

**104 CMR 28.00: LICENSING AND OPERATIONAL STANDARDS FOR
COMMUNITY SERVICES**

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28.01: Scope

(1) Scope.

(a) 104 CMR 28.00: *Subpart A* applies to all community mental health services which are operated, licensed or contracted for by the Department and establishes standards for such services.

(b) 104 CMR 28.00: *Subpart B* applies to all residential sites which are subject to licensing pursuant to 104 CMR 28.15 and state operated residential sites and establishes standards for such sites.

(c) 104 CMR 28.00: *Subpart C* specifies the residential sites that are subject to licensure, and the provisions for enforcement of Subparts A and B as to all community mental health services which are operated, licensed or contracted for by the Department.

(d) Services and residential sites that are subject to licensure by the Department of Early Education and Care pursuant to M.G.L c. 15D are not subject to licensure under the provisions 104 CMR 28.00, *Subparts B and C*; provided, however, that provisions of 104 CMR 28.00, *Subpart A* that do not conflict with licensing requirements of the Department of Early Education and Care shall apply to such services and residential sites if operated or contracted for by the Department. Compliance with such provisions shall be enforced in accordance with 104 CMR 28.15(2)(c).

(e) The Department may exempt by contract certain provision of 104 CMR 28.00 that have no practical application to a particular service, such as services purchased for a specific single individual.

(2) Definitions. For purposes of 104 CMR 28.00, the following definitions shall apply:

Director. The senior administrator(s) for a provider who has overall responsibility for a service. Except where otherwise specified, a Director's responsibilities under 104 CMR 28.00 may be delegated by the Director to appropriate designated administrator(s) within the service.

Office of Community Licensing. The Departmental unit charged with issuing of licenses pursuant to, and oversight and enforcement of 104 CMR 28.00.

Person. An individual who receive mental health services subject to 104 CMR 28.00.

Provider. The entity responsible for the provision of a service, including without limitation the operation of a residential site.

Service. A community mental health service that is operated, licensed, or contracted for by the Department.

Service Site. The location where services are provided, including residential sites. The term shall include the provider's administrative offices where applicable.

SUBPART A: STANDARDS FOR COMMUNITY SERVICES

28.02: Standards to Promote Recovery and Resiliency

The Department establishes the following standards to promote recovery and resiliency, and to support and increase the capacity of persons who receive services subject to 104 CMR 28.00 for independent living in the community. Providers shall provide services which promote:

- (1) Human dignity and respect;
- (2) Humane and adequate care, treatment and treatment environments;
- (3) Person-centered planning, self-determination and freedom of choice and personal responsibility;
- (4) The opportunity to receive services which are, to the maximum extent possible, culturally competent, adequate, responsive to a person's needs, and least restrictive of a person's freedom;
- (5) The opportunity to move toward independent living; and
- (6) The opportunity for normal life experiences, even if such experiences may entail an element of risk; provided, however, that a person's safety or well-being or that of others shall not be unreasonably jeopardized.

28.03: Legal and Human Rights

(1) The utmost care shall be taken to protect the legal and human rights of all persons who receive services. These rights shall not be exercised in a manner as to infringe on the rights of other persons and staff. No person shall be subjected to retaliation as a result of the exercise of any right under any provision of the Department's regulations or other provision of law. These rights include, but are not limited to, the following:

- (a) The right to be free from unlawful discrimination on the basis of race, creed, national origin, color, ethnicity, religion, sex, sexual orientation, gender identity, age, physical or mental disability or degree of disability, or such other bases as may be prohibited by law. However, classifications based on age, sex, or category or degree of disability shall not be considered discriminatory if based on written criteria developed by a provider and approved by the Department
- (b) The right to religious freedom and practice without compulsion according to the preference of the person;
- (c) The right to vote, unless a minor or under guardianship which expressly restricts such right. Persons shall receive reasonable assistance when desired in registering and voting, and accessing voter registration information. Such assistance shall be provided in a non-partisan and non-coercive manner;
- (d) The right to communicate, including:
 1. The right to have reasonable access to a telephone and to make and receive confidential calls and to assistance, when desired and necessary to implement this right, provided that such calls do not constitute a criminal act or represent an unreasonable infringement of another person's rights to make and receive telephone calls;
 2. The unrestricted right to send and receive uncensored and unopened mail, to be provided with writing materials and postage in reasonable amounts and to reasonable assistance when desired and necessary in writing, addressing and posting letters and other documents; and
 3. The right to receive or refuse visits and telephone calls from an attorney or legal advocate, physician, psychologist, clergy or social worker at any reasonable time, regardless of whether the person initiated or requested the visit or telephone call;
- (e) The right to be represented by an attorney or advocate of the person's own choice,

including for persons receiving services in a residential site, the right to meet in a private area at the residential site with an attorney or advocate;

(f) The right to be protected from commercial exploitation;

(g) The right to be visited and visit with others, daily and in private, provided that reasonable restrictions may be placed on the time and place of the visit but only to protect the privacy of other persons or to avoid serious disruptions in the normal functioning of the service. Hours during which visitors may be received shall be sufficiently flexible as to accommodate individual needs and desires of persons and their visitors;

(h) The right to a humane psychological and physical environment. Where applicable to the service, persons shall be provided living quarters and accommodations which afford privacy and security in resting, sleeping, dressing, bathing and personal hygiene, reading and writing, and in toileting. 104 CMR 28.03 shall not be interpreted as requiring individual sleeping quarters;

(i) The right to file complaints and to have complaints responded to in accordance with 104 CMR 32.00: *Investigation and Reporting Responsibilities*;

(j) The right to informed consent. Informed consent means knowing consent, voluntarily given by a person who has the capacity to weigh the risks and benefits of the particular treatment being proposed. If a person does not have the capacity to provide informed consent, authorization for treatment may be obtained from a court of competent jurisdiction or the person's legally authorized representative, with the following exceptions:

1. Extraordinary medical care as it is defined by statute or court decision, including but not limited to, treatment with antipsychotic medication and electroconvulsive treatment (ECT), shall only be provided:

a. pursuant to a court order; or

b. in the case of a minor, upon the consent of a legally authorized representative with authority to authorize such medical care; or

c. in the case of a duly activated health care proxy, upon the consent of the health care agent acting within the scope of such proxy.

2. If the person has no legally authorized representative, the Director may consent to routine or preventive medical care, including standard medical examinations, clinical tests, standard immunizations and treatment for minor illnesses and injuries. However, such medical care shall only be authorized upon recommendation of the treating physician that such care is necessary and appropriate, and provided the person agrees to such care, the person is not a minor or under guardianship, and has been found to lack capacity to make informed decisions about his or her medical care at his or her last service planning review.

3. Prior to an adjudication of incapacity, and court approval of a treatment plan, if applicable, a person retains the right to accept or refuse treatment as prescribed.

(k) The protections afforded under the Community Residence Tenancy Law, M.G.L. c.186 §17A, as applicable.

(2) A notice of the human rights as set forth in 104 CMR 28.03(1)(a) through (k) shall be posted in appropriate and conspicuous places to which persons and family members have access in each service site, and available to any person upon request. The notice shall be written in language that is easy to understand and, to the extent practicable, translated into the requesting person's preferred language.

28.04: Protection from Mistreatment

(1) No provider shall mistreat a person or permit the mistreatment of a person by staff subject to its direction. Mistreatment includes any intentional or negligent action or omission which exposes a person to a serious risk of physical or emotional harm. Mistreatment includes but is not limited to:

(a) Corporal punishment or any unreasonable use or degree of force or threat of force;

(b) Infliction of mental or verbal abuse, such as abusive screaming or name calling;

(c) Incitement or encouragement of persons or others to mistreat a person;

(d) Transfer or the threat of transfer of a person for punitive reasons;

(e) The use of restraint as punishment or for the convenience of staff;

(f) Any act in retaliation against a person for reporting any violation of the provisions of the Department regulations or other provisions of law.

(2) The Director or designee shall report to the Department allegations of mistreatment in accordance with 104 CMR 32.00: *Investigation and Reporting Responsibilities*.

(a) Provider staff shall cooperate with investigations of incidents or allegations of mistreatment in accordance with 104 CMR 32.00: *Investigation and Reporting Responsibilities*.

(b) Provider staff shall comply with all applicable reporting requirements as required by law

including reporting allegations of abuse or neglect to the Disabled Persons Protection Commission in compliance with M.G.L. c. 19C, the Executive Office of Elder Affairs in compliance with M.G.L. c. 19A, and the Department of Children and Families in compliance with M.G.L. c. 119.

(3) The identity of persons making reports under 104 CMR 28.04 shall not be disclosed by the Director or designee or by the Department, except as necessary to investigate the subject matter of the report.

