intrusive, less restrictive Intervention and that the predictable risks, as weighed against the benefits of the procedure, would not pose an unreasonable degree of intrusion, restriction of movement, physical harm or psychological harm.
 3. General Prohibition on the Use of Level III Aversive Interventions. No program which is operated, funded or licensed by the department, shall employ the use of Level III Aversive Interventions to reduce or eliminate challenging behaviors, except as provided in 115 CMR 5.14A(4)(b)4.
 4. Level III Aversive Interventions are prohibited except as specifically provided in 115 CMR 5.14A(4)(b)4. Individual-specific exceptions allowing the use of Level III Aversive Interventions to reduce or modify behavior may be granted only to individuals who, as of September 1, 2011, have an existing court-approved treatment plan which includes the use of Level III Aversive Interventions; provided further that any such exception may be granted each year thereafter if the exception is contained in the behavior treatment plan that has been approved by the court prior to September 1, 2011.
 5. Such determination shall be made and the Level III Interventions shall be approved and consented to in accordance with the special requirements of 115 CMR 5.14A(4)(d) and (e).
 6. Only those Interventions which are, of all available Interventions, least restrictive of the individual's freedom of movement and most appropriate given the individual's needs, or least intrusive and most appropriate, may be employed.
 7. Any procedure designed to decrease inappropriate behaviors such as Level III Aversive Interventions, Deprivation Procedures and Time Out may be used only in conjunction with Positive Behavior Support Programs.
 8. Level III Aversive Interventions that are allowed under 115 CMR 5.14A(4)(b)4. may be used only to address extraordinarily difficult or dangerous behavioral problems that significantly interfere with appropriate behavior and or the learning of appropriate and useful skills and that have seriously harmed or are likely to seriously harm the individual or others.
 9. No Level III Intervention may be administered to any client in the absence of a written behavior modification plan.
In the case of Level III Interventions, the plan shall conform to the special requirements of 115 CMR 5.14A(4)(c) and shall be subject to the special consent requirements of 115 CMR 5.14A(4)(e).
 10. Programs using Time Out shall conform such use to the following standards and restrictions:
 - a. The head of the facility or program or his/her designee shall approve the room or area as safe and fit for the purposes of Time Out.
 - b. Behavior modification plans employing forms of Time Out that involve placing an individual alone in a room with an open door shall comply with all safety, checking, and monitoring requirements set forth at 115 CMR 5.11(1)(b)(2).

5.14A: continued

11. All behavior modification plans shall be developed in accordance with 115 CMR 5.14A and in accordance with the policies of the facility or program within which the plan is to be implemented, insofar as those policies do not conflict with 115 CMR 5.14A.

12. In the event of a serious physical injury to or death of a person who is the subject of a Level III Intervention, whether or not such injury or death occurs during the implementation of the behavior modification program, the injury or death shall be reported immediately to the Commissioner or designee who may thereupon initiate an investigation pursuant to 115 CMR 9.00: *Investigations and Reporting Responsibilities*.

(c) Written Plan. All proposed uses of Level III Aversive Interventions for treatment purposes shall be set forth in a written plan containing at least the following:

1. A clear specification of the behaviors which the treatment program seeks to decelerate or decrease, a specification of the methods by which the behaviors are to be measured (using measures such as frequency, severity, duration, etc.) and the available data concerning the current state of the behaviors with respect to these methods of measurement.

2. A clear specification of the behaviors which the treatment program seeks to have replace the behaviors targeted for deceleration, the methods by which these behaviors are to be measured, and available data concerning the current state of the behaviors with respect to these methods of measurement.

3. A description and classification by Level of each Intervention to be used; a rationale, based on a comprehensive functional analysis of the antecedents and consequences of the targeted behavior, for why each Intervention has been selected; the conditions under which each Intervention will be employed; the duration of each Intervention, per application; the conditions or criteria under which an application of each Intervention will be terminated; in measurable terms, the behavioral outcome expected from the use of each proposed Intervention; the criteria for measuring success of each Intervention and the behavior modification plan as a whole and for revising and terminating the plan; the risks of harm to the individual with each Intervention and the plan as a whole; the individual's prognosis if the treatment is not provided; feasible treatment alternatives; and, a statement indicating the nature of the less restrictive or less intrusive Interventions which have been employed and the clinical results thereof, or those which have been considered and the reasons they have not been tried.

