Prescription Monitoring Program State Profiles – Rhode Island

Research current through December 2014.

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RHODE ISLAND

http://www.health.ri.gov?hsr/professions/cr_reporting.php
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- Status of Program – operational
- Housing Entity – Department of Health
- Advisory Commission – no
- Funding – not specified in PMP statutes or regulations
- Drugs Monitored – Schedules II – IV
- Who's Required to Report Dispensing Information – all retail and institutional pharmacies dispensing 25 or more prescriptions per month
- Exemptions from Reporting – hospital inpatient or patient in correctional institution
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – no
- Data Collection Interval – 72 hours
- Notice to Consumers – yes
- Interstate Sharing – with other PMPs
- Persons Authorized to Receive Information – law enforcement officials; licensing/regulatory boards; patient or parent of minor child; prescribers; dispensers
- Delegates Allowed – yes
- De-identified Data Provided – yes
- Unsolicited Reports – to prescribers, pharmacists, law enforcement, and licensing boards
- Training Required – no
- Mandatory Enrollment – yes; all practitioners
- Mandatory Access – yes; opioid treatment programs are required to check the PMP for each new admission and prior to advancement to a new take-home phase

West's General Laws of Rhode Island Annotated (2014)
Title 21. Food and Drugs
Chapter 28. Uniform Controlled Substances Act
Article III. Regulation of Manufacturing, Distributing, Prescribing, Administering, and Dispensing Controlled Substances

§ 21-28-3.32. Electronic prescription database

(a) The information contained in any prescription drug monitoring database maintained by the department of health pursuant to section 3.18 of this chapter shall be disclosed only:

(1) To a practitioner who certifies that the requested information is for the purpose of evaluating the need for or providing medical treatment for a current patient to whom the practitioner is prescribing or considering prescribing a controlled substance;

(2) To a pharmacist who certifies that the requested information is for a current client to whom the pharmacist is dispensing or considering dispensing a controlled substance;

(3) To an authorized designee of the practitioner and/or pharmacist to consult the prescription drug monitoring database on the practitioner's and/or pharmacist's behalf, provided that:

(i) The designee so authorized is employed by the same professional practice or pharmacy;

(ii) The practitioner or pharmacist takes reasonable steps to ensure that such designee is sufficiently competent in the use of the database;

(iii) The practitioner or pharmacist remains responsible for ensuring that access to the database by the designee is limited to authorized purposes as provided for in subsections (a)(1) and (a)(2) of this section;

(iv) The practitioner or pharmacist remains responsible for ensuring access to the database by the designee occurs in a manner that protects the confidentiality of information obtained from the database, and remains responsible for any breach of confidentiality;

(v) The practitioner or pharmacist terminates the designee's access to the database at the termination of the designee's employment; and

(vi) The ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the practitioner or pharmacist and is reasonably informed by the relevant controlled substance history information obtained from the database.

(4) Pursuant to a valid search warrant based on probable cause to believe a violation of federal or state criminal law has occurred and that specified information contained in the database would assist in the investigation of the crime;

(5) To a patient who requests his or her own prescription information, or the parent or legal guardian of a minor child who requests the minor child's prescription information;

(6) To a health professional regulatory board that documents, in writing, that the requested information is necessary for an investigation related to licensure, renewal or disciplinary action involving the applicant, licensee or registrant to whom the requested information pertains;

(7) To any vendor or contractor with whom the department has contracted to establish or maintain the electronic system of the prescription drug monitoring database; or

(8) To public or private entities for statistical, research, or educational purposes, after removing the patient and prescriber information that could be used to identify individual patients. This shall not include entities receiving a waiver from the institutional review board.

(b) Information stored in the prescription drug monitoring database shall include only the following:

(1) Patient's first and last name, and/or patient identification number; provided, however, the patient's social security number shall not be recorded in whole or in part, patient sex, patient date of birth, and patient address;

(2) Prescribing practitioner's name and drug enforcement administration prescriber information number;

(3) Prescribing practitioner's office or hospital contact information;

(4) Prescription name, prescription number, prescription species code, national drug code number, prescription dosage, prescription quantity, days' supply, new-refill code, number of refills authorized, date the prescription was written, date the prescription was filled, payment type; provided, however, no credit card number shall be recorded in whole or in part; and

(5) The drug enforcement administration pharmacy number of the pharmacy filling the prescription.

