115 CMR 5.00: STANDARDS TO PROMOTE DIGNITY

Section

5.01: Scope

115 CMR 5.03 through 5.16: *Standards to Promote Dignity*, applies to all providers and to all services or supports which are operated, certified, licensed, or contracted for or otherwise funded by the Department.

5.02: 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.

Pursuant to M.G.L. c. 19B, § 14, the Department is authorized to adopt such regulations which it deems necessary to carry out the provisions of that chapter. All regulations adopted pursuant to M.G.L. c. 19B and c. 123B are subject to appropriation.

5.03: General Principles

To further the Department's goal of promoting the welfare and dignity of all persons with intellectual disability, 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) 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. Maintaining a personal appearance which is appropriate to the individual's chronological age and the practices of the surrounding community and which is

consistent with his or her choices and preferences and social and cultural background;

5.03: continued

3. 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;
4. Communication by staff in a manner appropriate to the individual's age and the practices of the surrounding community;
5. 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;
6. 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;
7. Possessions which are appropriate to the individual's age and the practices of the local community and consistent with the individual's interests;
8. Privacy, including the opportunity wherever possible, to be provided clearly defined private living, sleeping and personal care spaces; and
9. 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 5.03 through 5.16 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 and opportunities to make and receive confidential calls, 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.

(2) The right to be protected from private and commercial exploitation including: the right not to be exposed to public view by photograph, film, videotape, interview, or other means unless prior written consent of the individual or guardian is obtained for each occasion of 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;
(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.

(4) The right to enjoy basic goods and services without threat of denial or delay for any purpose by providers subject to 115 CMR 5.03 through 5.16. 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;

5.04: continued

(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 that is individually owned;
(e) Opportunities for social contact in the individual's home, work, or community environments;
(f) Opportunities to keep and use personal possessions;
(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

(1) No provider subject to 115 CMR 5.03 through 5.14 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 which is 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 physical, mechanical, or chemical restraint as punishment, for the convenience of staff, or otherwise in violation of 115 CMR 5.11 (restraint);
(h) Sexual abuse of an individual;
(i) Intentional failure to obtain or render medical services; and
(j) 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, 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 and shall be grounds for disciplinary action which may include dismissal.

(2) Failure of an employee of the Department to report to the Department any allegation or instance of mistreatment within any provider including the Department shall be grounds for disciplinary action which may include dismissal.

(3) Failure by the employee of any provider other than the Department which is subject to the provisions of 115 CMR 5.00 to report to the Department any allegation or instance of mistreatment shall be grounds for disciplinary action which may include dismissal.

5.06: continued

(4) 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 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 and, if the provider is the Department, grounds for disciplinary action against the head of the provider (as defined at 115 CMR 2.01), which may include dismissal.

5.07: Legal Competency, Guardianship, and Conservatorship

(1) All Adults Deemed Competent Absent Court Determination to Contrary. An individual who has reached 18 years of age shall be deemed to be competent to manage his or her affairs; to contract, to hold a professional, occupational, or vehicle operator's license; to make a will, or to vote and no individual shall be deemed 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, conservatorship or trusteeship proceeding.

(2) Notification if Competency in Fact Doubted and Preference for Least Restrictive Response. If an individual's ISP team has reason to believe that he or she is not competent in fact to make informed decisions with regard to financial affairs, the Department or the head of the provider shall notify the individual's nearest living relatives in writing, with an accompanying recommendation that steps to protect the individual's finances be taken. These may include appointment of a representative payee, co-signatory bank account, or a shared or delegated money-management plan. A trustee, conservator, or guardianship of the estate 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.

(3) Guardianship of the Person Recommended Only if Other Supports Inadequate; Least Restrictive Form of Guardianship. If an individual's ISP team has reason to believe that an individual is not competent in fact 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.

(4) Actions Taken Where Appropriate Nominee for Guardian does not Exist. Where the nearest living relative cannot be found or is incapable or 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 trustee, conservator, or guardian, as appropriate. These procedures shall attempt to ensure that:

(a) temporary guardians are available to meet emergency situations;

(b) individuals requiring trustees, 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 trusteeship, 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 incompetent 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, in accordance with the requirements of 115 CMR 5.15 (medication);

(c) Prior to involvement of the individual in research activities, in accordance with the requirements of the Department's regulations on research, 115 CMR 10.00;

(d) Prior to the initiation of a level II or level III behavior modification interventions, in accordance with 115 CMR 5.14 (behavior modification); and

(e) 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, in which release is permitted without the individual's consent.

(2) Informed consent means 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.

(3) 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 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 which:

1. details the procedure utilized to obtain the consent;

2. identifies the name, position, and affiliation of the individual securing the consent;

3. summarizes the information provided to the individual from whom consent is secured, in accordance with 115 CMR 5.08(3)(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 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;

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;

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.

5.09: continued

(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; unless the interference or restriction is part of a duly developed and reviewed ISP or behavior modification plan; unless otherwise ordered by the court; or unless 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 documented in the individual's record, and a copy sent promptly to the provider's human rights committee.

(b) Such restriction shall be accompanied where appropriate by a training plan, documented in the individual's record, to eliminate the need for the restriction.

(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.

(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 is not competent in fact 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 in the management and expenditure of that portion of the person's funds, in accordance with the individual's needs, capabilities, interests, and desires. This written plan to advise and assist the individual 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, in ascending order of restrictiveness: advice and training in the management and expenditure of funds, two-signature (co-signatory) accounts, and representative payee accounts.

(b) The provider shall obtain the agreement of the individual, if not under guardianship or conservatorship, or the guardian or conservator, if any, for any plan involving 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(2), (3), and (4) 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 which 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 survivor-ship 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.

5.10: continued

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: Seclusion, Locked Buildings and Emergency Restraint

(1) Definition of Terms. The following terms used in 115 CMR 5.11 and 5.12 shall have the following meaning:

Emergency shall mean that a reasonable person would perceive one or more of the following:
(a) the present occurrence of serious self-injurious behavior;
(b) the present occurrence of serious physical assault;
(c) the imminent threat of serious self-injurious behavior or behavior which is likely to lead to self injury, where the individual has the present ability to effect such behavior and has engaged in any action which indicates a present intention or inclination to carry out such behavior immediately;
(d) the imminent threat of serious physical assault, where the individual has the present ability to effect such assault and has engaged in any act which indicates a present intention or inclination to carry out such assault immediately. The occurrence or imminent threat of property damage is not an emergency unless such damage is also likely to lead to the serious self injury of the individual or to the serious harm of those present.