4. The name of the treating clinician or clinicians who will oversee implementation of the plan.

5. A procedure for monitoring, evaluating and documenting the use of each Intervention, including a provision that the treating clinician(s) who will oversee implementation of the plan shall review a daily record of the frequency of target behaviors, frequency of Interventions, safety checks, reinforcement data, and other such documentation as is required under the plan. Such treating clinician(s) shall review the plan for effectiveness at least weekly and shall record his/her assessment of the plan's effectiveness in achieving the stated goals.

(d) Review and Approval. In addition to consent requirements stated in 115 CMR 5.14A(4)(e), the following reviews and approvals are required prior to the implementation of any behavior modification plan involving the use of Level III Interventions:

1. All such plans shall be developed by those clinicians who provide services to the individual, and such other clinicians as they may designate (the treating clinician(s)).

2. All such plans shall be classified, reviewed and approved prior to implementation by a clinician designated by the head of the program. Such clinician shall have a demonstrated history of experience and training in applied behavior analysis and behavioral treatment. Such clinician may be the same clinician as the clinician who develops the plan pursuant to 115 CMR 5.14A(4)(d)1.

5.14A: continued

3. Each such plan shall be reviewed by the program's human rights committee (*i.e.*, a committee established in accordance with the provisions for human rights committees set forth at 115 CMR 3.09: *Protection of Human Rights/Human Rights Committees*). The committee's review shall occur no later than the next meeting following the meeting at which the plan is first presented to the committee, provided that the committee shall further expedite such review on request of the program head or designee for cases where the program head or designee determines that there is an urgent need for treatment that may be jeopardized if prompt attention is not given to the proposed plan. Except in an emergency (*i.e.*, in circumstances where the treating clinician, subject to the approval of the program head, determines that the immediate application of the Interventions provided for by the proposed plan is necessary to prevent serious harm to the individual or to others), such review shall occur and the comments (if any) of the human rights committee shall be addressed by the treating clinician(s) prior to implementation of the plan.

a. The committee shall review a plan to determine if it conforms to the requirements for protection of human rights established by 115 CMR 5.14A.

b. The committee's review of a plan may be based on such record reviews, interviews, inspections, and other activity as the Committee may in its discretion deem necessary and may include requests that the plan be resubmitted for such periodic review as the Committee may deem appropriate.

c. In the event that the human rights committee concludes that the plan or a part of the plan violates the requirements of 115 CMR 5.14A the plan or part thereof shall not be implemented unless:

i. the problem is resolved informally with the treating clinician(s), or

ii. the client or his or her representative or guardian initiate(s) an appeal under 115 CMR 6.30 through 6.34, and the plan or part thereof is determined pursuant to such appeal to conform to 115 CMR 5.14A.

4. Each such plan shall be reviewed by a physician or by a qualified health care professional working under a physician's supervision who shall determine whether, given the individual's medical characteristics, the Intervention is medically contraindicated. No Intervention that is medically contraindicated shall be implemented.

5. Each such plan shall, in addition to other requirements set forth in 115 CMR 5.14A, be reviewed by a Peer Review Committee appointed by the program head or designee. The Peer Review Committee shall conduct such review in a timely manner consistent with the individual's needs for treatment as represented by such plan, and shall further expedite its review on request of the program head or designee in cases where the program head or designee determines that there is an urgent need for treatment that may be jeopardized if prompt attention is not given to the proposed plan. Except in an emergency (*i.e.*, in circumstances where the treating clinician, subject to the approval of the program head, determines that the immediate application of the Interventions provided for by the plan is necessary to prevent serious harm to the individual or to others), such review shall occur and the comments (if any) of the Peer Review Committee shall be addressed by the treating clinician(s) prior to implementation of the plan.