28.05: Prohibition of Medication Restraint and Mechanical Restraint or Seclusion; Prevention of Physical Restraint and Requirements for Emergency Physical Restraint When Necessary

(1) Medication restraint, mechanical restraint or seclusion shall not be used. Physical restraint may only be used if the requirements of 104 CMR 28.05(4) are met.

(2) Physical restraint occurs when a manual method is used to restrain a person by restricting the person's freedom of movement or normal access to his or her body. Physical restraint does not include taking reasonable steps to prevent a person at imminent risk of entering a dangerous situation from doing so with a limited response to avert injury, such as blocking a blow, breaking up a fight, or preventing a fall, a jump, or a run into traffic.

(3) Prevention of the Use of Physical Restraint. Each provider shall develop and implement a plan to reduce, and wherever possible eliminate, the use of physical restraint in its service. A provider's plan shall include, at a minimum, the following:

- (a) policies and procedures supporting the prevention of physical restraint;
- (b) staff training focusing on:
 - 1. crisis prevention and de-escalation; and
 - 2. the safe and appropriate use of physical restraint;
- (c) the development of a supportive environment that incorporates the teaching of and use of coping strategies to reduce the need for physical restraints;
- (d) the development and use of individual crisis prevention plans for all clients;
- (e) the development and use of debriefing procedures following an episode of restraint to address, at a minimum, what led to the incident, what might have prevented or curtailed the incident, and how to prevent future incidents. Debriefing activities shall at a minimum include:
 - 1. identification of what led to the episode;
 - 2. determination of whether the individual crisis prevention plan was used;
 - 3. assessment of alternative interventions that may have avoided the use of restraint or seclusion;
 - 4. determination of whether the person's physical and psychological needs were appropriately addressed and that the person's right to privacy was maintained;
 - 5. Whether the restraint resulted in any injuries and the results of such injuries
 - 6. consideration of counseling or medical evaluation and treatment for the involved person and/or staff for any emotional or physical trauma that may have resulted from the incident;
 - 7. consideration of whether other persons and staff who may have witnessed or otherwise been affected by the incident should be involved in debriefing activities or offered counseling;
 - 8. determination of whether the legally authorized representative, if any, family members, or others should be notified of and/or involved in debriefing activities;
 - 9. consideration of whether additional supervision or training should be provided to staff involved in the incident;
- (f) documentation requirements that will ensure an adequate record of the authorization, the less restrictive means attempted, if any, and the reason for their failure and all debriefing activities. These requirements must, at a minimum, meet the documentation requirements set forth in 104 CMR 28.05(4);
- (g) requirement that debriefings documentation be reviewed by appropriate staff for the purpose of identifying and addressing opportunities to prevent or eliminate future occurrences of restraint;
- (h) appropriate administrative review of the use of physical restraint by the Director or designee;
- (i) the process for addressing any person's concern or complaint about the use of physical restraint;
- (j) the use of data to monitor and improve quality and prevent and minimize the use of restraint, such as identifying times or shifts with a high incidence of restraint, and to modify the plan as indicated. Plan reviews should occur in the event there are repeated instances of restraint at the program site, but no less frequently than on an annual basis;

and

(k) the identification and utilization of support measures after a restraint, including debriefing activities which may include peer support, advocacy, Human Rights Officer participation and inclusion of family and friends designated by the person.

(4) Emergency Physical Restraint.

(a) Physical restraint may be used only under the following conditions:

1. In the presence of an emergency where there is a substantial risk of, or the occurrence of, serious self-destructive behavior, or serious physical assault. A substantial risk includes only the serious imminent threat of bodily harm where there is the present ability to enact such harm, including instances where property damage may result in bodily harm.
2. Less restrictive alternatives, including strategies identified in the person's crisis plan, if any, have been tried and failed, or a determination has been made that such alternatives would be inappropriate or ineffective under the circumstances; and
3. Written authorization for the use of physical restraint has been obtained from the Director or an administrator designated to act on his or her behalf.
 - a. Where neither person is available, physical restraint may be used, provided the authorization of the Director or the designee is obtained immediately thereafter, and in no event later than four hours after the initial occurrence.
 - b. The authorization shall be dated and recorded in the person's record.
4. The Director, or designee, may not write an "as needed," or "as required" (PRN) authorization for physical restraint.

(b) If physical restraint is used:

1. It may only include bodily holding of a person with no more force than necessary to limit an individual's movement.
2. It may be used only for the purpose of preventing the continuation or renewal of such emergency condition and only to the minimum extent and duration necessary.
3. It shall be employed to allow the person the greatest possible comfort and to avoid physical injury and mental distress.
4. The person being restrained shall be held or placed in a position that allows airway access and does not compromise respiration. A face-down position shall not be used, unless:
 - a. there is a specified patient preference and no psychological or medical contra-indication to its use; or
 - b. there is an overriding psychological or medical justification for its use, which shall be documented.
5. A staff debriefing shall be conducted in accordance with the provider's plan for prevention of the use of physical restraint. The person who was subject to physical restraint shall separately be asked to debrief. These debriefings shall occur as soon as possible after the restraint.

(c) The use of physical restraint shall be noted in the person's record. This notation shall include:

1. A description of the restraint;
2. The reason for the restraint;
3. The types of less restrictive alternatives, if any, which were utilized and failed;
4. The name of the staff person authorizing the restraint and of all staff involved in the restraint;
5. The time or times the restraint was used;
6. The duration of the restraint; and
7. A summary of the debriefing activities.

(d) If physical restraint is used, the Director or designee shall ensure there is a timely review of the person's individualized action plan and crisis prevention plan as applicable to evaluate the need for appropriate clinical interventions. If the person requires the prolonged use of physical restraint or more than one physical restraint within a 24-hour period, the Director or designee shall initiate the review immediately.

(e) Notifications; Monthly Reports; Human Rights Committee Review.

1. The person's legally authorized representative, if any, shall be notified of the physical restraint as soon as possible but no later than the next business day.
2. The service's Human Rights Officer shall be notified of the physical restraint as soon as possible, but no later than the next business day.
3. At the end of any month in which physical restraint was utilized in a service, the Director shall submit a report to the Human Rights Committee on the nature and frequency of physical restraint in the program during that month.
 - a. A copy of this report shall be kept on file at the applicable service site or at the provider's administrative office;
 - b. The Human Rights Committee shall review the report to determine if there has

been an inappropriate reliance on the use of restraint, either as to the service as a whole or as to any individual person(s) at a service site;

c. The Human Rights Committee may make recommendations concerning necessary technical assistance or modification of the service to the Director and the appropriate Area Director.

(5) The Human Rights Committee shall review all complaints concerning the threat or use of restraint and, where appropriate, refer complaints for investigation in accordance with the requirements of 104 CMR 32.00: *Investigation and Reporting Responsibilities*.

28.06: Medication

(1) The following terms as used in 104 CMR 28.06 shall be interpreted as follows:

Certified Staff. Unlicensed staff members who are certified to administer medications pursuant to the Medication Administration Program. Certified staffs are authorized to administer medications at MAP registered service sites. These individuals have successfully completed the training and examination requirements established in 105 CMR 700.003(F) and 104 CMR 28.06(13) to be certified.

Non-self Administering. Personally taking, consuming or applying medication in the manner directed by the Prescribing Practitioner with more than minimal assistance or direction by provider staff in accordance with the procedures and criteria approved by the Department of Public Health.

Self-administering or Self-administration of Medication. Personally taking, consuming or applying medication in the manner directed by the Prescribing Practitioner, with no more than minimal assistance or direction by provider staff in accordance with the procedures and criteria approved by the Department of Public Health.

MAP Registered Service Site. The service site has been issued a MAP Massachusetts Controlled Substance Registration by the Department of Public Health to administer medications pursuant 105 CMR 700.003: *Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)* at the site.

Medication Administration Program (MAP). A program administered by the Department of Public Health (DPH) in conjunction with the Department, the Department of Developmental Disabilities and the Department of Children and Families pursuant to 105 CMR 700.003(F).

Prescribing Practitioner. A licensed physician, a licensed psychiatric nurse clinical specialist, licensed nurse practitioner, licensed dentist, or licensed physician assistant, acting within the scope of applicable practice.

(2) For prescription medication to be administered by a provider, the medication shall be prescribed by the Prescribing Practitioner.

(3) Each person receiving medication shall be encouraged to see his or her Prescribing Practitioner at clinically appropriate intervals, as determined by the Prescribing Practitioner. The prescription shall be documented in the person's record together with the following information, if provided by the Prescribing Practitioner:

- (a) The current dosage
- (b) a reconciliation of all medications being taken by the person;
- (c) Any signs or complaints of neurologic side effects including tardive dyskinesia, metabolic syndrome, or other side effects;
- (d) The reason for the use of the medication;
- (e) The effectiveness of the medication.