Emergency Restraint, Physical Restraint, Mechanical Restraint, and Chemical Restraint shall have the meaning found at 115 CMR 2.01.

5.11: continued

Health-related Protection means limitation of movement ordered by a physician or authorized clinician if absolutely necessary during a specific medical or dental procedure or if necessary for the individual's protection during the time that a medical condition exists. It is not a form of emergency restraint and may not be used for the convenience of staff. It may be used only in accordance with 115 CMR 5.12.

Seclusion shall mean the placement of an individual alone in a room or other area from which egress is prevented, unless such placement has been approved as "time out" pursuant to a behavior modification plan that meets all applicable requirements of the Department's regulations concerning such plans. Seclusion shall not include the placement of an individual in his bedroom for the night.

Support Needed to Achieve Proper Body Position, Balance, or Alignment means a limitation of movement necessary for the individual to achieve proper body position, balance, or alignment. It is not a form of emergency restraint and may not be used for the convenience of staff. It may be used only in accordance with 115 CMR 5.12.

Transportation Restraint shall mean any limitation of movement necessary for the safety of the individual during transportation. It is not a form of emergency restraint and may not be used for the convenience of staff. It may be used only in accordance with 115 CMR 5.13.

(2) Seclusion Prohibited. Seclusion is prohibited by any provider and in any service or support subject to the Department's regulations.

(3) Locked Buildings. The locking of exits from buildings is prohibited, except for the safety of the occupants and only if behavioral or other teaching interventions or less restrictive alternatives will not suffice to address safety concerns. Locks on bedroom doors which are in the path of egress from the building are prohibited. Locks on other bedroom doors are permitted only if the individual is able to unlock the door from within (see 115 CMR 7.00), but at all times staff must carry a key to open the door in the event of an emergency.

(4) Emergency Restraint - Requirements For Use. The use of emergency restraint must conform to the requirements set forth in 115 CMR 5.11(4) through (8).

(a) Use Permitted Only in Emergency. Emergency restraint - whether physical, mechanical, or chemical - may be used only in cases of emergency, which is defined in 115 CMR 5.11(1): Emergency.

(b) Least Restrictive Alternative. Emergency restraint may be used only after the failure of less restrictive alternatives or after a determination, based upon professional judgment, that such alternatives would be ineffective under the circumstances.

(c) Duration of Emergency Restraint. Emergency restraint may be used only for the period of time necessary to accomplish its purpose, but in no event may physical or mechanical restraint be used beyond the periods established in 115 CMR 5.11(6) (additional requirements and restrictions on use of physical and mechanical restraint).

(d) Duration of Transportation Restraint. Transportation restraint may be used only for the period of time necessary to accomplish its purpose and only during transportation.

(e) P.R.N. Orders Prohibited. No "P.R.N." or "as required" authorization of restraint may be written.

(5) Chemical Restraint - Additional Requirements and Limitations on Use.

(a) Authorization for Use. An individual may be given chemical restraint only on the order of an authorized physician who has determined that such chemical restraint is the least restrictive, most appropriate alternative available. Such an order may not be implemented unless:

1. the authorized physician giving the order is or was present at any time during the course of the emergency justifying the use of the restraint; or

5.11: continued

2. prior to issuing the order, the authorized physician has a telephone consultation with a physician, registered nurse or nurse practitioner, or certified physician assistant who is or was present at the time and site of the emergency and who has personally examined the individual.

(b) Documentation of Order. An order for chemical restraint along with the reasons for its issuance shall be recorded in writing at the time of its issuance.

1. Such order shall be signed at the time of its issuance by the authorized physician if present at the time of the emergency.

2. Such order, if authorized by telephone, shall be transcribed and signed at the time of its issuance by the physician, registered nurse or nurse practitioner, or certified physician's assistant.

(c) Limitation on Telephone Orders. No medication may be used for chemical restraint purposes pursuant to a telephoned order unless the medication so ordered has been previously authorized as part of the individual's current treatment plan.

(d) Recording of Behavioral Effects of Drug. Notations shall be made in the individual's program record as to any behavioral effects of the drug, or lack thereof, after clinically appropriate lengths of time, as specified by the authorizing physician. Checks for such behavioral effects shall be made by staff trained in the administration of medicine.

(e) Chemical Relaxation for Medical or Dental Treatment. Sedatives or anti-anxiety medication prescribed by a qualified practitioner for the sole purpose of relaxing or calming an individual so that he or she may receive medical or dental treatment is not a restraint. Administration of such medication shall be deemed incidental to the treatment, and, except in a medical emergency, requires the consent of the individual or guardian. Providers should incorporate into an individual's ISP objectives that assist the individual to learn how to cope with medical treatments and that lead to the decrease or elimination of medication for chemical relaxation incidental to treatment.

(6) Additional Requirements and Restriction on Use of Physical or Mechanical Restraint. The following requirements apply only to physical and mechanical restraint. They do not apply to transportation restraint.

(a) Staff Training. Providers utilizing mechanical or physical restraint shall train all direct contact staff in the safe and appropriate use of such restraint. Training shall include techniques which deal with the prevention and management of potentially violent behavior, as well as health and safety precautions for the individual during restraint.

(b) Limitations on Mechanical Restraint.

1. Mechanical restraint is permitted in an emergency by providers of day and residential services and supports.

2. Mechanical Restraint Prohibited in Non-facility Providers Absent Waiver. Notwithstanding 115 CMR 5.11(6)(b)1., no form of mechanical restraint other than mitts shall be employed by a provider that is not a facility except with respect to a particular individual for whom a waiver from 115 CMR 5.11 is obtained. A waiver may be granted at the discretion of the Department after the head of the provider submits a written waiver request with an explanation as to why other forms of restraint will not be effective in addressing emergencies for the individual.

a. The written waiver request must specify the type of and procedures for the mechanical restraint to be used for such individual and include a written report from a physician, nurse practitioner, certified physician's assistant or registered nurse who has evaluated the proposed mechanical restraint device and the individual to be placed in the mechanical restraint for contraindications.

b. The waiver request must be submitted to the Regional Director. Prior to its submission, the request must receive the approval of the provider's human rights committee.

c. The Regional Director may either support or reject the request for a waiver. The Regional Director shall forward all supported requests to the Office for Human Rights, which shall have sole discretion for final issuance of approved waivers for mechanical restraint by the Department. Rejected requests shall be returned to the provider and shall not be approved.

d. A waiver is valid for one year. The renewal of a waiver request requires the submission of a new written request to the Regional Director, including information on the efficacy of the restraint, and justification for the waiver.