a. For each such review, the Peer Review Committee shall be composed of three or more clinicians with combined expertise in the care and treatment of individuals with needs similar to those served by the facility or program and in behavior analysis and behavioral treatment, at least one of whom shall be a licensed psychologist.

b. For reviews of Level III Aversive Interventions, the Committee shall be specially constituted so as to exclude any clinician serving as a treating clinician within the program proposing to use the Intervention.

c. The Committee shall review a plan to determine if it conforms to the requirements for appropriate treatment established by 115 CMR 5.14A.

d. The Committee's review of a plan may include such record reviews, interviews, inspections, and other activity as the Committee may in its discretion deem necessary and may include requests that the plan be resubmitted for such periodic review as the Committee may deem appropriate.

5.14A: continued

- e. In the event that the Peer Review Committee concludes that the plan or a part of the plan violates the requirements for appropriate treatment established by 115 CMR 5.14A, the plan or part thereof shall not be implemented unless:
 - i. the problem is resolved informally with the treating clinician(s); or
 - ii. the client or his or her representative or guardian or the treating clinician(s) initiate(s) an appeal under 115 CMR 6.30 through 6.34, and the plan or part thereof is determined pursuant to such appeal to conform to 115 CMR 5.14A.
6. The head of any program using or proposing to use a Level III Aversive Intervention shall notify the Commissioner or his or her designee upon the filing of any guardianship petition, temporary or permanent, seeking authorization by substituted judgment for such Intervention. The Commissioner may upon receipt of such notice, provide for an independent clinical review by one or more clinicians designated by the Commissioner or designee of the proposed treatment and may advise the court having jurisdiction of the matter of said clinician's treatment recommendations. Said program shall cooperate fully with said clinicians and shall afford full access to each individual, his or her record and the staff working with the individual.
7. *In lieu* of having the human rights and/or peer review functions specified in 115 CMR 5.14A performed by committees appointed by the same program that is proposing to use Level III Interventions, the director of such a program may request the Commissioner or designee to provide for the performance of such reviews by human rights committees and/or peer review committees established by the Commissioner or designee. The Commissioner or designee may provide for such reviews in response to such a request in the event that he or she determines that the program is unable to provide itself for such reviews or that the purposes of 115 CMR 5.14A will be served by the provision of such reviews by committees established by the Commissioner or designee.
- (e) Consent. In addition to consent requirements generally applicable to individual service plans, a behavior modification plan employing Level III Aversive Interventions may not be implemented, unless it has been consented to in accordance with the following requirements:
 1. Where the individual is 18 years of age or older, or is deemed a mature minor under the applicable law, and is able to provide informed consent to a plan of treatment, the plan may be implemented upon his or her acceptance of its provisions.
 Before a plan involving the use of Level III procedures is implemented pursuant to such consent, the head of the program shall notify the Commissioner or his or her designee who shall be afforded an opportunity to evaluate the individual. In the event that the Commissioner or designee doubts the individual's ability to provide informed consent, a petition for the appointment of a temporary or permanent guardian shall be filed by the Commissioner or designee or by some other suitable person.
 2. Where the individual is a minor and is not deemed a mature minor capable of giving informed consent:
 - a. that portion of the plan which does not involve the use of Level III Procedures may be implemented upon a parent's or legal guardian's informed consent to its provisions.
 - b. in the event that no parent or legal guardian exists or is available, then that portion of the plan which does not involve the use of Level III Procedures may be implemented upon its approval by the head of the program, provided that actions to initiate proceedings for the appointment of some suitable person as guardian or, where applicable, actions to provide for the availability of a temporarily unavailable parent or legal guardian are commenced by the head of the program concurrently with such approval.
 - c. that portion of the plan which involves the use of Level III Interventions may be implemented only upon authorization of a court of competent jurisdiction utilizing the substituted judgment criteria.
 3. Where the client is an adult, but is unable to provide informed consent to the implementation of the plan,
 - a. that portion of the plan which does not involve the use of Level III Interventions may be implemented when informed consent is provided by the individual's temporary or permanent guardian.