(4) Each person administered medication by a provider shall be encouraged and offered assistance, if needed, to receive a yearly physical examination and to authorize the sharing of the results with the practitioner prescribing psychotropic medication.

(5) A provider administering medication must have information relating to common risks and side effects of the medications used by the persons it served, the procedures to be taken to minimize such risks, and a description of any clinical indications that might require suspension or termination of a medication shall be available to persons and staff at every service site. Such information shall also be available to a persons' legally authorized representative, if applicable.

(6) Medication shall not be arbitrarily withheld, or used as punishment, or administered in quantities that are excessive in relation to the amount necessary to attain the person's best possible functioning.

(7) Medication shall not be used for the convenience of staff or as a substitute for programming.

(8) Administration. Prescription medication shall be administered in accordance with the written prescription of a Prescribing Practitioner and the provisions of M.G.L. c. 94C: *The Controlled Substances Act*, 105 CMR 700.003: *Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C*, § 7(g) and 104 CMR 28.06.

(a) Medications administered to an individual who is non-self-administering must be done by a practitioner, including a registered nurse or a practical nurse, currently licensed in the state of Massachusetts and who is legally authorized to administer a controlled substance in accordance applicable licensing requirement, or if the individual is at a MAP registered site, by Certified Staff in accordance with applicable procedures and criteria approved by the Department of Public Health.

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

(c) The provider shall have a policy which specifies the administrative procedures to be followed in the event of a medical emergency. This shall include: 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. Such policy shall include provisions for ensuring the list of names and telephone numbers of staff persons and medical personnel to be contacted in an emergency is current. 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 may only administer prescription medications which are oral, topical, ophthalmic, otic, intranasal, or products which are administered by inhalation.

(e) Parenteral drugs generally intended for self-administration or drugs administered by gastrostomy and jejunostomy tube may be administered by Certified Staff who have successfully completed a specialized training program in such technique taught by a physician, physician assistant, pharmacist, registered nurse, or nurse practitioner and approved by the Department and the Department of Public Health. Such technique shall be used only with the written authorization and in accordance with the written instructions of the Prescribing Practitioner.

(f) Whenever possible, a prescription for medication shall be limited to a 37 day supply and one refill.

(g) Administration of an over-the-counter drug by Certified Staff to a non-self-administering person requires the prior approval of a Prescribing Clinician and must be done in accordance with the procedures and criteria approved by the Department of Public Health.

(h) Providers shall permit and encourage self-administration of medication by individuals capable of self-administering, provided that:

1. the risks of misuse or abuse to the individual and other persons within the service site are minimal; and
2. the provider provides the individual with adequate training assistance and supervision; and
3. the Prescribing Practitioner's directions are consistent with self-administration for the individual.

(i) All persons who are non-self-administering shall be offered training to obtain or enhance self-administration consistent with the individual's preferences, capacity, and assessed goals.

(j) Medication may not be administered PRN for restraint purposes, but may be administered PRN for treatment purposes. For individuals who are prescribed medication PRN for treatment, the provider shall obtain from the Prescribing Practitioner a statement of specific target signs, symptoms and instructions for determining when medication is needed.

(9) Storage. In accordance with 105 CMR 700.005: *Security Requirements*, drug security and storage requirements of federal and state laws shall be enforced at all storage sites where medications are stored. The following requirements shall also be followed:

(a) Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and security.

(b) Medications for all persons who are not self-administering shall be labeled and stored in a locked container or area, in which nothing except such medications are stored. Medications

required to be refrigerated must be stored in a locked container within the refrigerator. The provider 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.

(c) Prescription Medications for persons who are self-administering shall be stored in such a way as to make them inaccessible to all other persons. Such medications shall be stored in a locked container or area in which nothing except such medications are stored, unless the Director makes a determination that unlocked storage of the medication poses no threat to the health or safety of the person taking the medication or other persons; provided, however, that all controlled substances set forth in the Department of Public Health's Controlled Substances Schedules II-V shall be secured in a locked container or area.

28.06: continued

(d) 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 provider, provided, that prescription medications are disposed of in accordance with the procedures and criteria approved by the Department of Public Health.

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

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

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

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

(c) The provider shall have policies for obtaining a properly labeled container where there is a change in prescription or where the person frequently or regularly receives medication at two or more locations.

(11) Documentation and Communication. All prescriptions for, and administration of, medication shall be documented in accordance with 105 CMR 700.003: *Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)* and the following requirements:

(a) All prescriptions for medication shall be documented in the person's record. The documentation shall specify for each person the name and dosage of medication, the condition for which the medication is prescribed, when and how the medication is to be administered, instructions for self-administration, 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.

(b) The provider shall establish appropriate policies and procedures to address how provider staff may obtain relevant prescription information as set forth in 104 CMR 28.06 (3) and (5). In addition such policies and procedures shall ensure that telephone medication orders and/or medication changes are received from licensed practitioners and properly documented in the person's record.

(c) The provider shall ensure that staff have ready access to the information specified in 104 CMR 28.06(5) by maintaining at each site where medications are administered a copy of a medication-specific drug information sheet which states in plain language generally why the drug is used, when it is to be administered, how it should be administered, any special instructions or precautions, proper storage conditions, possible side effects and what is to be done if a dose is missed.

(d) To ensure proper communication among all providers serving the same person, a provider that is responsible for a non-self administering person's medication shall, with necessary authorization, ensure that the other providers are appropriately informed of any prescription or non-prescription medications which the person is taking on a regular basis, and the information set forth in 104 CMR 28.06(11)(a) for each prescription medication which the person receives.

(e) The provider shall ensure that the appropriate consent or court order for medication is obtained in accordance with 104 CMR 28.03(1)(j) and is documented in the person's record.

(f) The administration of medication for non self-administering persons, including Prescribing Practitioner ordered over-the-counter drugs, shall be documented in the person's record as follows:

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

Persons who are self-administering shall not be required to document their own self-administration of medication.

- (g) Any change in medications or dosage levels of a medication shall be treated as a new medication order for the purposes of documentation.
- (h) The provider shall establish procedures to document the date that a person's prescription is filled and the quantity of medication dispensed by the pharmacy.
- (i) Except for persons who are self-administering, the provider shall maintain a documented accounting of the quantities of controlled substances set forth in the Department of Public Health's Controlled Substances Schedules II-V stored at each service site, which shall be reconciled at the end of each shift, or as otherwise approved by the Department of Public Health.
- (j) Whenever a non-self-administering person is taking an over-the-counter medication administered by a Certified Staff, the approval of the appropriate Prescribing Practitioner, as required under 104 CMR 28.06(8)(g), shall be documented in the person's record.

(12) Compliance. A provider shall:

- (a) ensure that each service it provides establishes, maintains, and operates pursuant to, policies that ensure that prescription medication is administered only by a Massachusetts licensed nurse or properly trained and Certified Staff and is in compliance with the requirements of 104 CMR 28.06;
- (b) maintain a current listing of all licensed nurses and Certified Staff and who are authorized by the service to administer prescription medications;
- (c) permit the Department, and where applicable the Department of Public Health, to inspect provider and persons' records pertaining to the use and administration of medication and to make announced or unannounced on-site visits or inspections of common areas and such other inspections as deemed necessary by the Department to monitor the provider's compliance with 104 CMR 28.06;
- (d) promptly notify the Department and, where applicable, the Department of Public Health, of any suspected shortages or diversion of prescription medications;
- (e) promptly report to the Department and, where applicable, the Department of Public Health, any suspected misuse of prescription medication arising from the administration of medication in a manner inconsistent with the practitioner's prescription or in violation of 104 CMR 28.00 which the provider has reason to believe created a risk of harm to the person;
- (f) for registered sites, 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 medication administration practices or the effects of medications. The provider shall establish policies and procedures which ensure reasonable access to such assistance and advice.

(13) Requirements Applicable to MAP Certification; Training, Duration, Suspension, Revocation and Denial.

- (a) MAP Certification. Certification will be awarded to individuals who complete the training program and pass the examination requirements as established by the Department of Public Health in concert with the Department, the Department of Developmental Services, and the Department of Children and Families (collectively, "the Departments").
 - 1. The training program for certification shall be taught by a registered nurse, nurse practitioner, physician assistant, pharmacist, or physician who meets applicable requirements for a trainer jointly approved by the Department of Public Health, and the Departments. The Department of Public Health and, as appropriate, the Departments shall have the authority to monitor the training program for compliance with established standards.
 - 2. Certification will be valid for two years and may be renewed upon the person meeting the standards for retraining and/or retesting approved established by the Department of Public Health and the Departments.
- (b) Suspension, Revocation and Denial of MAP Certification. Certification may be suspended, revoked or denied if the Department finds that there is reasonable cause to believe the holder of, or the applicant for, the certification:
 - 1. has been charged with or 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. poses a risk to the health, safety and welfare of persons; or

4. is unfit to perform the duties for which the certification was granted.