5.11: continued

e. Any mechanical restraint employed by a provider pursuant to a waiver must be used in accordance with all requirements of 115 CMR 5.00 applicable to mechanical restraint.

f. The granting of a waiver under these provisions has no effect on the requirements of 115 CMR 5.14 for behavior modification interventions.

3. Any device used for mechanical restraint must provide appropriate and safe ventilation, and must allow for appropriate attention to the physical and emotional comfort of the individual in restraint.

4. Locked mechanical restraint devices requiring the use of a key for their release are prohibited.

(c) Mechanical Restraint or Physical Restraint - Initial Order.

1. Head of the Provider, Designee or Authorized Physician. An individual may be placed in mechanical restraint or physical restraint at the order of the head of the provider or an authorized physician if the head of the provider or the authorized physician is present at any time during the course of an emergency justifying the use of the restraint. A designated person who is otherwise authorized to act for the head of the provider in his or her absence may authorize restraint in accordance with 115 CMR 5.00.

a. Such order along with the reasons for its issuance shall be recorded in writing and signed at the time of its issuance by the head of the provider, designee, or physician.

b. Such order shall authorize use of mechanical restraint or physical restraint for no more than two hours, shall terminate whenever a release decision is made pursuant to 115 CMR 5.11(6)(f), and shall be subject to the monitoring, examination, release, and documentation provisions of 115 CMR 5.00.

c. Such order may be renewed in accordance with 115 CMR 5.11(6)(d).

2. In Absence of Head of the Provider, Designee, or Authorized Physician. If the head of the provider, the designee, or an authorized physician is not present at any time during the course of an emergency justifying the use of mechanical restraint or physical restraint, an individual may be placed in mechanical restraint or physical restraint at the order of a staff person authorized to give such orders by the head of the provider. (Such a staff person shall be hereinafter referred to as an "authorized staff person.")

a. Authorization of staff for ordering restraint shall be in writing and documented in such staff's personnel file(s).

b. A staff person may be authorized to give such orders by the head of the provider only if he or she had basic orientation and training in the applicable legal, clinical, and safety requirements for restraint justification and implementation. A staff person will not be deemed to have received such training unless this fact is recorded by the provider in his or her personnel record.

c. An order for restraint issued by an authorized staff person, along with the reasons for its issuance, shall be recorded in writing and signed at the time of the incident by such authorized staff person.

d. Such order shall authorize the use of mechanical restraint or physical restraint for no more than one hour, shall terminate whenever a permanent release decision is made pursuant 115 CMR 5.11(6)(f), and shall be subject to the monitoring, examination, release, and documentation provisions of 115 CMR 5.00.

e. Such order may be renewed only in accordance with 115 CMR 5.11(6)(d), for no more than the one or two hour periods noted in 115 CMR 5.11(6)(d).

(d) Mechanical Restraint or Physical Restraint - Renewal Order to Continue its Use.

1. Continuation for Additional Two-hour Periods. For mechanical and physical restraint, orders issued pursuant to the provisions of 115 CMR 5.11(6)(c)1., 5.11(6)(c)2., and 5.11(6)(d)2. may be renewed prior to the expiration of the order by the head of the provider, the designee, or an authorized physician, and, thereafter, may similarly be renewed in accordance with 115 CMR 5.11(6) at two hour intervals.

a. Such renewal order may only be issued if the person authorized to issue such order determines that it is necessary to prevent the continuation or renewal of an emergency condition or conditions as defined in 115 CMR 5.11(1)(a). In reaching such a determination, the person authorized to issue the renewal order must consider whether use of a chemical restraint would at this point present a less restrictive alternative to maintaining the individual in physical or mechanical restraint beyond the initial two hours.

5.11: continued

b. Such renewal order along with the reasons for its issuance shall be recorded in writing and signed by the person issuing it only after examination of the individual in restraint by such person.

c. Such renewal order shall authorize continued use of physical or mechanical restraint for no more than two hours from the time of expiration of the preceding order, shall terminate whenever a permanent release decision is made pursuant to 115 CMR 5.11(6)(f) and shall be subject to the monitoring, examination, release, and documentation provisions of 115 CMR 5.11.

2. Continuation for a Second Hour of an Initial One-hour Order by Authorized Staff Person. A single renewal of a one hour order issued pursuant to the provisions of 115 CMR 5.11(6)(c)2. may be issued by an authorized staff person if the individual in mechanical restraint or physical restraint has not been examined by the head of the provider, designee or an authorized physician prior to the end of the first hour.

a. Such renewal order may be issued only if such authorized staff person determines that such restraint is necessary to prevent the continuance or renewal of an emergency condition or conditions as defined in 115 CMR 5.11((1)(a). In reaching such a determination, the person authorized to issue the renewal order must consider whether use of a chemical restraint would at this point present a less restrictive alternative to maintaining the individual in physical or mechanical restraint beyond the initial one hour.

b. Such renewal order along with the reasons for its issuance shall be recorded in writing and signed at the end of the first hour by such authorized staff person.

c. Such renewal order shall authorize use of mechanical restraint or physical restraint for no more than one hour, shall terminate whenever a release decision is made pursuant to 115 CMR 5.11(6)(f), shall be subject to the monitoring, examination, release, and documentation provisions of 115 CMR 5.11, and may be renewed in accordance with 115 CMR 5.11(6)(d).

d. If the examination was not completed by the end of the first hour of such mechanical restraint or physical restraint, the head of the provider or authorized physician shall attach to the individual's restraint form a written explanation in accordance with 115 CMR 5.11(8) (Documentation Requirements).

(e) Monitoring and Examination of Individuals in Emergency Restraint (Mechanical and Physical).