5.14A: continued

b. in the event that no permanent or temporary guardian has been appointed or is available, then that portion of the plan which does not involve the use of Level III Interventions may be implemented upon its approval by the head of the program, provided that actions to initiate proceedings for the appointment of some suitable person as guardian or, where applicable, actions to provide for the availability of a temporarily unavailable parent or legal guardian are commenced by the head of the program concurrently with such approval.

c. that portion of the plan which involves the use of Level III Aversive Interventions may be implemented only upon authorization of a court of competent jurisdiction utilizing the substituted judgment criteria.

(f) Special Certification Requirement for Programs Utilizing Level III Aversive Interventions. No behavior modification plans employing Level III Aversive Interventions may be implemented except in a program or a distinct part of a program that meets the standards established by 115 CMR 5.14A(4) and that is therefore specially certified by the Department as having authority to administer such treatment. The following standards and procedures shall govern all such certifications:

1. Only those programs or facilities which meet the following standard shall be certified under 115 CMR 5.14A(4): the program or facility must demonstrate that it has the capacity to safely implement such behavior modification plan in accordance with all applicable requirements of 115 CMR 5.14A.

2. Any program seeking such certification shall submit a written application to the Commissioner or designee.

3. Such application shall include a comprehensive statement of the program's policies and procedures for the development and implementation of plans employing Level III Aversive Interventions, including a description of the program's actual use, or proposed use, of such procedures, and of the program's policies and practices regarding the training and supervision of all staff involved in the use of such procedures, and further including current resumes of all members of the Peer Review Committee required by 115 CMR 5.14A(4)(d)5. and a description of the review procedures followed by such Committee.

4. Such application shall further include a certification by the program of its ability to comply 115 CMR 5.14A.

5. The Commissioner or designee shall review such application upon its receipt and, after a determination that the written application is complete and satisfies all applicable requirements, shall provide for an inspection of the program by authorized Department representatives.

6. In the course of any inspection pursuant to 115 CMR 5.14A(4)(f)5. or 115 CMR 5.14A(4)(f)10., inspection staff shall have access to the records of the program's clients (including any written plans required by 115 CMR 5.14A(4)(c) and 115 CMR 5.14(8) and data and information developed pursuant to such plan), the physical plant of the facility, the employees of the program, the professional credentials of such employees, and shall have the opportunity to observe fully the treatment employed by the program and to review with the program's staff the procedures for which certification was granted or is sought and the manner in which such procedures have been or are to be implemented.

7. After such review and inspection, the Commissioner or designee shall approve, approve with conditions, or disapprove the program's application and, if approved, shall certify the program subject to any applicable conditions based upon his or her determination of the program's compliance with all applicable requirements.

The Commissioner or designee may, as a condition of approval, require appointment of one or more persons approved by the Commissioner or designee to the program's peer review committee or human rights committee in the event that he or she determines that such appointment or appointments are necessary to ensure performance by such committees of their review responsibilities consistent with the requirements established by 115 CMR 5.14A.

8. If disapproved, or if certification is revoked in accordance with 115 CMR 5.14A(4)(f)10., programs not operated by the Department shall have the right of appeal established by the applicable provisions of M.G.L. c. 19B and M.G.L. c. 30A.

5.14A: continued

9. Any such certification of a program shall be effective for a maximum of two years and may be renewed thereafter upon the Commissioner or designee's approval of a renewal application pursuant to the standards and procedures set forth in 115 CMR 5.14A(4)(f).

10. The performance of a provider certified for Level III Interventions may be reviewed as part of the survey required by the Department's regulations on certification and licensing, 115 CMR 8.00: *Certification, Licensing and Enforcement*, and shall be further subject to such additional inspections as the Commissioner in his or her discretion deems appropriate. Such Level III certification may be revoked, and the Department may revoke, suspend, limit, refuse to issue or refuse to renew a provider's Level III certification or license pursuant to 115 CMR 8.13: *Suspension, Revocation, and Denial of a License or Renewal*, upon a finding that the conditions for certification are no longer met, as well as for any of the grounds stated at 115 CMR 8.13.