No suspension, revocation or denial of certification will be made by the Department until it has given the holder or applicant notice of its intent to suspend, revoke or deny certification and the opportunity for an informal hearing before the Department to consider whether reasonable cause exists, and a hearing has been held, if timely requested. The hearing shall not be an adjudicatory proceeding within the meaning of M.G.L. c. 30A. The decision of the Department to suspend, revoke or deny a certification shall be final. Notwithstanding the foregoing, the Department may in its sole discretion immediately suspend an individual's certification pending delivery of notice and results of the hearing, if one has been requested.

(c) Notification. The Department shall notify the training program registry and all other Departments of any suspensions, revocations or denials of certification.

(d) Reinstatement. An individual whose certification has been suspended, revoked or denied may apply for recertification upon a showing that the conditions that led to such suspension, revocation or denial have been remediated. If the Department determines that such conditions have been remediated, the Department may approve such individual's application under terms of retraining and supervision as the Department may impose.

28.07: Labor

(1) No person, other than an employee or contractor of the service, shall be required to perform labor which involves the essential operation and maintenance of a service site or the regular care, treatment or supervision of other persons; provided, however, that:

- (a) Persons who reside at a residential site may be required to perform labor involving normal housekeeping and home maintenance functions;
- (b) Persons may perform labor in accordance with a planned and supervised program of vocational and rehabilitation training as set forth in the person's individual service plans or individualized action plans.

(2) The requirements of federal and state laws relating to wages, hours of work, worker's compensation and other labor standards shall be met to the extent that such laws apply to such required and voluntary labor.

28.08: Possessions

(1) No provider shall interfere with the right of a person to acquire, retain and dispose of personally-owned property unless:

- (a) the person is a minor, under guardianship or conservatorship, or has had a representative payee appointed; or
- (b) in accordance with the provisions of 104 CMR 30.02: *Client Funds in Community Programs* or 30.07: *Disposition of Personal Property Abandoned at Facilities or Programs*; or
- (c) the person possesses contraband or any item prohibited by law; or
- (d) ordered by a court of competent jurisdiction; or
- (e) possession of such property poses an imminent threat of serious physical harm to the person or others.

If the provider takes possession of a person's personally-owned property for the purposes of storage, the provider shall issue a receipt to the person and place the property in safekeeping.

(2) Any restriction on the possession of personally-owned property shall be documented in the person's record, and reviewed and monitored by the Human Rights Officer and Human Rights Committee.

(3) Persons have the right to be free from unreasonable searches of their person or property.

(4) A provider shall ensure that its service establishes, maintains and operates pursuant to written policy, consistent with applicable law and the requirements of 104 CMR 28.08, regarding personal possessions and the implementation of searches and seizures at service sites. Persons shall be informed of the policy prior to their enrollment into the service. The policy shall require, at a minimum, except emergency circumstances, that persons and their legally authorized representative, if applicable:

- (a) be informed of a search prior to the search;

- (b) be provided an opportunity to consent to the search; and
- (c) be present during the search of their property.

All searches, including the reasons for the search, must be documented. If a search of a person's room or property needs to be performed in an emergency to avoid imminent risk of harm, and the person is not present during the search, the nature of the emergency and the reason the person is not present should be documented in the record. The person, the person's legally authorized representative, if applicable, and the program's Human Rights Officer shall be notified of the emergency and search as soon afterwards as practicable and the notification must be documented.

28.09: Records and Record Privacy

(1) A provider shall ensure that each of its services maintains an individual record of services provided to each person served. Such records shall contain accurate, complete, timely, and relevant information, and shall be sufficiently detailed to enable a person to identify the types of services the person receives.

- (a) Records shall be maintained in a consistent format that facilitates information retrieval. Records may be handwritten, printed, typed or in electronic digital format, or any combination of such thereof.
- (b) A provider shall employ reasonable physical, technical and administrative safeguards to ensure the confidentiality, integrity and availability of records, and shall comply with all applicable federal and state laws and regulations.
- (c) A person who is the subject of a record, or the person's legally authorized representative, who believes that the record contains inaccurate or misleading information, may request that it be amended. A service provider shall respond to such request in accordance with applicable state and federal requirements.

(2) Records of a person who is currently receiving or has received services from a provider shall be confidential and not open to inspection except as provided in 104 CMR 28.09.

(3) Inspection by Person, Legally Authorized Representative or Person's Attorney.

- (a) A person and the person's legally authorized representative shall be permitted to inspect the person's records unless the Commissioner or designee, being a licensed health care professional of the provider, determines that:
 1. inspection by the person is reasonably likely to endanger the life or physical safety of the individual person or another person; individual;
 2. the record makes reference to another person (other than a health care provider) and its inspection is reasonably likely to cause substantial harm to such other person; or
 3. inspection by the legally authorized representative is reasonably likely to cause substantial harm to the person or another person.
- (b) If access to any portion of a record is denied based on the criteria in 104 CMR 28.09(3)(a), the person or the person's legally authorized representative shall be informed of, may appeal such denial, and shall be informed of and have, the right to appeal such denial. The determination on appeal must be made by a licensed health care professional, other than the person who made the initial decision to deny access, and such determination shall be final.
- (c) The person's attorney shall be permitted to inspect the person's record upon request. The Commissioner or designee may require that the request be in writing and may further require appropriate verification of the attorney-client relationship.
- (d) Clinical Staff staff may offer to read or interpret the record when necessary for the understanding of the person or his or her legally authorized representative. However, in no circumstance may an individual be denied access to a record solely because he or she declines the offer of staff to read or interpret the record.
- (e) The program director may require the legally authorized representative's consent before permitting a patient under the age of 18 to inspect his or her own records; provided that the records of medical or dental treatment of a patient under 18 years of age who has been determined to be an emancipated or mature minor as provided in 104 CMR 25.03 shall be confidential between the minor and physician or dentist and shall not be released, except in accordance with [M.G.L. c. 112, § 12F. The records of emergency medical or dental treatment of a person under 18 years of age who consented to such care in accordance with M.G.L. c. 112, § 12F shall be confidential between the minor and physician or dentist and shall not be released except upon the written authorization of the person or a proper judicial

order.

(4) Inspection by or Disclosure to Other Persons.

(a) Records of a person shall be open to inspection or disclosure upon proper judicial order, whether or not such order is made in connection with pending judicial proceedings.

1. For the purpose of 104 CMR 28.09(4), "proper judicial order" shall mean an order signed by a justice or special justice of a court of competent jurisdiction, or a clerk or assistant clerk of such court acting upon instruction of such a justice. A subpoena shall not be deemed a "proper judicial order."

2. Whenever practicable, a person and the person's legally authorized representative, if any, shall be informed of a court order for the production of the person's record.

(b) The Records records of a person, or parts thereof, shall be open to inspection by or disclosure to other third parties, upon receipt of written authorization from the person or the person's legally authorized representative, provided that such written authorization shall meets the requirements set forth in 45 CFR 164.508.

(c) The Commissioner or designee may permit inspection or disclosure of the records of a person without written authorization as provided in 104 CMR 28.09(4)(b) where he or she has made a determination that such inspection or disclosure:

1. such inspection or disclosure would be in the best interest of the person; and
2. such inspection or disclosure is permitted by the privacy regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA) at 45 CFR Parts 160 and 164;, including that the records to be released are the minimum necessary to accomplish the purpose of such release; and.
3. it is not possible or practicable to obtain the written authorization of the person, if he or she has capacity, or the person's legally authorized representative.

(d) Without limiting the discretionary authority of the Commissioner or designee to identify other situations where inspection or disclosure is in the person's best interest, the following such inspections or disclosures are deemed to be in the person's best interest: may be made in in the following cases, if the requirements of 104 CMR 28.09(4)(d) are met:

1. to a physician or other health care provider who requires such records in the treatment of a medical or psychiatric emergency; provided, however, that the individual is given notice of such access as soon as possible;
2. to a medical or psychiatric facility currently caring for the person, where the disclosure is necessary for the safe and appropriate treatment and discharge of the person;
3. where the person has provided consent for a particular treatment or service, to those persons involved in such treatment or service;
4. to enable the person or someone acting on his or her behalf, to obtain benefits, protective services, or third party payment for services rendered to such individual;
1. for purposes of treatment, payment, and health care operations as permitted by the privacy regulations promulgated under HIPAA at 45 CFR Parts 160 and 164;
2. to obtain authority for a legally authorized representative to act on the person's behalf, or to obtain a judicial determination of substituted judgment, when a clinical determination has been made that the person lacks capacity to render informed consent to treatment;
3. to persons conducting an investigation involving the person pursuant to 104 CMR 32.00: *Investigation and Reporting Process*;
45. to persons engaged in research if such access is approved by the Department pursuant to 104 CMR 31.00: *Human Subject Research Authorization and Monitoring*;
6. to The Joint Commission or other accrediting bodies;
5. to make reports of communicable and other infectious disease to the Department of Public Health and/or local board of health consistent with 105 CMR 300.000: *Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements. et seq.*; and
76. in the case of death, to coroners, medical examiners, or funeral directors.