(c) The department shall disclose any information relating to a patient maintained in the prescription drug monitoring database to that patient, at no cost to the patient, within thirty (30) business days after the department receives a written request from the patient for the information. This information shall include the records maintained by the department pursuant to subsection (e). Notwithstanding the above, the department may, at the request of the law enforcement agency, withhold for up to sixty (60) days following the conclusion of a law enforcement investigation, the disclosure to the patient that information has been obtained pursuant to subdivision (a)(3).

(d) A patient may request from the dispensing pharmacy correction of any inaccurate information contained within the prescription drug monitoring database in accordance with the procedure specified by subsection 5-37.3-5(c).

(e) The department shall, for the period of time that prescription information is maintained, maintain records of the information disclosed through the prescription drug monitoring database, including, but not limited to:

(1) The identity of each person who requests or receives information from the prescription drug monitoring database and the organization, if any, the person represents;

(2) The information released to each person or organization and the basis for its release under subsection (a); and

(3) The dates the information was requested and provided.

(f) Prescription information contained within the prescription drug monitoring database shall be removed no later than five (5) years from the date the information is entered into the database. Records in existence prior to the enactment of this section shall be removed no later than ten (10) years from the date the information is entered into the database.

(g) The department shall promptly notify any affected individual of an improper disclosure of information from the prescription drug monitoring database or a breach in the security of the prescription drug monitoring database that poses a significant risk of disclosure of patient information to an unauthorized individual.

(h) At the time of signing a prescription which is required by the department to be entered into the prescription drug monitoring database, the prescribing practitioner shall inform the patient in writing of the existence of the prescription drug monitoring database, the patient's right to access their own prescription information, and the name and contact information of the agency operating the program.

(i) No person shall access information in the prescription monitoring database except to the extent and for the purposes authorized by subsection (a).

(j) In any civil action allowing a violation of this chapter, the court may award damages, including punitive damages, and reasonable attorneys' fees and costs to a prevailing plaintiff, and injunctive and any other appropriate relief.

(k) Any pharmacist who, in his or her professional judgment, refuses to fill a prescription based on information contained within the prescription drug monitoring database shall inform the prescribing physician within twenty-four (24) hours.

(l) All practitioners shall, as a condition of the initial registration or renewal of the practitioner's authority to prescribe controlled substances, register with the prescription drug monitoring database maintained by the department of health.

West's Rhode Island Administrative Code (2014)
Title 31. Health Department
Division 2. Drug Control
Rule 1. Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III

31-2-1:2.0. General Requirements

2.1 There shall be established within the Department a system for the monitoring of the prescribing and dispensing of schedules II and III controlled substances, by all professionals licensed to prescribe or dispense such substances for any resident of this state.

2.2 The prescription system that is established shall be an electronic monitoring system, that shall be maintained under the direction of the Department.

2.2.1 Said system shall collect and maintain prescription and dispensing information for schedules II and III controlled substances.

2.3 All retail and institutional pharmacies dispensing twenty-five (25) or more prescriptions per month for schedules II and III controlled substances in this state shall electronically transmit to the Department, by the fifth (5th) day of each month following the date of dispensing, the record of each prescription dispensed.

2.3.1 This requirement shall not apply to an inpatient of a hospital or correctional institution.

2.4 Any pharmacy dispensing fewer than twenty-five (25) prescriptions per month for schedules II and III controlled substances may submit the data on a form provided by the Department and mailed by the fifth (5th) day of the month following dispensing to:

Rhode Island Department of Health, Pharmacy Unit

3 Capitol Hill, Room 205

Providence, RI 02908-5097

West's Rhode Island Administrative Code (2014)
Title 31. Health Department
Division 2. Drug Control
Rule 1. Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II, III and IV [R21-28-Edt]

31-2-1:3.0. Reporting and Management of Information

3.1 (a) A pharmacy that dispenses a schedule II, III or IV controlled substance to a person, who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit electronically to the Department the information set forth in the edition of the Electronic Reporting Standard for Prescription Monitoring Programs, established by the American Society for Automation in Pharmacy, that is currently approved by the Department.