11. A program shall be eligible for consideration for certification for use of Level III Interventions only if, prior to the effective date of 115 CMR 5.14A (formerly 115 CMR 5.14), the program had been using one or more Level III Interventions pursuant to a behavior modification plan for one or more clients of the program. This restriction on eligibility shall continue in effect indefinitely and shall be modified only by amendment of 115 CMR 5.14A. Such amendment shall only be proposed or adopted by the Commissioner in the event that he or she finds that there exists a compelling need for treatment with such Interventions that cannot be met within existing programs or through alternative programs.

12. When necessary to prevent discontinuity in existing programming or to provide for an emergency, the Commissioner may in his or her discretion provide for the interim certification of a program, provided that the application and review process required for certification by 115 CMR 5.14A shall be initiated and completed as soon as possible thereafter.

5.15: Medication

(1) The use of medications by programs subject to 115 CMR 5.00 is prohibited except as provided in 115 CMR 5.15.

(2) Medication shall not be used by programs subject to 115 CMR 5.00 as punishment, or in quantities that interfere with the individual's habilitation.

(3) Medication shall not be used by programs subject to 115 CMR 5.00 for the convenience of staff or as a substitute for programming.

(4) Medication used to manage or treat challenging behavior shall be administered subject to the requirements of 115 CMR 5.15.

(a) Medication used to manage or treat challenging behavior shall be administered in accordance with the recommendations of the prescribing health care provider and contained in a medication treatment plan referencing the individual's PBSP, if appropriate. The presence of a medication treatment plan should be noted at the next annual individual support planning meeting.

(b) The medication treatment plan shall contain at least the following information identified by the prescribing health care provider:

1. a description of the challenging behavior described in objective terms, to be managed or treated;
2. information concerning the common risks and side effects of the medication, procedures to minimize such risks, and description of clinical indications that might require suspension or termination of the drug therapy;
3. data tracking necessary for ongoing monitoring such that the individual's clinical course may be evaluated; and
4. in the case of antipsychotic medications only where there is a court order specifying the treatment, unless the individual is capable of giving informed consent for such treatment and has given consent or a medical emergency exists. A medical emergency is a situation in which the individual's mental condition requires medical attention or treatment to prevent immediate, substantial and irreversible deterioration of a serious mental illness.

5.15: continued

(5) Medication Incidental to Treatment.

- (a) Administration of medication incidental to the treatment requires the consent of the individual or guardian, except in a medical emergency.
- (b) It is expected that efforts to desensitize the individual to the treatment would be instituted in order to reduce or eliminate the need for medication incidental to treatment.
- (c) Medication incidental to treatment is not a restraint.
- (d) Medication may not be prescribed PRN for restraint purposes.
- (e) Medication may be prescribed PRN for treatment purposes. For non-self-administering individuals who are prescribed medication PRN for treatment, the program shall obtain from the prescribing health care provider: a statement of specific criteria, in the form of observable symptoms, for determining when the medication is to be administered.

(6) Medication shall be administered in accordance with the written prescription of a practitioner and the provisions of 105 CMR 700.003: *Registration of Persons for Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)*. For non-self-medicating individuals, prescription medication shall be administered by licensed professional staff; provided, however, that for non-self-medicating individuals receiving services in the community, prescription medication may be administered by community program staff who have successfully completed the Department approved Medication Administration Program (MAP) Training and have been certified by the Department in accordance with 105 CMR 700.003(F)(2): *Training*.

(7) Certified program staff of community programs may administer prescription medications to non-self-medicating individuals, provided that the community program is registered with the Department of Public Health in accordance with 105 CMR 700.004: *Registration Requirements* and staff meet the requirements set forth in 105 CMR 700.003(F) and 115 CMR 5.15(7).

(a) Medication shall only be administered by unlicensed program staff that possess current Department MAP certification in accordance with 105 CMR 700.003(F)(2): *Training*, 115 CMR 5.15(5), and the MAP Policy Manual.