(e) Records may be disclosed as required by law. In addition to the laws and regulations of the Department, such laws include, but are not limited to:

1. M.G.L. c. 6, §§ 178C through 178Q (the Sex Offender Registry Law);
2. M.G.L. c. 19A, § 23 (Executive Office of Elder Affairs - abuse of elderly persons, 60 years of age or older);
3. M.G.L. c. 19C, § 10 (Disabled Persons Protection Commission – abuse of disabled persons 18 years of age through 59 years of age);
4. M.G.L. c. 119, § 51A and 51B (Department of Children and Families – abuse or neglect of children younger than 18 years of age);

5. 42 U.S.C. 10806 (Protection and Advocacy for Mentally Ill Individuals);
6. M.G.L. c. 221, § 34E (Mental Health Legal Advisors Committee).

7. Reports of communicable and other infectious disease to the Department of Public Health and/or local board of health consistent with 105 CMR 300.000: *Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements*.

(f) Pursuant to M.G.L. c. 6A, § 16, the Department must offset the costs of the services which it provides directly or through contract by maximizing all Title XIX and other federal, state, and private health insurance reimbursement which might be available for such services.

Accordingly, without limiting 104 CMR 28.09(4)(d)(1), records may be disclosed by the Department and/or its agents for the purpose of:

1. benefits/insurance coverage/availability inquiries;
2. for obtaining third party reimbursement;
3. for appeals of reimbursement denials; and
4. for charging fee payers as set forth in 104 CMR 30.04 *Charges for Services* and 30.06 *Charges for Residential Services and Supports in the Community*.

(g) Any inspection or disclosure under the exceptions enumerated in 104 CMR 28.09(4)(c) through (gf) shall be limited to the minimum information necessary to achieve the permitted inspection or disclosure purpose of the exception.

(5) Notwithstanding the provisions of 104 CMR 28.09(3) and (4), inspection or disclosure of records or information shall not be permitted in the following circumstances:

- (a) if the record or information was obtained from someone other than a health care provider on under a promise of confidentiality, and the requested disclosure would likely reveal the source;
- (b) on a temporary basis only, by or to the person, during the course of research involving treatment, where the subject of the research person agreed to such temporary suspension of access when consenting to participation in the research study;
- (c) if the subject of the record is in the custody of a correctional institution and the correctional institution has requested that access not be provided for health and safety reasons; or
- (d) if the records are restricted under the Federal Clinical Laboratory Improvement Amendments;
- (de) if the records are created in anticipation of litigation.

28.10: Legal Capacity, Guardianship and Conservatorship

(1) No person shall be deemed to be incapacitated to manage his or her affairs, to contract, to hold a professional, occupational or vehicle operator's license, to make a will, to vote or to exercise any other civil or legal right solely by reason of enrollment in a service.

(2) All persons who are 18 years of age or older shall be presumed to have the legal capacity to conduct their personal and financial affairs, unless otherwise determined by a court of competent jurisdiction.

(3) In any assessment of capacity, an individual's need for a guardian, conservator, or for other fiduciary, shall be based on the following considerations:

- (a) Generally, an individual shall be determined to be in need of guardianship, conservatorship, or other fiduciary services only if the individual's capacity to make informed decisions concerning his or her life, property, or both is so limited that the individual lacks the ability to meet essential requirements for physical health, safety or self-care. That an individual may even routinely make what others consider to be poor decisions is not a proper basis for recommending guardianship, conservatorship or other fiduciary.
- (b) Although the capacity of the individual to make important decisions is the central benchmark for determining the individual's need for guardianship, conservatorship or other fiduciary, the capabilities of the individual's family and other persons with whom the individual is associated, particular strengths and weaknesses in the individual's living circumstances, and the availability and utility of non-judicial alternatives to guardianships such as trusts, representative payees, citizen advocacy programs, or community support services should also be considered and may increase or lessen the degree of the individual's need;
- (c) The assessment should identify the specific areas of the individual's functioning which are the basis of the recommendation relative to the need for a guardian, conservator or other

fiduciary, such as inability to respond appropriately to health problems or consent to medical care, or inability to manage savings or routine expenses.

(4) If at any time a person is determined to lack capacity to make informed decisions with regard to his or her health, welfare, or property and if non-judicial less restrictive alternatives such as trusts, representative payees, co-signatory bank accounts and citizen advocates are inadequate, the person's nearest living relatives shall be notified, if appropriate, and the provider shall assist in the appointment of a conservator or guardian or other fiduciary, as appropriate.

(5) If at any time a person is determined to have regained the capacity to make informed decisions with regard to his or her health, welfare, or property, the provider shall assist in the removal of the person's guardian, conservator or other fiduciary, as applicable.

(6) The provider shall implement procedures to ensure that suspected improprieties of a guardian, conservator, trustee, representative payee or other fiduciary are reported to the Department and other appropriate authorities.

28.11: Human Rights Committee; Human Rights Officer

(1) The provider of a service shall establish, appoint and empower at least one Human Rights Committee in accordance with the provisions of 104 CMR 28.11. A provider shall establish more than one Human Rights Committee if the total number of persons served, or the number, geographical separateness, or programmatic diversity of the service is so great as to limit the effectiveness of a single Committee in meeting the requirements of 104 CMR 28.11 as determined by the Department.

(2) Subject to the approval of the Department, a single Human Rights Committee may be established to cover more than one service; provided that the total number of persons served, or the number, geographical separateness, or programmatic diversity of the services is not so great as to limit the effectiveness of the Committee in meeting the requirements of 104 CMR 28.11, as approved by the Department.

(3) The general responsibility of the Committee shall be to monitor the activities of the service with regard to the human rights of persons served by the provider. The specific duties of the Committee shall include:

- (a) Reviewing and making inquiry into complaints and allegations of mistreatment, harm or violation of a person's rights and referral of such complaints for investigation in accordance with the requirements of 104 CMR 32.00: *Investigation and Reporting Responsibilities*.
- (b) Reviewing and monitoring the use of physical restraint and other limitations on movement in accordance with 104 CMR 28.05.
- (c) Reviewing and monitoring the methods utilized by the provider to inform persons and staff of persons' rights, to train persons served by the provider in the exercise of their rights, and to provide persons with opportunities to exercise their rights to the fullest extent of their capabilities and interests.
- (d) Making recommendations to the provider and to the Department to improve the degree to which the human rights of persons served by the provider are understood and enforced.
- (e) Visiting the service sites of the applicable service, including all staffed residential sites as defined in 104 CMR 28.13, at least once per year, with prior notice, or without notice, provided good cause exists.

(4) The Human Rights Committee shall be composed of a minimum of five members, a majority of whom shall be current or former consumers of mental health services, family members of current and former consumers, or advocates; provided, however, that any member who has any direct or indirect financial or administrative interest in the provider or in the Department must comply with any applicable disclosure or other requirements under M.G.L. c.286A and related regulations.

(5) The Human Rights Committee shall meet as often as necessary upon call of the Chairperson, or upon request of any two members, but no less often than quarterly. Minutes of all Committee meetings shall be maintained and provided to the Department upon request. The Committee shall develop, review and update as necessary operating rules and procedures, which include specific reference to: quorum requirements, respecting persons' confidentiality, and removal of members.