1. Staff in Attendance. Whenever an individual is in mechanical or physical restraint, a staff person trained to understand an individual's emotional and physical reactions to restraint shall be in attendance, except under the special circumstances discussed at 115 CMR 5.11(6)(f).

a. Such staff in attendance may also be an authorized staff person within the meaning of 115 CMR 5.11(5)(c)2.

b. Such staff in attendance shall have access to the assistance or services of back-up clinical staff, for the purpose of providing therapy to the individual in restraint as needed and as appropriate.

c. The staff person shall be deemed in attendance for an individual in mechanical or physical restraint by being situated so that the staff person is able to communicate with and see the individual at all times.

d. One staff person may be in attendance for more than one individual at any time provided that the monitoring, examination, release, and documentation requirements of 115 CMR 5.11(6) are met for each such individual in restraint.

e. In the case of physical restraint, the staff person or persons applying the restraint may constitute the staff in attendance, if such staff satisfy the requirements of 115 CMR 5.11(5)(e)1. for staff in attendance, and provided that a separate staff person who is not applying the restraint observes the individual being restrained periodically at least every 15 minutes.

f. In situations when a staff person trained to understand the reactions of an individual in restraint is not available to be in attendance, an adult may be kept in mechanical or physical restraint for a period not to exceed two hours, if and only if the following conditions are met:

5.11: continued

i. For mechanical restraint, the adult must be observed by staff every five minutes.

ii. The head of the provider or authorized physician shall attach to the restraint form a written report as to why the specially trained staff in attendance was not available.

2. Safety Checks. Mitts or other mechanical restraints shall be checked at least every 15 minutes for comfort, body alignment, and circulation by an authorized staff person or the staff in attendance. Notation of such checks shall be entered onto the restraint order form required by 115 CMR 5.11(8)(a).

3. Continuous Physical or Mechanical Restraint Beyond Six Hours Prohibited. No individual shall be restrained for a continuous period exceeding six hours.

4. Non-continuous Mechanical Restraint Beyond Eight Hours. No adult may be maintained in mechanical restraint for more than eight hours in any 24 hour period. As noted in 115 CMR 5.11(6)(e)3., any continuous mechanical restraint over six hours is prohibited.

5. Special Examination and Review Requirements for Minors. Any minor placed in mechanical restraint or physical restraint shall be examined within fifteen minutes of the initial order for such restraint by an authorized physician, or, if an authorized physician is not available, by a registered nurse, nurse practitioner, or certified physician's assistant, provided, however, that said minor shall be examined by a physician within one hour of the initial order for restraint.

a. Every hour thereafter, an authorized physician, or, if an authorized physician is not available, a registered nurse, nurse practitioner, or certified physician's assistant, shall review the restraint order and the status of such minor, either by personal examination of the minor or by consultation with staff attending the minor.

b. Any use of restraint of a minor exceeding one hour in any 24 hour period shall be reviewed within two working days by the head of the provider who shall forward a copy of his or her report on each such instance of restraint to the human rights committee of the provider, and to the Department.

(f) Release from Emergency Restraint - Mechanical and Physical.

1. Temporary Relief. Relief periods for individuals in mechanical or physical restraint must occur for at least ten minutes of every two hours of restraint, except when precluded due to obvious and substantial risk of harm to the individual in restraint or others. These checks shall be noted in the restraint form. Provision must be made for reasonable access to drinking water and bathrooms.

2. Permanent Release. An individual shall be released from mechanical or physical restraint:

a. no later than the expiration of an order for such restraint, unless such order is renewed in accordance with the requirements of 115 CMR 5.11(4)(d).

b. prior to the expiration of an initial or renewed order for such mechanical restraint or physical restraint if a person authorized to issue an order for restraint determines, after examination of the individual or consultation with provider staff, that such mechanical restraint or physical restraint is no longer needed to prevent the continuation or renewal of an emergency condition or conditions as defined in 115 CMR 5.11(1)(a). The relaxing of a hold during an authorized restraint for the purposes of determining whether the restraint is needed to prevent the continuation or renewal of an emergency shall not in itself be deemed a permanent release.

c. when the individual in restraint is asleep.

The circumstances considered in arriving at such release determination shall be documented and signed by the person making the determination.

(7) Behavior Plan. Where the behavior necessitating the use of any restraint other than transportation restraint recurs beyond the first 24 hour period more than once within a week or more than two times within a month, an intervention strategy must be promptly developed to respond to the behavior and to reduce the likelihood of its recurrence.

(a) Such intervention strategy shall be included in the individual's ISP.

(b) If such intervention strategy involves the use of behavior modification, it must comply with the requirements of 115 CMR 5.14 on behavioral interventions.

(c) Such intervention strategy must also be reported to the provider's human rights committee.

5.11: continued

(8) Documentation Requirements.

(a) The Restraint Form. Each provider shall ensure that a restraint form is completed on each occasion when an individual is placed in emergency restraint (not transportation restraint, as it is not a form of emergency restraint) and on each occasion when an order for such restraint is renewed. The completion of the restraint form shall conform to the following requirements:

1. The restraint form must be in a form approved by the Commissioner.
2. Copies of the restraint form shall be filed as follows:
   a. One copy placed in the individual's record;
   b. One copy sent to the Department's Office for Human Rights, as the Commissioner's designee;
   c. One copy sent to the area office director;
   d. One copy sent to the provider's human rights committee.
3. The completed restraint form shall identify the individual who is the subject of the restraint.
4. The completed restraint form shall identify the name and title of each person issuing the initial restraint order or a renewal order and shall include a description of any less restrictive alternatives which were utilized before the restraint was ordered or renewed, the date and time of each such order, the signature of each such person written at the time of the order, the name and title of the person(s) applying the restraint, the nature of the restraint, and a description of the emergency situation (including relevant behavioral antecedents) upon which the restraint order or renewal order is based.
5. The completed restraint form shall document all examinations and other safety checks made of the individual in restraint and shall identify the time of such examinations or checks and the name and title of each person who conducted such examinations or checks.
6. The completed restraint form shall identify each staff person in attendance and shall document the periods when such person was in attendance on the individual.
7. The completed restraint form shall identify the time and extent of all relief periods and observations of the individual during such relief periods including the name of the person monitoring such relief periods and observations.
8. The completed restraint form shall identify the date and time when the individual was released from restraint.
9. The completed restraint form shall be reviewed by the head of the provider or his or her designee prior to its distribution to the individual under 115 CMR 5.11(8)(c).

(b) Attachments to the Restraint Form. When applicable, there shall be attached to each copy of the restraint form the written reports required by 115 CMR 5.11(6)(d)2.d. (explanation of failure of head of provider to examine individual within one hour); (6)(e)1.f.i. (special explanations relating to monitoring and examination); and 115 CMR 5.11(8)(c) (individual's comments).