(b) The information transmitted electronically by the pharmacy shall include the following:

(1) Pharmacy Drug Enforcement Administration identification number;

(2) Patient last name;

(3) Patient first name;

(4) Patient street address;

(5) City;

(6) State;

(7) Date of birth;

(8) Gender code;

(9) Prescription species code;

(10) Prescription number;

(11) Date prescription written;

(12) Number of refills authorized;

(13) Date prescription filled;

(14) Refill number;

(15) National Drug Code number;

(16) Quantity dispensed;

(17) Days supply;

(18) Payment code for either cash or third-party provider; and

(19) Prescriber Drug Enforcement Administration identification number.

3.2 (a) A pharmacy shall transmit the required prescription information by means of a secure web-based data system, or other approved electronic methods, designated by the Department.

(b) A pharmacy shall transmit the information required pursuant to these Regulations within seventy-two (72) hours following the date of dispensing.

(c) [DELETED]

(d) A pharmacy shall transmit the information required pursuant to these Regulations to the Department in such a manner as to insure the confidentiality of the information in compliance with all applicable federal and state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

(e) Any pharmacist who, in his or her professional judgment, refuses to fill a prescription based on information contained within the prescription drug monitoring database shall inform the prescribing physician within twenty-four (24) hours.

3.3 Management of Information.

(a) The Department shall only disclose information obtained pursuant to these Regulations:

(1) To a practitioner who certifies that the requested information is for the purpose of evaluating the need for or providing medical treatment for a current patient to whom the practitioner is prescribing or considering prescribing a controlled substance;

(2) To a pharmacist who certifies that the requested information is for a current client to whom the pharmacist is dispensing or considering dispensing a controlled substance;

(3) Pursuant to a valid search warrant based on probable cause to believe a violation of federal or state criminal law has occurred and that specified information contained in the database would assist in the investigation of the crime;

(4) To a patient who requests his or her own prescription information, or the parent or legal guardian of a minor child who requests the minor child's prescription information;

(5) To a health professional regulatory board that documents, in writing, that the requested information is necessary for an investigation related to licensure, renewal or disciplinary action involving the applicant, licensee or registrant to whom the requested information pertains;

(6) To any vendor or contractor with whom the Department has contracted to establish or maintain the electronic system of the prescription drug monitoring database; or

(7) To public or private entities for statistical, research or educational purposes, after removing the patient and prescriber information that could be used to identify individual patients. This shall not include entities receiving a waiver from the Institutional Review Board.

(b) A patient may request from the dispensing pharmacy correction of any inaccurate information contained within the prescription drug monitoring database in accordance with the procedure specified by RIGL § 5-37.3-5(c).

(c) The Department shall, for the period of time that prescription information is maintained, maintain records of the information disclosed through the prescription drug monitoring database, including, but not limited to:

(1) The identity of each person who requests or receives information from the prescription drug monitoring database and the organization, if any, the person represents;

(2) The information released to each person or organization and the basis for its release under § 3.3(a) of these Regulations; and

(3) The dates the information was requested and provided.

(d) Prescription information contained within the prescription drug monitoring database shall be removed no later than five (5) years from the date the information is entered into the database.

(1) Records in existence prior to 24 June 2013 shall be removed no later than ten (10) years from the date the information is entered into the prescription drug monitoring database.

(e) The Department shall promptly notify any affected individual of an improper disclosure of information from the prescription drug monitoring database or a breach in the security of the prescription drug monitoring database that poses a significant risk of disclosure of patient information to an unauthorized individual.

(f) At the time of signing a prescription which is required by the Department to be entered into the prescription drug monitoring database, the prescribing physician shall inform the patient in writing of the existence of the prescription drug monitoring database, the patient's right to access their own prescription information, and the name and contact information for the Department.