- (6) The Human Rights Committee may delegate its duties to one or more subcommittee(s) comprised of members of the Committee; provided, however, that any recommendation for action by such subcommittee(s) must be ratified by the Human Right Committee.
- (7) The service shall have a designate Human Rights Officer.
 - (a) The Director shall designate and empower a person or persons employed by or affiliated with the program to serve as a Human Rights Officer, taking into consideration the number of persons served and, the number, geographical separateness and diversity of the service sites. The number of Human Rights Officers so designated shall be sufficient to ensure that persons have timely access to a Human Rights Officer.
 - (b) If more than one Human Rights Officer is designated, then the Director shall also designate and empower a person or persons employed by the provider to serve as Human Rights Coordinator. The Human Rights Coordinator, who may also be a Human Rights Officer, is responsible to provide or arrange regular training, support, and coordinate the work of the Provider's various Human Rights Officers. This individual shall ensure the availability of Human Rights Officer assistance to persons. Each Human Rights Coordinator must participate in training programs for Human Rights Officers, including training provided by the Department.
 - (c) Each Human Rights Officer must, as a formal component of his or her job description:
 1. Participate in training programs for Human Rights Officers, including training provided by the Department;
 2. Serve as staff to the provider's Human Rights Committee;
 3. Under the general direction of the Human Rights Committee and with the technical assistance of the Department, inform, train and assist persons served in the exercise of their rights in accordance with 104 CMR 28.00 and providing information about the availability of legal advocacy assistance;
 4. Assist persons in obtaining legal information, advice and representation through appropriate means, including referral to independent attorneys or legal advocates;
 5. Provide information to provider staff regarding persons' rights.

28.12: Standards Applicable to All Services

- (1) Written Policies and Procedures. Each provider shall ensure that each service it provides has and implements written policies and procedures which are consistent with the requirements of 104 CMR 28.00 and which address:
 - (a) Provider philosophy and objectives;
 - (b) Enrollment, intake and discharge, including criteria for enrollment into and discharge from the service;
 - (c) Maintenance of person records, consistent with the provisions of 104 CMR 28.09 and all other applicable state and federal laws and regulatory requirements;
 - (d) Development, implementation and review of individualized action plans consistent with 104 CMR 29.00: *Application for DMH Services, Referral, Service Planning and Appeals*, as appropriate;
 - (e) Quality and utilization management;
 - (f) Medication, for those services prescribing or administering medications, consistent with 104 CMR 28.06;
 - (g) Protection of human rights consistent with 104 CMR 28.03;
 - (h) Searches of property consistent with 104 CMR 28.08;
 - (i) Use of physical restraints consistent with 104 CMR 28.05;
 - (j) Billing third party payers and persons for residential services and supports and Department charges, when applicable, cancellation procedures, fee reductions, and abandoned of property consistent with 104 CMR 30.00: *Fiscal Administration* and any agreements with the Department;
 - (k) Personnel, including job descriptions and minimal staff qualifications, staff supervision, and training;
 - (l) Fire safety and other emergencies and disasters, including at least:
 1. Procedures for evacuating persons and staff;
 2. Provision for first aid, through the availability of first-aid supplies, and appropriate staff training;
 3. Provision for notification of fire, police, and hospital facilities for assistance;
 4. Training for persons and staff in emergency procedures and regular fire drill

- procedures;
 - 5. Ensuring the provision of transportation, when necessary;
 - 6. The identification of an alternate site for relocation, when necessary; and
 - 7. Notification and coordination with the Department and other state or federal agencies as applicable;
 - (m) Implementation of appropriate protocols for when a person is missing;
 - (n) Risk management and mitigation;
 - (o) Procedures for compliance with the Community Residence Tenancy Law, G.L. c.186 §17A, as applicable.
- (2) Staffing, Supervision and Consultation.
- (a) Director. The Director shall be responsible for the direction and control of all staff and operation of the service. The Director shall possess sufficient training, education, and professional experience.
 - (b) The service shall have adequate staffing and staff shall have relevant work, personal and educational qualifications to enable the service to satisfy the requirements of 104 CMR 28.00.
 - (c) Staff shall receive an orientation to all relevant provider policies and procedures; including, but not limited to, those required by 104 CMR 28.12(1).
 - (d) All staff and volunteers shall receive on-going training as appropriate to their responsibilities, including training on human rights.
 - (e) Staffing patterns must be appropriate to meet the linguistic and cultural needs of persons within the service.
 - (f) Staff positions and qualifications shall be documented in writing through:
 - 1. An organizational outline detailing the working relationships and responsibilities of staff.
 - 2. Documentation of individual staff training, education and experience.
 - 3. Individual job descriptions.
 - 4. Individual work schedules.
 - (g) The provider shall provide regular supervision and/or consultation for all staff as appropriate to their responsibilities.
 - 1. The provider shall provide adequate supervision of staff and shall maintain records concerning supervised staff.
 - 2. The supervisor shall have adequate training, knowledge and experience to supervise any service performed by the supervised staff member.
- (3) Location and Physical Plant.
- (a) Services shall be located in areas and among other buildings which are appropriate to the services provided, the general design of which does not emphasize the service's separateness or differences from the surrounding community in such a way as to stigmatize or devalue persons.
 - (b) Service sites shall comply with applicable state and federal laws including physical accessibility for individuals with disabilities.
 - (c) Buildings shall meet all applicable fire, health, building, and safety codes.
 - (d) Requirements for fire drills. The provider shall conduct fire drills at each service site at least quarterly and shall maintain written records of such fire drills.
 - (e) As appropriate, a service shall provide adequate space for administration needs, privacy in evaluation, and treatment. For programs that serve distinct groups, *e.g.*, children, separate space shall be provided for use by the distinct groups, consistent with their needs.
- (4) Notification of Legal Proceedings. Every provider shall report in writing to the Commissioner any legal proceeding brought against the provider or any person employed by the provider, if such proceeding arises out of circumstances related to the provision of services or would impact the provider's ability to provide such services. Such report shall be made as soon as practicable after the provider has received notice of the initiation of such legal proceeding.
- (5) Emergency Procedures. For each service, a provider shall:
- (a) Have the capacity to access staff as appropriate to provide or arrange crisis intervention and stabilization support to meet the individual needs of persons.
 - (b) Have a written plan for providing or arranging emergency services during all hours of the service's operation.
 - (c) Be responsible for providing or arranging transportation in an emergency situation.

(d) Maintain an emergency fact sheet(s) for each person which shall be readily available to staff and held in more than one location. The emergency fact sheet shall include, to the extent available:

1. Name (and nicknames, if any);
2. Age;
3. General physical characteristics, including gender identity, weight, height, build, hair and eye color;
4. A recent photograph;
5. General nature of abilities and physical disabilities;
6. Strengths and limitations;
7. Location of person's crisis plan, if any;
8. Special medical problems, including allergies and the names and doses of medications used;
9. Preferred language, and contact information for an interpreter, if available;
10. Pattern of movement, if missing previously;
11. Current addresses of family members, previous residence, place of employment, school, or day programs, and places frequented; and
12. Name, telephone, and address of person's treating physician.
13. The person's legally authorized representative contact information, if applicable.

SUBPART B: STANDARDS FOR RESIDENTIAL SERVICE SITES

28.13: Physical Standards

(1) General Provisions. A residential service site in a service must meet the following requirements:

- (a) The site shall be located on state property or in a residential neighborhood or other setting appropriate to the services provided, the general design of which does not emphasize the site's separateness or differences from the surrounding community in such a way as to stigmatize or devalue persons.
- (b) The site shall meet all applicable building and sanitary, and safety requirements, including without limitation standards for persons who are classified as impaired or partially impaired in accordance with 104 CMR 28.14, as appropriate.
- (c) The site shall provide space for all the residential functions characteristic of a comfortable and homelike environment, including cooking, dining, recreation, socializing, sleeping, bathing and storing belongings.
- (d) The site, including its heating, plumbing, lighting and ventilation systems, furnishings and equipment shall be maintained in good repair to ensure safety and physical comfort.
- (e) Major environmental controls, including those for lighting, plumbing, windows and shades, shall be operable by and accessible to persons.
- (f) The site shall store medication in accordance with 104 CMR 28.06(9).
- (g) Persons shall be provided with bedroom space adequate for sleeping, dressing, personal care, and caring for personal possessions.
 - 1. No more than two persons may occupy one bedroom.
 - 2. Smoking shall be prohibited in resident sleeping rooms.
 - 3. Each bedroom must meet minimum space requirements. Closet space shall not be included when calculating square footage:
 - a. A bedroom to be occupied by one person must be at least 100 square feet
 - b. A bedroom to be occupied by two persons must be at least 120 square feet.
 - 4. Every bedroom shall have sufficient space to accommodate comfortably a bed, dresser, and closet space for each person.
 - 5. Bedroom may not have security chains, night latches, double cylinder dead bolts, flush bolts or surface bolts; and an allowable lock on a bedroom door must be able to be opened by means of a master key.
- (h) Each site shall provide bathroom facilities adequate for all persons and staff to carry out normal bathroom functions, including bathing and personal care, with staff assistance as needed.
- (i) Each site shall have one means of egress and one escape route serving each floor and leading to grade. Any proven useable path to the open air outside at grade shall be deemed acceptable as an escape route, including, but not limited to, connecting doors, porches, windows within six feet of grade, ramps, fire escapes, and balcony evacuation systems. There shall not be locks which prevent unimpeded exit on any doors which lead to a means or egress or escape route.
- (j) Each site shall have smoke detectors and carbon monoxide detectors and fire extinguishers in accordance with the following:
 - 1. A minimum of one smoke detector shall be provided for each 1200 square feet of area, or part thereof; provided however, one smoke detector shall be located outside each bedroom;
 - 2. Carbon monoxide detectors shall be provided in accordance with the requirements of 527 CMR 1.05: *Modifications to NFPA 1 – 2012 Edition*.
 - 3. A minimum of one portable fire extinguisher tagged and inspected shall be provided for each level of the site where persons served have access, including the attic and the basement, if any.
 - 4. Providers are responsible for ensuring that smoke and carbon monoxide detectors and fire extinguishers are in good working condition at all times.
- (k) All doors leading to areas where persons are not allowed under applicable building codes shall be maintained locked by provider staff.