- 1. MAP certification issued by the Department will be valid for two years.
- 2. The Department may recertify unlicensed program staff to administer medication upon the person meeting the standards for retraining and/or retesting established by the Department of Public Health and the Department.
- 3. For purposes of 115 CMR 5.15(7)(a), the Department shall accept current MAP certification issued by the Department of Mental Health.
- 4. Certification to administer medication may be withdrawn or rejected if the Department finds, after an informal hearing, that the holder of the certification:
 - a. has been convicted of a crime involving controlled substances;
 - b. has furnished or made any misleading or false statement in the application for, or renewal of, certification;
 - c. has failed to exercise proper regard for the health, safety and welfare of community program residents; or
 - d. is unfit to perform the duties for which the certification was granted.

The informal hearing is not an adjudicatory proceeding within the meaning of M.G.L. c. 30A and the decision of the Department is final.

(b) The program shall establish, maintain, and operate in accordance with policies that ensure that prescription medication is administered only by certified personnel.

- (c) The program shall maintain a current written list of those staff who have
- 1. successfully completed a training program meeting the requirements of 105 CMR 700.003(F)(2): *Training*;
 - 2. are authorized by the program to administer prescription medications; and
 - 3. are currently certified by the Department to administer medication.

(d) The Department of Public Health and the Department shall be permitted by the program to inspect program and individuals' records pertaining to the use and administration of prescription medication and are permitted announced or unannounced on-site visits or inspections of common areas and such other inspections as the Department of Public Health is authorized to make in order to monitor the program's compliance with 105 CMR 700.003: *Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)* and 115 CMR 5.15;

5.15: continued

(e) The program shall promptly notify the Department of Public Health and the Department of:

1. any suspected shortages or diversion of prescription medications;
2. any other suspected misuse of prescription medication in accordance with guidelines established by the Department and the Department of Public Health; and
3. any violations of Department or Department of Public Health regulations or inconsistencies from the physician's prescription that staff believe created a risk of harm to the individual.

(f) The program shall provide or arrange for technical assistance and advice to be provided as needed by a registered nurse, registered pharmacist, or other licensed practitioner, when questions arise regarding appropriate administration practices or the effects of medications. The program shall establish policies and procedures which insure reasonable access to such assistance and advice.

(g) Individuals whose ISP teams have determined they may be capable of benefitting from training to obtain or enhance self medication skills, shall receive such training.

(8) Storage. In accordance with 105 CMR 700.003: *Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)* and 115 CMR 5.15(7), medication security and storage requirements of federal and state laws shall be enforced at all storage locations and shall, in addition, meet the following requirements:

(a) Prescription medications for all individuals who are non-self-medicating shall be labeled and stored in a locked container or area, in which nothing except such medications are stored. Prescription medications required to be refrigerated must be stored in a locked container within the refrigerator. The program shall have a written policy describing the persons and the conditions under which persons may have access to such container or area and restrictions for access to the locked container.

(b) Prescription medications for individuals who are self-medicating shall be stored in such a way as to make them inaccessible to all other individuals. Such medications shall be stored in a locked container or area, in which nothing except such medications are stored, unless the head of the provider makes a determination that unlocked storage of the medication poses no threat to the health or safety of the individuals taking the medication or other individuals; provided however, that all controlled substances in Schedules II through V shall be stored in a locked container or area. If a locked container or area is deemed necessary, and the medications are also required to be refrigerated, they must be stored in a locked container within the refrigerator.

(c) Outdated medications, medications which have not been administered due to a change in the prescription or a stop order, and medications with worn, illegible or missing labels shall be disposed of and the disposal shall be documented in accordance with 105 CMR 700.003(F)(3)(c).

(d) Medications for external use shall be stored separately from medications taken internally.

(9) Labeling. All medications shall be properly labeled in accordance with M.G.L. c. 94C, § 21, and 105 CMR 700.003(F)(4): *Labeling*, and the *MAP Policy Manual*.