(c) Individual's Comments. No later than 24 hours after the individual's release from restraint, a copy of the completed restraint form shall be given to the individual along with a form, in duplicate, approved by the Commissioner on which the individual will be invited to comment on the circumstances leading to the use of restraint and on the manner of restraint used. Staff shall provide individuals with assistance in commenting on the restraint form by talking to reluctant or noncommunicative individuals in a non-threatening manner or by interpreting communication by speech or hearing-impaired individuals. One copy of the individual's comments, if any, shall be placed in the individual's record and the second copy shall be used for the review required by 115 CMR 5.11(8)(d).

(d) Commissioner's Review. At the end of each month, copies of all restraint forms and attachments, if any, required to be completed by 115 CMR 5.11(8)(b) shall be sent to the Office for Human Rights, which has been designated by the Commissioner for review and signature of the forms within 30 calendar days of their receipt.

(e) Human Rights Committee Review. At the end of each month, the provider shall send to its human rights committee copies of all restraint forms and attachments, if any, sent to the Office for Human Rights and to the area office pursuant to 115 CMR 5.11. The committee shall have the authority to:

1. Review all pertinent data concerning the behavior which necessitated restraint.
2. Obtain information about the individual's needs from appropriate staff, relatives, and other persons with direct contact or special knowledge of the individual;

5.11: continued

3. Consider all less restrictive alternatives to restraint in meeting the individual's needs;
4. Review any existing behavior plans or intervention strategies in place and consult with the appropriate clinician;
5. Recommend referral of the individual to a professional to develop an intervention strategy or plan where appropriate to modify the undesired behavior;
6. Review or refer for investigation and action all complaints that the rights of any individual are being abridged by the use of restraint; and
7. Generally monitor the use of restraint in the provider or location.

(9) Statistical Records. Statistical records of all uses of emergency restraint, including information organized by provider and by authorized physician, shall be maintained by the Department and shall not be considered research activity.

(10) Public Record. The statistical records required by 115 CMR 5.11(9) shall be maintained by the Department as a public record.

5.12: Supports and Health-related Protections

Supports needed to achieve proper body position, balance, or alignment (*see* 115 CMR 2.01 and 5.11(1)), and health-related protections (see 115 CMR 2.01 and 5.11(1)) are not emergency restraint.

Supports may be used only to achieve proper bodily position and balance, to permit the individual to actively participate in ongoing activities without the risk of physical harm from those activities, to prevent reinjury 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, supportive body bands, and physical holding in a gentle manner for no more than five minutes, as further specified in 115 CMR 2.01.

Health-related protections (permitted under federal regulation 42 CFR 483.450(d)(iii)) are ordered by a physician or other authorized clinician if absolutely necessary during a specific medical or dental procedure or for the individual's protection during the time that a condition undergoing treatment pursuant to that clinician's orders exists. When used in accordance with 115 CMR 5.12, these devices shall not be considered a type of restraint.

(1) Physical Holding which is and is not Restraint. If, in order to physically hold the individual, physical force is required to overcome his or her active resistance, then the holding is not a physical holding in a gentle manner nor a support or health-related protection (unless the holding is employed to evacuate an individual from his or her residence), but rather is an emergency restraint subject to the requirements for restraint set forth in 115 CMR 5.11. Physical holdings necessary to evacuate an individual from his or her residence shall be deemed to be a support and not an emergency restraint, regardless of whether physical force is necessary to overcome the individual's active resistance.

(2) Limitations on Health-related Protections and Supports. Health-related protections ordered by a physician or other authorized clinician for the individual's protection during the time that a medical, dental, or other condition requiring treatment exists may be employed if authorized by the clinician. Supports needed to achieve holding, including devices, needed to achieve proper body position, balance, or alignment shall be authorized only if determined in the individual's ISP to be the least restrictive means of achieving a therapeutic objective. Where such determination is required, the ISP shall specify the device to be used, and the individual's record shall contain the indications for use and discontinuance, the alternatives considered, the frequency and duration of use, procedures for safety checks, and the qualified professional supervising use of the device.

(3) Further Limitations on Supports. Supports permitted under 115 CMR 5.12(2) shall be designed and applied:

(a) With the authorization and supervision of a qualified practitioner;

(b) In accordance with principles of good body alignment, concern for circulation, and allowance for change of position;

5.12: continued

(c) In accordance with safety checks and opportunities for exercise as specified by the qualified professional, and, if applicable, set forth in the individual's ISP; and
(d) With documentation as to the frequency and duration of use, safety checks, and opportunities for exercise.

(4) Medication Incidental to Treatment not Restraint. Sedatives or anti-anxiety medication prescribed by a qualified practitioner for the sole purpose of relaxing or calming an individual so that he or she may receive medical treatment is not an emergency restraint. Administration of such medication shall be deemed incidental to the treatment, and, except in a medical emergency, requires the consent of the individual or guardian.

5.13: Transportation Restraint

(1) Any limitation of movement (LOM) necessary for the safety of the individual during transportation shall not be deemed an emergency restraint, a support, or a health-related protection for purposes of 115 CMR 5.11 and 5.12. Such transportation restraint is also not subject to the requirements in 115 CMR 5.11 applicable to emergency restraint, regardless of whether an emergency exists at the time the LOM is implemented.

(2) Duration Limited to Activities Included In Transportation. Transportation restraint is permitted during and limited to transportation of the individual. For purposes of 115 CMR 5.11, "transportation" includes all activities incidental to transportation, including, but not limited to:
(a) Relocating or assisting an individual from the point of departure to the transporting vehicle;
(b) Relocating or assisting the individual from the transporting vehicle to the point of destination;
(c) Temporary stops during transportation where the individual remains in or near the transporting vehicle.

(3) Any use of transportation restraint beyond the use of standard passenger safety devices (for example, seat belts) shall be the least restrictive method of ensuring passenger safety during transportation. The specific method of restraint shall be determined on an individualized basis and shall be included in the passenger's Individual Service Plan. Any use of transportation restraint not approved as part of an individual's service plan shall be reported according to the Department's regulations on incident reporting, found in 115 CMR 9.00 *Investigations and Reporting Responsibilities*. Any such use of unapproved transportation restraint shall also be reported in accordance with 115 CMR 9.00 if the reporter has reason to believe that such use constituted abuse or neglect.