(g) The Department will disclose any information relating to a patient maintained in the prescription drug monitoring database to that patient, at no cost to the patient, within thirty (30)

business days after the Department receives a written request from the patient for the information. This information will include the records maintained by the Department pursuant to § 3.1 of these Regulations.

(1) Notwithstanding the provisions of § 3.3(g) of these Regulations, the Department may, at the request of the law enforcement agency, withhold for up to sixty (60) days following the conclusion of a law enforcement investigation, the disclosure to the patient that information has been obtained pursuant to § 3.3(a)(3) of these Regulations.

West's Rhode Island Administrative Code (2014)
Title 46. Mental Health Retardation & Hospitals Department
Division 1. General
Rule 13. Rules and Regulations for the Licensing Behavioral Healthcare Organizations
Part VI. Services and Programs

46-1-13:45.0. Opioid Treatment Programs

This section applies to all public or private opioid treatment and maintenance programs. These programs must also comply with all applicable sections of the General Regulations and with 42 CFR Part 8 (DHHS/SAMHSA, DEA Regulations), and Rhode Island General Laws section 21-28-1 et seq. (Uniform Controlled Substance Act), Rhode Island General Laws section 21-28.2-1 et seq. (Drug Abuse Control Act), Rhode Island General Laws section 21-28.3-1 et seq. (Drug Abuse Reporting System), Rhode Island General Laws section 5-19-1 et seq. (Pharmacy Statute), and Rhode Island State Methadone Authority. Programs shall reference the State Methadone Treatment Guidelines/ TIP1 (Treatment Improvement Protocol Series/CSAT) and Buprenorphine Treatment Guidelines.

45.1 Opioid treatment programs (OTPs) shall use only opioid replacement treatment medications that are approved by the Food and Drug Administration, and the Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction.

45.2 All federal laws and regulations that pertain to the handling of any opioid replacement medication shall apply in these regulations.

45.3 All opioid treatment programs shall be open seven (7) days per week or have the capacity to arrange for dispensing medication(s) to clients on Sundays or Holidays should the program be closed or have reduced hours. Any such closure or reduction in clinic hours would require pre-approval by the State Opioid Treatment Authority. A closure request or a request to reduce clinic hours shall be made in writing to the State Opioid Treatment Authority.

45.4 Each OTP shall have written policies and procedures describing admission requirements that shall include:

45.4.1 Documentation of a one (1) year history of opioid addiction for persons eighteen (18) years of age and over. Exceptions may be granted by the program physician for applicants who have been released from prison or from chronic care facilities, are HIV positive, are pregnant, and/or have previously been treated for opioid addiction.

45.4.2 For individuals under eighteen (18) years of age, the program must verify a minimum of two (2) prior short term detoxifications or drug free treatment episodes in a twelve (12) month period and must obtain parental or legal guardian's consent.

45.4.3 No person under sixteen (16) years of age may be admitted to an opioid treatment program unless the program has received prior written approval of the admission from the State Methadone Authority.

45.4.4 All women of childbearing potential shall be tested for pregnancy:

A. Before admission to an OTP

B. Before any detoxification or medially supervised withdrawal is initiated.

C. Medical staff shall document test results in the woman's treatment record.

45.4.5 A physical health assessment, including a medical history and physical examination, shall be completed within the first twenty-four (24) hours of a person's admission to the program.

A. This assessment shall include: an assessment of the possibility of: infectious diseases, including HIV, TB, Viral Hepatitis and sexually transmitted diseases; pulmonary, liver, and cardiac abnormalities; dermatological and neurological consequences of addiction; and possible concurrent surgical problems.

B. The assessment shall include laboratory tests, the results of which must be returned no later than fourteen (14) days after admission. The licensee shall ensure that such laboratory tests are completed by licensed facilities which shall comply with all applicable federal and state laboratory licensure and certification requirements. The laboratory tests shall include the following:

1. Tests to determine liver function;

2. Complete blood count and lipid panel; and

3. Screening test for syphilis.

C. If the Medical Director determines that laboratory tests are not clinically indicated at the time of admission, this justification shall be documented in the patient record.