(10) Administration. All prescription medications shall be administered in accordance with M.G.L. c. 94C, applicable Department of Public Health regulations, and the following requirements:

(a) MAP certified staff of community programs registered with the Department of Public Health are permitted to administer medications which are oral, topical, ophthalmic, otic, suppository, intranasal or products which are administered by inhalation. Such staff shall not administer any medication by injection. MAP certified staff who have successfully completed a specialized training program taught by a physician, physician assistant, nurse practitioner, pharmacist, or registered nurse, approved by the Department or the Department of Public Health, may administer certain parenteral medications generally intended for self-administration and medications by gastrostomy or jejunostomy tube. Such specialized training shall include on site competency evaluation. The specially certified staff shall perform these activities in accordance with written instructions and only with the written authorization of a prescribing practitioner.

5.15: continued

(e) The community program shall not store on-site more than a 30-day supply of any medication prescribed for an individual.

(f) For any consumer who is non-self-medicating, and who receives prescription medication at a location other than the program site where staff are certified to administer prescription medication (off-site), the program shall, whenever possible, identify an individual responsible for administering the medication and make available to that person instructions as to how the medication is to be administered.

(g) For non-self-medicating individuals who are currently receiving prescription or non prescription (over-the-counter) medication, the approval of the appropriate practitioner (a physician, dentist, pharmacist, physician assistant, nurse practitioner or registered nurse) must be obtained and noted in the individual's record prior to administration to the individual of an additional over the counter medication. Compliance with 115 CMR 5.15(9)(g) shall constitute compliance with 105 CMR 700.003(F)(5)(h).

(11) Documentation. All prescriptions for, and administration of, medication shall be documented in accordance with 105 CMR 700.003(F)(6): *Documentation*, 115 CMR 5.15(9), and the *MAP Policy Manual*, and the following requirements:

(a) All prescriptions for medication shall be noted in the individual's record on a medication and treatment form(s) approved jointly by the Department and the Department of Public Health. Such form(s) shall specify for each individual, the type and dosage of medication, the reason for which the medication is prescribed, when and how the medication is to be administered, instructions for self-medication, if applicable, any contraindications or possible allergic reactions, and special instructions. The program shall establish appropriate policy and procedures to address how program staff shall obtain relevant information in accordance with the requirements of 115 CMR 5.15(10). In addition, such policy and procedures shall ensure that telephone orders for medication and/or changes in medication are received from licensed practitioners and properly documented according to the *MAP Policy Manual*.

The program shall establish appropriate policies and procedures to insure that staff receive assistance as needed from registered nurses, registered pharmacists, or licensed practitioners to obtain the information required in 115 CMR 5.15(9)(a). In addition, such policies and procedures shall include specific instructions for staff which insure that written or telephoned medication orders or changes to such orders, received from licensed practitioners, are properly documented in the individual's medication record.

(b) To ensure proper communication among all programs providing services to the same individual, an individual's residential program shall notify the individual's day program of any prescription or nonprescription medications which the individual is taking on a regular basis, including medication scheduled to be taken solely at the day program, and shall provide the day program with a copy of a pharmacological reference approved by the Department of Public Health that covers each prescription medication that the individual receives.

(c) The administration of medication, including practitioner ordered over-the-counter drugs, shall be documented in the individual's record as follows:

1. The time that the medication is administered to the individual;
2. Any off-site administration of medication which would normally be administered at the program site; and
3. Any inconsistencies from the physician's prescription regardless of whether such inconsistencies resulted in harm or a risk of harm.

Individuals who are self-medicating shall not be required to document their own self-administration of medication;

(d) Any change in prescription medications or dosage levels of a medication shall be treated as a new medication prescription order for the purposes of documentation.

(e) The program shall establish procedures to document the date that an individual's prescription is filled and the quantity of medication dispensed by the pharmacy.

(f) Except for persons who are self-medicating, the program shall maintain a documented accounting of the quantities of Schedule II controlled substances stored by the program which shall be reconciled at the beginning and the end of every shift or at such other frequency otherwise approved by the Department of Public Health.

5.15: continued

(g) Whenever a non self medicating individual is taking an over-the-counter medication in addition to a prescription medication or another over-the-counter medication, the consultation with the appropriate practitioner required under 115 CMR 5.15(8)(g) shall be documented in the individual's record.