5.14: Behavior Modification

(1) Authority, Applicability and Policy.
(a) Authority. 115 CMR 5.14 is promulgated under the authority of M.G.L. c. 19B and M.G.L. c. 123B.
(b) Application. 115 CMR 5.14 applies to all programs which are operated, funded or licensed by the Department.
(c) Policy. It is the purpose of the Department, reflected in 115 CMR 5.14, to assure the dignity, health and safety of its clients. Behavior modification is a widely accepted and utilized treatment which in many cases has enabled clients to grow and reach their maximum potential. Behavior modification emphasizes the use of positive behavioral approaches. It is the Department's expectation that strategies used to modify the behavior of clients will not pose a significant risk of harm to clients and will not be unduly restrictive or intrusive. Indeed, the Department believes that it is both sound law and policy that in individual cases the only procedures which may be used are those which have been determined to be the least restrictive or least intrusive alternatives.

5.14: continued

(2) Definitions.

Behavior Modification means treatment using Interventions designed to increase the frequency of certain behaviors and to decrease the frequency of or eliminate other behaviors which behaviors have, as a result of a behavior analysis by persons experienced in such analysis, been identified as needing to be changed in order to enable the individual to attain the most self-fulfilling, age appropriate and independent style of living possible for the individual.

Intervention or Interventions means one or more of the following Behavior Modification procedures:

Aversive Intervention means procedures involving things or events that, when presented contingent upon some specified target behavior(s), have a decelerating effect upon that behavior.

Deprivation Procedures means procedures which withdraw or delay in delivery goods or services or known reinforcers to which the individual normally has access or which the individual owns or has already earned by performing or not performing specified behavior.

Positive Reinforcement Programs means procedures in which a positive reinforcer (*i.e.*, any consequent action which increases the likelihood of the immediately precedent behavior) is contingent on a specified behavior.

Time Out means socially isolating an individual by removing the individual to a room or an area physically separate from, or by limiting the individual's participation in, ongoing activities and potential sources of reinforcement, as a suppressive consequence of an inappropriate behavior.

(3) Classification of Interventions. Interventions used for Behavior Modification purposes shall be classified by Level pursuant to the provisions of 115 CMR 5.14(3).

(a) Advisory Panel for Classification of Behavior Modification Interventions. The Commissioner shall establish a joint Advisory Panel for the Classification of Behavior Modification Interventions for the purpose of ensuring that all Behavior Modification Interventions are properly classified by level.

1. The Advisory panel shall be composed of no fewer than five individuals, a majority of whom shall possess doctoral level degrees in psychology, with significant training and experience in applied behavior analysis and behavioral treatment. Such individuals shall be appointed for such terms as the Commissioner shall designate.

2. The Advisory Panel shall meet as often as may be necessary to ensure the proper classification of Interventions.

3. The Advisory Panel shall assist the Commissioner or designee in responding to requests for advisory opinions pursuant to 115 CMR 5.14(3)(e) and in ensuring that the provisions of 115 CMR 5.14 are met.

(b) Level I Interventions. The following shall be deemed Level I Interventions for purposes of 115 CMR 5.14, provided that use of such Level I procedures shall conform to the applicable standards specified in 115 CMR 5.14(4)(b):

1. Positive Reinforcement Programs utilizing procedures which have no discernible aversive properties, pose minimal risk of physical or psychological harm, and that do not involve significant physical exercise or physical enforcement to overcome the individual's active resistance, including but not limited to the following:

a. Positive reinforcement: procedures wherein a positive reinforcer is provided following a particular behavior.

b. Differential reinforcement of other behavior: procedures wherein a positive reinforcer is given after a specific behavior has not occurred for a certain period of time.

c. Differential reinforcement of incompatible behavior: procedures wherein a positive reinforcer is provided following a given behavior which is physically incompatible with the occurrence of one or more inappropriate behaviors.

d. Differential reinforcement of alternative behavior: procedures wherein a positive reinforcer is provided after a given behavior which is designed to replace one or more inappropriate behaviors.

5.14: continued

e. Satiation: continued or repeated presentation of a positive reinforcer that poses no risk to health and is made available until it no longer is effective as a positive reinforcer.

f. Token/point gain: procedures wherein a symbol or physical object or other tokens or points are provided after a given behavior and a given number of these tokens or points can be exchanged for a positive reinforcer.

2. Aversive Interventions or Deprivation Procedures that involve no more than a minimal degree of risk, intrusion, restriction on movement, or possibility of physical or psychological harm, and that do not involve significant physical exercise or physical enforcement to overcome the individual's active resistance, including but not limited to the following:

a. Corrective feedback and social disapproval: the use of disapproving facial expressions and verbal statements such as "no", "wrong" or "stop that" following the occurrence of an unacceptable behavior.

b. Relaxation: procedures wherein, following the occurrence of unacceptable behavior with and agitated component, the individual is requested to assume and maintain a relaxed posture in a quiet location, with staff present.

c. Restitution: procedures wherein, following the occurrence of unacceptable behavior that disturbs the environment, the individual is requested to restore the environment to its original condition (or to a cleaner and/or more orderly state) by, for example, picking-up fallen objects, cleaning, apologizing, or otherwise providing restitution.

d. Ignoring: physical and social inattention during the occurrence of an unacceptable behavior.

e. Extinction: failing to supply (or otherwise arranging the absence of) the accustomed consequence(s) after a given inappropriate behavior occurs.

f. Token fines: procedures wherein points or tokens (which were previously earned or otherwise supplied) are removed or lost, contingent upon the occurrence of an inappropriate behavior.

g. Reinforcement Restriction: the withholding or decrease in the availability of positive reinforcements such as tea, coffee, desserts or edible treats that a dietician would find to be nonessential to a nutritious diet or specified leisure activities that are not part of the facility's or program's daily living routine.

h. Positive Practice: procedures wherein an individual is required to undertake repeated performances of an appropriate behavior.

i. Negative Practice: procedures wherein an individual is required to undertake repeated performances of an inappropriate behavior for a given time or repetitions following the occurrence of the inappropriate behavior.

j. Contingent exercise: procedures wherein a designated exercise or physical activity is performed for a given period of time or number of repetitions following the occurrence of an inappropriate behavior.

3. Time Out wherein:

a. the individual is moved away from the location where positive reinforcement is available, but remains in the same area and in view; or

b. the material, activity or event providing positive reinforcement is removed for a given period; or

c. the individual is placed in a room alone for brief periods of time, in no case more than 15 minutes, provided that the door of the room is open and that staff are present at or near the door of the room to monitor the individual's behavior while in the room; or

d. the individual is placed in a room with the door closed, with staff present in the room, for brief periods of time, in no case more than 15 minutes.