(2) Capacity. The capacity of a residential site shall be subject to approval by the Department, which may consider such factors as size, location, and other characteristics of the residence, the ages and needs of the persons, the experience and capability of the service, and the requirements of the State Building Code 780 CMR: *State Board of Building Regulations and Standards*.

28.14: Self Preservation Standards(1) Classification of Persons.

(a) Self-preservation means the capability both mentally and physically to take action to preserve one's own life, specifically to egress the building in which one resides unassisted with 2½ minutes.

(b) The Department and Providers shall classify persons residing at each residential site as follows:

1. Impaired. An impaired person is a person who is not capable of self-preservation, who requires physical assistance to exit the building within 2½ minutes.

2. Partially Impaired. A partially impaired person is a person who is not capable of self-preservation, who is capable of exiting the building within 2½ minutes without physical assistance, but with supervision and/or instruction.

3. Unimpaired. An unimpaired person is a person who is capable of self-preservation, who is capable of exiting the building within 2½ minutes without physical assistance and/or supervision or instruction.

(c) Procedures and documentation requirements for person classification.

1. The provider shall conduct a test of the person's ability to exit the building from the person's sleeping quarters, and common areas if more remote, prior to placement into the service; except that a provider may classify a person as impaired without such a test.

2. Test documentation shall include the time required to exit the building, the type of assistance required, if any, either physical or verbal, date of testing, and name of the person(s) conducting the test.

3. Test results shall be documented in the person's record.

4. The provider shall keep a central record of the classification of each person in the residential site.

5. Except for a residence or apartment for up to four persons in which all of the residents are capable of self-preservation, testing for person classification shall be conducted at least quarterly, and may be part of the quarterly fire drill. Where quarterly fire drills are not required self-preservation testing shall be conducted at least annually.

6. No person shall have his or her status changed to a less restrictive classification without substantiating documentation for at least two consecutive tests, which shall be conducted at least one week apart.

(2) Self-Preservation Training. The provider shall provide or arrange for annual training in self-preservation, including knowledge of fire safety. The provider shall maintain documentation of such training.

(3) Staffing Requirements. If a person is classified under 104 CMR 28.14(1) as impaired or partially impaired, the provider must develop and maintain a staffing pattern to ensure the safety of the person and egress of all persons within 2½ minutes.

(4) Evacuation Training. All staff shall be trained in evacuation procedures for impaired and partially impaired persons.

(5) Fire Drills. The following are requirements for fire drills at residential sites.

(a). The provider shall conduct fire drills at each residential site at least quarterly, and at least two of which shall be after 6:00 P.M. and shall maintain written records of such fire drills. If there is an over-night staff, one of the two drills after 6:00 PM must be done during the overnight shift.

(b) The provider shall maintain sufficient staff to ensure safe egress of all persons within 2½ minutes.

(c) The requirements of 104 CMR 28.14(5) shall not apply to a residential site for up to four persons in which all of the residents are capable of self-preservation as provided in 104 CMR 28.14(1)(a).

SUBPART C: LICENSING REQUIREMENTS AND COMPLIANCE WITH STANDARDS

28.15: General Provisions

104 CMR 28.15 through 28.17 describes the residential sites that are subject to licensure, and the provisions for enforcement of Subparts A and B as to all community mental health services which are operated, licensed or contracted for by the Department.

(1) Licensing Requirements. In accordance with M.G.L. c. 19, § 19, the Department shall issue and renew a license to operate residential sites to providers under contract with the Department and providers of private residential programs if the residential sites meet the requirements set forth in 104 CMR 28.15. For purposes of 104 CMR 28.15, a private residential program is a program not operated by or under contract to the Department that is organized primarily to provide treatment, of mental illness to persons in a residential environment that operates one or more residential sites. Treatment includes, but is not be limited to, rehabilitation, support or supervision

(a) A license is required for providers under contract with the Department for each residential site where one or more persons reside, or are provided with sleeping accommodations, and the provider has a direct or indirect ownership interest, or leases or co-leases. If the provider is a guarantor of a person's residential lease, the provider is not required to obtain a residential site license for the leased property; provided, however, the Director of the service shall provide the Area Director or designee with a letter attesting that the leased property meets applicable health, safety and fire codes. For good cause the Department may require a site inspection to assess the general condition of the leased property. A license is not required for residential sites located outside of the state or licensed by another state agency.

(b) A license is required for a provider of a private residential program for each residential site where one or more persons reside and the provider has a direct or indirect ownership interest, or leases or co-leases with a party other than the person residing at the residential site.

(c) To obtain or retain a license for a residential site a licensing applicant shall satisfy the Department that the residential site meets all applicable requirements of 104 CMR 28.00: *Subpart B* and that the service or program of which the site is a part of meets all applicable requirements of 104 CMR 28.00: *Subpart A*.

(d) Operation of an Unlicensed Residential Site. When the Department has reason to believe that a provider is operating without a required residential site license; and the provider has failed to apply for a license within ten days after notice by the Department, the Department may:

1. Notify the District Attorney with jurisdiction over the provider that the provider appears to be operating in violation of M.G.L. c. 19, § 19;
2. Petition the Superior Court with jurisdiction over the provider to restrain its operation or to take such other actions as may be necessary in the interest of the persons utilizing the service;
3. Undertake to provide alternative placements with the most adequate and appropriate alternative service arrangement available for persons as needed; or
4. Take such other action as it deems appropriate to ensure person health, safety or welfare.

(2) Compliance With 104 CMR 28.00: *Subparts A and B*.

(a) Services and Private Programs Operating Residential Sites Subject to Licensure. Compliance with the provisions of 104 CMR 28.02 through 28.12 (Subpart A) and 104 CMR 28.13 through 28.14 (Subpart B) by all services and private programs operating residential sites subject to licensure shall be enforced by the Office of Community Licensing, pursuant to 104 CMR 28.17. Nothing in 104 CMR 28.15 through 28.17 shall preclude the Department from also taking enforcement action under a contract when appropriate or assigning enforcement of 104 CMR 28.02 through 28.12 (Subpart A) to the Area Director having primary responsibility for the contract.

(b) Department Operated Services with Residential Sites. Compliance with the provisions of 104 CMR 28.02 through 28.12 (Subpart A) and 104 CMR 28.13 through 28.14 (Subpart B) by services operated by the Department that include residential sites shall be subject to audit by the Office of Community Licensing and enforcement by the applicable Area Director or designee.

(c) Services Not Having Residential Sites Subject to Licensure. Compliance with the

provisions of 104 CMR 28.02 through 28.12 (Subpart A) by services operated or contracted for by the Department that do not have a residential site subject to licensing or otherwise subject to 104 CMR 28.15(2)(b), shall be subject to audit and enforcement by the applicable Area Director or designee.

(d) For the purpose of carrying out audit and enforcement responsibilities under 104 CMR 28.15(2), Area Directors or designees shall have the same right to inspect service sites as the Department has the right to inspect residential sites under 104 CMR 28.17.

(3) Waiver of a Standard for Community Services or for Residential Service Sites.

(a) The requirements of 104 CMR 28.00 shall be strictly enforced and shall only be waived by the Department upon approval of a written request of a provider in accordance with the provisions of 104 CMR 28.15(3).

(b) A provider's written request for a waiver of one more of the provisions of 104 CMR 28.00 must:

1. Demonstrate that the health, safety or welfare of either persons or staff of the service shall not be adversely affected by granting the waiver; and
2. Provide a substitute provision or alternative standard that will result in comparable services to the persons and to which the provider agrees to be held accountable to the same degree and manner as any applicable provision of 104 CMR 28.00 or demonstrate why the waiver is in the best interest of the persons served.

(c) The Department may grant a provider's request for waiver upon a determination that the petition meets the requirements of 104 CMR 28.15(3).