D. Programs are required to check Department of Health's Prescription Monitoring Program for each new admission.

45.4.6 All persons served shall have a drug test upon admission. A specimen positive for opiates is not necessary for admission to an OTP, if other criteria, such as the following, have been satisfied.

A. Individual meets the DSM diagnostic requirements for opiate dependence.

B. Individual is clearly at risk for relapse while receiving services in an abstinence-based program.

45.4.7 Prior to an individual's admission to an OTP, the following information shall be entered into the Department's Substance Abuse Database Central Registration System:

A. The individual's initials (first, middle, last)

B. Date of birth

C. Last four (4) digits of the person's Social Security number

D. Anticipated date of admission

E. Gender.

45.4.8 If the Central Registry is inoperable, prior to admitting any individual, the program shall contact each of the other OTPs in Rhode Island to verify that the individual is not receiving services from another OTP.

A. The documentation of these contacts shall be noted in the individual's treatment record and the OTP shall submit the individual's data to the Central Registry as soon as it is operable.

45.4.9 In emergencies, the program medical director or other qualified physician shall make the clinical judgment as to when opioid treatment is initiated.

45.5 Each OTP shall forward to the Central Registry daily reports on admissions, transfers, and discharges.

45.6 The OTP shall have written policies and procedures regarding drug testing that shall include but not be limited to the following:

45.6.1 All drug testing screen results shall be documented in the person's treatment record.

45.6.2 Required drug tests include screening for the following substances: opiates, methadone, cocaine, benzodiazepines, and substances prevalent in the community as determined by the OTP and the Department. Any additional drug tests ordered at the discretion of the program shall be specific to the individual's treatment needs.

45.6.3 The OTP drug testing policy and procedure shall be approved by the designated State Methadone Authority.

45.6.4 Random drug testing shall be conducted as clinically indicated, but no less than eight (8) times/year while an individual remains in treatment.

45.6.5 Specimens shall be collected in a manner that minimizes falsification and shall be stored in a secure place to avoid substitution.

45.6.6 Testing facilities shall be licensed in Rhode Island pursuant to Rhode Island General Laws section 23-16.2-1 et seq. and qualified to do drug testing.

45.6.7 Results of drug testing shall not be used in a punitive manner, but rather, shall serve as one factor in making treatment decisions.

45.6.8 Each OTP shall have its own protocol regarding the increased frequency of drug testing.

45.7 A physician shall determine, and document in writing, the initial dose and schedule to be followed for each individual admitted to the OTP.

45.7.1 Initial doses of methadone shall not exceed thirty (30) milligrams and the total dose for the first twenty four (24) hours shall not exceed forty (40) milligrams, unless the program physician documents in the individual's treatment record that forty (40) milligrams did not suppress opiate abstinence symptoms.

45.7.2 The initial dose and schedule for each person shall be communicated to the licensed medical staff supervising the dispensing of any opioid replacement treatment medication.

45.7.3 Individuals transferring from one OTP to another may receive their daily dose as ordered by the transferring physician after medical personnel at the transferring OTP verify the dose to medical personnel at the new OTP.

45.7.4 Before the initial dose is dispensed, the individual shall complete all screening and admission procedures, except in an emergency or in a courtesy dosing situation, which shall be documented in the treatment record.

45.8 The OTP shall develop and implement the following drug dispensing and administering procedures:

45.8.1 A standardized method that includes the use of identification by photograph shall be implemented to properly identify each individual before any opioid replacement treatment medication is dispensed. A dose shall not be administered or dispensed until an individual is identified and assessed to be medically and clinically appropriate.

45.8.2 The prescribed drugs shall only be administered and dispensed by licensed professionals authorized by law to do so.

45.8.3 Each opioid replacement treatment medication used by the program shall be administered and dispensed in accordance with its approved product labeling.

A. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. Any decision to deviate from the labeling must be documented in the individual's record, along with the rationale for that decision.

45.8.4 The dosage to be dispensed shall be verified with the current dosage ordered. Ingestion shall be observed and documented by the person who administered the opioid replacement treatment medication.

45.8.5 Methadone shall be dispensed in oral form in one dose per container when liquid form is dispensed and in a multiple dose container when tablets are used. Buprenorphine shall be dispensed in sub-lingual tablets.