(c) Level II Interventions. The following shall be deemed Level II Interventions for purposes of 115 CMR 5.14, provided that no such Level II Interventions may be used except in accordance with the applicable standards and procedures set forth in 115 CMR 5.14(4):

1. All Positive Reinforcement Programs, Aversive Interventions and Deprivation Procedures otherwise classified as Level I where the procedure must be physically enforced to overcome the individual's active resistance.

5.14: continued

2. Time Out wherein an individual is placed in a room alone with the door closed (but not locked) for brief periods of time, in no case more than 15 minutes; provided that staff are present at or near the door of the room to monitor the individual's behavior in the room.

(d) Level III Interventions. The following shall be deemed Level III Interventions for purposes of 115 CMR 5.14, provided that no such Level III Intervention may be used except in accordance with the standards and procedures set forth in 115 CMR 5.14(4), including without limitation the special certification requirement of 115 CMR 5.14(4)(f) and the general requirement of 115 CMR 5.14(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:

1. Any Intervention which involves the contingent application of physical contact aversive stimuli such as spanking, slapping, hitting or contingent skin shock.

2. Time Out wherein an individual is placed in a room alone for a period of time exceeding 15 minutes.

3. Any Intervention not listed in 115 CMR 5.14 as a Level I or Level II Intervention which is highly intrusive and/or highly restrictive of freedom of movement.

4. 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.

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

1. Upon receipt of any such request, the Commissioner or designee shall refer the request to the Advisory Panel.

2. 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.

3. 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.

4. 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 Behavior Modification.

(a) Scope. 115 CMR 5.14(4), establishes requirements for Interventions that are used, or that are proposed for use, for Behavior Modification purposes.

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 5.14(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 5.14.

3. The prescription and administration of psychotropic medication are not subject to 115 CMR 5.14.

5.14: continued

(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 Interventions shall be approved in the absence of a determination, arrived at in accordance with all applicable requirements of 115 CMR 5.14, 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 maladaptive behaviors, except as provided in 115 CMR 5.14(4)(b)4.

4. Level III Aversive Interventions are prohibited except as specifically provided in 115 CMR 5.14(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. In the case of Level II and Level III Interventions, such determination shall be made and the Interventions shall be approved and consented to in accordance with the special requirements of 115 CMR 5.14(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 Aversive Interventions, Deprivation Procedures and Time Out may be used only in conjunction with Positive Reinforcement Programs.

8. Level III Aversive Interventions that are allowed under 115 CMR 5.14(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 Intervention may be administered to any client in the absence of a written Behavior Modification plan.

In the case of Level II and Level III Interventions, the plan shall conform to the special requirements of 115 CMR 5.14(4)(c) and shall be subject to the special consent requirements of 115 CMR 5.14(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 or closed door shall comply with all safety, checking, and monitoring requirements set forth at 115 CMR 5.11(6)(e).

c. An individual may not be maintained in Time Out alone in a room the door of which is closed and locked (*i.e.*, secured by a key, bolt or door stop).

11. All Behavior Modification plans shall be developed in accordance with 115 CMR 5.14 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 5.14.

12. In the event of a serious physical injury to or death of a person who is the subject of a Level II or 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*.

5.14: continued

(c) Written Plan. All proposed uses of Level II and Level III Aversive Interventions for treatment purposes shall be set forth in a written plan which shall contain 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 of the 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 5.14(4)(e) the following reviews and approvals are required prior to the implementation of any Behavior Modification plan involving the use of Level II or 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 5.14(4)(d)1.

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.

5.14: continued

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

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 5.14 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 5.15.

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 5.14, 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 5.14.

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.

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 5.14, 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 5.14.

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.

5.14: continued

7. In *lieu* of having the human rights and/or peer review functions specified in 115 CMR 5.14 performed by committees appointed by the same program that is proposing to use Level II or 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 5.14 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 II or 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/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.

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 5.14(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:

5.14: continued

1. Only those programs or facilities which meet the following standard shall be certified under 115 CMR 5.14(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 5.14.
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 5.14(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 5.14: *Behavior Modification*.
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 5.14(4)(f)5. or 115 CMR 5.14(4)(f)10., inspection staff shall have access to the records of the program's clients (including any written plans required by 115 CMR 5.14(4)(c) 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 5.14.

8. If disapproved, or if certification is revoked in accordance with 115 CMR 5.14(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. 19 and M.G.L. c. 30A.
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 5.14(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 8.33, upon a finding that the conditions for certification are no longer met, as well as for any of the grounds stated at 115 CMR 8.33.

5.14: continued

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 5.14, 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 5.14. 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 5.14 shall be initiated and completed as soon as possible thereafter.

(5) Relationship to ISP Process. Behavior Modification treatment plans are subject to the ISP planning requirements of 115 CMR 6.00: *Eligibility, Individual Support Planning and Appeals* to the following extent only:

(a) Behavior Modification treatment plans employing Level II and III Interventions are subject to the procedural requirements concerning the development and implementation of individual service plans as set forth in 115 CMR 6.23: *Development of Individual Support Plans*, the modification of such plans as set forth in 115 CMR 6.25: *Modification of Individual Support Plans* and the requirements concerning periodic review as set forth at 115 CMR 6.24: *Annual Review of Individual Support Plans*. Furthermore, such plans are subject to ISP appeal as provided for in 115 CMR 6.30 through 6.34.

(b) Behavior Modification treatment plans employing Level I Interventions are subject to the requirements concerning periodic review as set forth at 115 CMR 6.24: *Annual Review of Individual Support Plans* and are subject to ISP appeal as provided for in 115 CMR 6.30 through 6.34.

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 or in 115 CMR 5.11 concerning chemical restraints.