(d) Waivers shall be granted for a specified period of time which if applicable to a licensed residential site shall not to exceed the duration of the license. A waiver may be renewed upon subsequent petition.

(e) The granting of a waiver shall not guarantee the granting of a waiver for a subsequent period or service.

(f) The Department may determine that one or more of the provisions of 104 CMR 28.00 is not applicable to a particular service, and may grant a waiver of such provision(s) to all such services.

28.16: Process for Obtaining or Renewing a License

(1) Application Process for License or Renewal.

(a) Any applicant seeking to obtain a license for a residential site as specified in 104 CMR 28.00: *Subpart C* shall file an application in writing with the Department in a manner and on a form prescribed by the Department. The applicant must be the agency or person with principal legal responsibility for the administration and operation of a residential site.

(b) If any agency or individual operates more than one residential site, such agency or individual must apply for a separate license for each such residential site.

(c) Any agency or person seeking to renew a license shall file an application for such renewal in writing with the Department, in a manner and on a form prescribed by the Department, not less than 90 days prior to the date of expiration of its current license. It shall be the responsibility of the Department to act upon an application for renewal within the 90-day period. Failure to do so shall not invalidate a previously existing license.

(d) A licensing applicant shall maintain the following documentation which shall be made available to the Department upon request:

1. For business corporations that are for profit, a copy of an Administration and Finance Form 4-A, together with any special or periodic reports submitted in amendment or supplementation to the annual report, as well as a copy of the Articles of Incorporation and by-laws.
2. For non-profit corporations, a copy of the last annual report filed with the Secretary of State pursuant to M.G.L. c. 180, § 26A, together with any special or periodic reports submitted in amendment or supplementation to the annual report, and a certified copy of the last annual report filed with the Office of the Attorney General pursuant to M.G.L. c. 12, § 8F; as well as, a copy of the Articles of Incorporation and by-laws.
3. A list of the names of all persons with any financial interest in the provider including, but not limited to, persons with ownership interests in the building or buildings used by the provider, paid or unpaid directors, shareholders, partners, loan creditor mortgagees, salaried employees and consultants. The financial interest statement shall be updated as necessary to accommodate changes.

(2) Departmental Action on Application for License or Renewal. Upon receipt and review by

the Department of all required documentation, and after any inspection made pursuant to 104 CMR 28.17, the Department shall take one of the following actions:

- (a) Issue a license if no deficiencies are outstanding.
- (b) Issue a license subject to implementation by the applicant of a plan of correction approved by the Department. Failure to implement a corrective action plan in accordance with its terms may result in suspension, revocation of the license as provided in 104 CMR 28.17.
- (c) Issue a provisional license for residential sites not currently in operation or for which the Department cannot fully determine compliance with the requirements of 104 CMR 28.00 without an evaluation of the residential site in operation. No later than 90 days after a service begins operation of a residential site under a provisional license, the Department shall conduct an inspection to determine whether to issue a license in accordance with 104 CMR 28.16.
- (d) Suspend, revoke or deny a license until such time as deficiencies are corrected.

(3) Duration of License. Licenses issued under 104 CMR 28.16 shall be valid for a term of two years and may be renewed for like terms, subject to revocation or suspension pursuant to 104 CMR 28.17.

(4) Change of Name, Ownership, Location or Services.

- (a) Except as approved by the Department, licenses shall not be transferable from one licensee to another individual or agency, or from one location to another.
- (b) The provider shall provide prior notification in writing to the Department of any change in name or ownership of the provider agency or program or of a licensed residential site.
- (c) The provider shall notify the Department in writing of any change in service affiliated with a licensed residential site within ten days of such change.
- (d) The provider shall notify the Department in writing if at any time it ceases to use the residential site or of any changes in the physical plant of the residential site, or of any other changes in the service or program of which the residential site is a part which is contrary to any requirement of licensure within ten days of such change or cease of use.
- (e) The failure of a provider to notify the Department of any change required by 104 CMR 28.16(4) shall be grounds for suspension or revocation of the license.

28.17: Licensing, Compliance and Enforcement

(1) Departmental Inspection.

- (a) Any employee or agent of the Department, including a consultant providing services for the Department, authorized by the Area Director or the Office of Community Licensing, may visit and inspect residential sites subject to 104 CMR 28.00, and any service site of the service or program of which the residential site is a part, to determine whether such sites are in compliance with law, including the regulations of the Department.
- (b) The Department shall inspect each licensed residential site at least annually and more frequently if deemed necessary.
- (c) Inspections should ordinarily be made with prior notice and at reasonable times, giving due regard to the privacy of the persons and the interruption that inspection may cause. However, the Department shall have the right to inspect any site at any time without prior notice providing good cause exists.
- (d) Refusal to permit an inspection in accordance with 104 CMR 28.17 shall be grounds for suspension or revocation of a license.
- (e) The personal belongings and clothing of persons shall not be subject to inspection by the Department; provided, however that storage spaces, including, but not limited to closets and storage areas may be inspected for purposes of determining compliance with applicable health and safety standards and the structural integrity of the site.
- (f) The scope of the Department's inspections shall include any aspect of the operation of the residential site or provider, and may include, but is not limited to confidential interviews with persons and staff, and examination and review of all records.
- (g) The Department shall provide a copy of the inspection report to the provider; provided, however, that confidential information concerning persons shall not be disclosed except in accordance with the confidentiality requirements of 104 CMR 28.09.
- (h) The contents of a Department inspection report are subject to the Massachusetts Public Records law, including all exemptions to disclosure.

(2) Deficiency Identification and Correction.

- (a) Whenever the Department finds that a service is not in compliance with any applicable law or regulation, other than in accordance with a waiver approved by the Department, the Department shall, if it deems the deficiency remediable, issue a corrective action order.
- (b) A correction order shall be in writing and shall include a statement of the deficiencies found, the period within which the deficiency must be corrected, and the provision of law and regulation relied upon.
- (c) Within seven days of receipt of the correction order, the provider may submit a written request to the Director of Community Licensing for administrative reconsideration of the findings or any portion thereof, which shall be granted forthwith.
- (d) If the provider fails to correct any deficiency within the period prescribed for correction, the Department may enforce its correction order under 104 CMR 28.17 or in accordance with M.G.L. c. 19.
- (e) Nothing in this section shall preclude the Department from also taking enforcement action under a contract when appropriate.

(3) Suspension, Revocation and Denial of Licenses.

- (a) The Department may revoke, suspend or deny issuance or renewal of a license if it finds any of the following:
 - 1. The provider failed to comply with any applicable regulation or any applicable deficiency correction order;
 - 2. The provider refused to admit at any time any person authorized by the Commissioner to inspect the service in accordance with 104 CMR 28.13;
 - 3. The provider refused to submit any report or to make available any records required under 104 CMR 28.00 or other Department regulations;
 - 4. The provider made misleading or false statements or failed to furnish information or reports required under 104 CMR 28.00 or other Department regulations.
 - 5. Staff or persons subject to the direction of a provider subjected a person to mistreatment as defined in 104 CMR 28.04(1).
- (b) When the Department determines to suspend, revoke, or deny a license, it shall provide written notice to the applicant or licensee, notifying it of the intended action, of the grounds therefore, and of the applicant or licensee's right to request of the Commissioner a hearing regarding the matter conducted pursuant to M.G.L. c. 30A.

(4) Suspension in Emergencies.

- (a) The Department may refuse to issue or renew or may suspend any license without providing the opportunity for a prior hearing if the failure of the provider to comply with any applicable regulations appears to have resulted in an emergency situation which endangers the life, health or safety of persons or staff.
- (b) Immediately upon such refusal or suspension, the provider shall notify the affected persons and their families, when appropriate, and persons' legally authorized representatives, and shall immediately provide or arrange for the most adequate and appropriate alternative service arrangements available for such persons, or take such other action as may be directed by the Department, including but not limited to placing Department employees within the service, as the Department deems necessary to protect the persons.
- (c) The Department shall hold a conference with the provider and, if it has not done so before, provide a written statement as to its reasons for its action within three days of suspension or refusal to issue or renew a license.
- (d) Upon written request of an aggrieved party to the Commissioner, a hearing shall be held within a reasonable amount of time after the license is refused or suspended, in accordance with the requirements of M.G.L. c. 30A.

(5) Reports and Notices. Reports and Notices. Private residential programs that have a residential site license(s) shall submit all reports or notices required under 104 CMR 28.00 to the Department's Office of Community Licensing.

REGULATORY AUTHORITY

104 CMR 28.00: M.G.L. c. 19, §§ 1, 16, 12, 18 and 19

(PAGES 381 AND 382 ARE RESERVED FOR FUTURE USE.)