(12) Programs shall permit and encourage self-medication by individuals capable of self-medication, provided that:

- (a) the risks of misuse or abuse to the individual and other persons within the program are minimal; and,
- (b) the program provides the individual with adequate training and assistance.

(13) Notwithstanding any of the foregoing provisions of 115 CMR 5.15, individuals served by programs subject to 115 CMR 5.00 shall have the right to control the provision of personal medical treatment by such programs in accordance with the requirements of 115 CMR 5.15(12).

(a) If a program subject to 115 CMR 5.15 arranges for but does not provide medical care, then such services shall be arranged only upon consultation with the individual or guardian to the fullest extent possible.

(b) If a program subject to 115 CMR 5.15 provides routine or preventive medical care, including standard medical examinations, clinical tests, standard immunizations, and treatment for minor illnesses and injuries, then such services shall be provided only in accordance with:

- 1. a specific or general written authorization, to be renewed annually, for routine or preventive care given freely and knowingly at the time of entry to the program by:
 - a. the individual, if not under guardianship and competent in fact to give informed consent concerning such routine and preventive care; or
 - b. the individual's guardian, if any.
- 2. a written authorization by the head of the provider, upon recommendation of the treating physician that such care is necessary and appropriate, where the individual is not under guardianship and is not competent in fact, as determined in an individual's ISP, to give informed consent concerning such routine or preventive medical care; or
- 3. an authorization by a probate court or other court of competent jurisdiction.

The provision of first and shall not be considered routine or preventative medical care.

(c) If a program subject to 115 CMR 5.15 provides any nonroutine or preventative medical care, other than that provided in emergency situations, such care shall be provided in accordance with a specific written authorization for care given freely and knowingly by:

- 1. the individual, if not under guardianship and competent in fact to give informed consent for such care;
- 2. the individual's guardian, if any; or
- 3. a probate court or other court of competent jurisdiction.

(d) Nothing in 115 CMR 5.15(12) shall be interpreted to:

- 1. restrict the right of physicians, nurses, and emergency medical technicians to render emergency care or treatment in accordance with M.G.L. c. 112, § 12B;
- 2. restrict the right of physicians to provide medical care involving drug dependency to consenting minors, in accordance with the provisions of M.G.L. c. 112, § 12E;
- 3. restrict the right of physicians, dentists, or hospitals to provide emergency medical care without the consent of the parent, guardian, or other person having custody of a minor, or the spouse of an individual, when delay in treatment will endanger the life of an individual; or
- 4. restrict the right of a minor to give consent for medical or dental care at the time such care is given in certain circumstances, in accordance with M.G.L. c. 112, § 12F.

5.16: Rights and Responsibilities of Service Providers

In addition to any other rights and responsibilities set forth elsewhere in 115 CMR or in other applicable state or federal laws or judicial decrees, all providers (including all those who contract with or are subject to certification, licensure or regulation by the Department) shall have the following rights and responsibilities:

5.16: continued

- (1) The responsibility to provide services or supports in accordance with the Department's regulations, its contract with the Department, and each individual's ISP;
- (2) The responsibility to provide service and supports in accordance with the standards for dignity set forth in 115 CMR 5.00;
- (3) The right and the responsibility not to accept for services any individuals who are beyond its professional or physical capacity to serve, unless directed to do so in an emergency pursuant to the emergency service provisions of the Department's regulations;
- (4) The responsibility to notify the Department if an individual accepted for services is no longer within its professional capacity to serve; and
- (5) The right and the responsibility to participate in the ISP planning process, including developing and implementing provider strategies to meet objectives set forth in an individual's ISP, subject to: the monitoring and coordinating responsibilities of the Department; the requirements of the provider's contract with the Department; and subject to the appeal rights of individuals and others authorized to appeal.

REGULATORY AUTHORITY

115 CMR 5.00: M.G.L. c. 19B, §§ 1, 13, 14, 26 and 29; M.G.L. c. 123B, §§ 2, 8, 9, 12 and 14.

NON-TEXT PAGE