(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) No medication shall be administered by programs subject to 115 CMR 5.00 for the purpose of controlling or modifying behavior, except:

(a) in accordance with the provisions of 115 CMR 5.11 regarding emergency chemical restraint if applicable; or

(b) in accordance with the recommendations of an individual service plan or support service plan containing at least the following information:

1. a description of the behavior to be controlled or modified;

2. appropriate data concerning the target behavior prior to intervention with the proposed drug therapy, phrased in objective terms, which shall constitute a basis from which the individual's clinical course is evaluated;

5.15: continued

3. information relating to common risks and side effects of the medication, the procedures to be taken to minimize such risks, and a description of any clinical indications that might require suspension or termination of the drug therapy; and, in the case of antipsychotic medications, only where there is a court order specifying the treatment, unless the individual is capable in fact of giving informed consent for such treatment and has given consent or unless 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) Prescription medication shall be administered in accordance with the written prescription of a practitioner and the provisions of 105 CMR 700.003 and M.G.L. c. 94C. 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 Training Program and have been certified by the Department for such activities.

(6) 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 and meets the requirements set forth in 115 CMR 5.15(6)(a) through (g). A community program may register with the Department of Public Health when the program has at least one direct contact staff person who is certified by the Department to administer prescription medication:

(a) No prescription medication shall be administered by unlicensed program staff unless they have successfully completed the training requirements established in 105 CMR 700.003(F)(2) and 115 CMR 5.15(5) and have been certified by the Department as having successfully completed such training. The certification will be valid for two years and may be renewed upon the person meeting the standards for retraining and/or retesting established by the Department. For anyone who holds a valid certification from the Department of Mental Health, the Department may certify that person to administer prescription medication without having to undergo the full training program required of all other applicants for certification. Certification may be withdrawn or rejected if the Department finds, after an informal hearing, that the holder of the certification:

1. has been convicted of a crime involving controlled substances; or
2. has furnished or made any misleading or false statement in the application for, or renewal of, certification; or
3. has failed to exercise proper regard for the health, safety and welfare of community program residents; or
4. 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 establishes, maintains, and operates in accordance with policies that ensure that prescription medication is administered only by certified personnel;

(c) The program maintains a current listing of those staff who have successfully completed the Department approved training and who are authorized by the program to administer prescription medications;

(d) The Department of Public Health is permitted by the program to inspect program and individuals' records pertaining to the use and administration of prescription medication and is 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 115 CMR 5.15;

5.15: continued

(e) The Department of Public Health is promptly notified by the program of any suspected shortages or diversion of prescription medications. The program shall also promptly report to the Department and to the Department of Public Health any other suspected misuse of prescription medication in accordance with guidelines established by the Department and the Department of Public Health and 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 determine them to be non-self-medicating but capable of benefitting from training to obtain or enhance self-medication skills, shall receive such training.

(7) Storage. In accordance with 105 CMR 700.004, 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 narcotics, tranquilizers and barbiturates 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 policies established by the program, provided that prescription medications are disposed of through incineration or other acceptable means in the presence of at least two witnesses.

(d) Medications or ointments used externally shall be stored separately from medications taken internally.

(8) Labeling. All medications shall be properly labeled in accordance with M.G.L. c. 94C, § 21 and the following requirements:

(a) Program staff shall not repack or relabel prescription medications which are taken or applied at any location or program regularly or frequently attended by the individual. All such prescription medications shall be packed and labeled by a pharmacist or, in the case of prescription medication dispensed for immediate treatment, by the dispensing practitioner.

(b) Where prescription medication is consumed by an individual at two or more locations on a regular or frequent basis, the prescription medication shall be stored in a separate, properly packaged and labeled medication container at each location. In circumstances where this is not practical or feasible, the Department shall establish an alternative procedure to be used approved by the Department of Public Health.

(c) The program shall have written procedures for obtaining a properly labeled container where there is a change in prescription or where the individual frequently or regularly receives prescription medication in two or more locations.

5.15: continued

(9) 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) All prescription medications shall be administered in accordance with the written prescription of a practitioner;

(b) Prescribed medications shall only be administered to or taken by the individual for whom the prescription has been written;

(c) The program shall have a policy which specifies the administrative procedures to be followed, the staff persons to be notified, the person(s) responsible for decision- making, and the physician, clinic, emergency room or comparable medical back-up to be contacted when there is a medical emergency. Such policy shall include provisions for an up-to-date list of names and telephone numbers of staff persons and medical personnel to be contacted in an emergency. This information must be readily available to staff, and must clearly indicate who is to be contacted on a 24-hour-a-day, seven-days-a-week basis. The medical personnel to be contacted shall include the prescribing practitioner or, if unavailable, another licensed practitioner or appropriate emergency room personnel;

(d) 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. However, specially certified staff may administer parenteral medications generally intended for self-administration and medications by gastric tube. Specially certified staff must have successfully completed a specialized training program in such techniques taught by a physician, physician assistant, nurse practitioner, pharmacist, or registered nurse, approved by the Department or the Department of Public Health. 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.

(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).

(h) Medication may not be prescribed PRN for restraint purposes, but may be prescribed PRN for treatment purposes. For non-self-medicating individuals who are prescribed medication PRN for treatment, the program shall obtain from the prescribing practitioner a statement of specific criteria, in the form of observable symptoms, for determining when the medication is needed.

(10) Documentation. All prescriptions for, and administration of, medication shall be documented in accordance with 105 CMR 700.003(F)(6), 115 CMR 5.19(9) and the following requirements:

5.15: continued

(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 condition 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, common risks and side effects and appropriate staff responses and special instructions including steps to be taken if a dose is missed. The program shall establish appropriate policy and procedures to address how program staff shall obtain relevant prescription information in accordance with the requirements of 115 CMR 5.15(10). In addition, such policy and procedures shall ensure that telephone orders for prescription medication and/or changes in prescription medication are received from licensed practitioners and properly documented in the individual's record;

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 consumer'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 non-prescription 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 narcotics, tranquilizers, and barbiturates stored by the program which shall be reconciled at the end of every shift or at such other frequency otherwise approved by the Department of Public Health.

(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.

(11) Programs shall permit and encourage self-medication by individuals capable of self-medicating, 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.

(12) 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).

5.15: continued

(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; or
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 non-routine 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.

(13) As Used in 115 CMR 5.15:

(a) Non-self-medicating means personally using prescription medication in the manner directed by the practitioner, with assistance or direction or by program or facility staff, in accordance with Department standards.

(b) Self-medicating means personally using prescription medication in the manner directed by the prescribing practitioner, without assistance or direction by program or facility staff, in accordance with Department standards. A verbal reminder that the time for taking a dose of medication has arrived does not constitute assistance or direction by program staff.

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:

(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;

5.16: continued

(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;

(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, 29 and c. 123B, §§ 2, 8, 9, 12, 14.