45.8.6 Pregnancy testing shall be performed monthly for women receiving buprenorphine.

45.8.7 A person's medication may be withheld when the OTP medical staff determines that administration of the dose would not be medically safe based on an assessment of the person.

A. The person shall be informed of the reason for withholding the medication.

B. The person shall be referred for medical treatment indicated.

1. The assessment and all subsequent actions shall be documented in the person's treatment record.

45.9 The OTP shall have a written policy describing procedures to be implemented when a person served needs “Courtesy Dosing” while enrolled in an approved treatment program.

45.9.1 Arrangements for “Courtesy Dosing” shall be made in advance, consistent with federal standards.

45.10 An initial treatment plan shall be completed within the first thirty (30) days of each person's admission to the OTP.

45.10.1 Treatment plans shall be reviewed, revised, and updated every six (6) months.

45.10.2 A new treatment plan shall be developed at least once every twelve (12) months.

45.11 Medical care, including referral for necessary medical service, and evaluation and follow-up of patient complaints must be compatible with current and accepted standards of medical practice. All patients must receive a medical examination at least annually. All other medical procedures performed at the time of admission shall be reviewed by the medical staff on an annual basis, and all clinically indicated tests and procedures shall be repeated. Medical staff shall record the results of this annual medical examination and review of patient medical records in each patient's record. Programs are required to check the Department of Health's Prescription Monitoring Program at each annual physical.

45.12 Rehabilitative counseling services (individual, group, and family) shall be provided by OTP staff and shall be consistent with the individual's treatment plan.

45.13 The type and number of counseling sessions received by each individual in the program shall be based on a clinical assessment of the person's service needs and goals as formulated in the person's treatment plan. Minimum requirements for the scheduling of counseling sessions are as follows:

45.13.1 A minimum of one (1) hour of individual counseling must be provided monthly (in one (1) or two (2) sessions) and shall be documented in the individual's treatment record for the first year of treatment.

45.13.2 Individuals admitted to long-term detoxification services must receive at least two (2) hours of individual counseling each month. Individuals admitted to short-term detoxification services must receive a minimum of four (4) hours of individual counseling each month.

A. Following an individual's detoxification, medical and clinical staff shall determine and document in the person's treatment plan, the type and frequency of counseling necessary.

45.13.3 After the first year of treatment, each person who is participating in group counseling, on at least a monthly basis, shall receive a minimum of one (1) hour of individual counseling every ninety (90) days.

45.13.4 Each individual, who is not participating in group counseling, shall receive at least one (1) hour of individual counseling every thirty (30) days.

45.13.5 An individual who has initiated medically supervised withdrawal shall be re-evaluated to determine the frequency of his or her counseling sessions and that evaluation and subsequent changes to the individual's treatment shall be documented in his or her record.

45.14 When an individual is transferred to another program within the organization, the individual's treatment record with completed, up-to-date documentation shall be transferred to the receiving program.

45.15 When an individual is transferred to another organization, copies of the following information from the individual's treatment record shall be provided to the receiving organization:

45.15.1 Dosing schedule

45.15.2 Laboratory work and toxicology

45.15.3 Current treatment plan

45.15.4 Discharge summaries

45.16 OTP's shall develop policies and procedures that ensure compliance with federal and state regulations before take-home medication privileges are granted. In addition, prior to advancement to a new take-home phase, programs are required to check the Department of Health's Prescription Monitoring Program. The policies and procedures shall, at a minimum, include the following:

45.16.1 The following treatment schedule shall be implemented:

A. At least a two (2) month probationary period with daily doses of medication ingested under appropriate supervision. During this time the individual must satisfactorily meet all requirements of the program. In the event that a program is closed on a Sunday or Holiday during a patient's two (2) month probationary period, if the patient meets the criteria established by the program and approved by the State Opioid Treatment Authority, the patient may receive one (1) take-home during this period. Written closure requests to the State Opioid Treatment Authority (as required in section 45.3 of these regulations) shall also include written detailed plans containing: patient inclusion/exclusion criteria, patient notification, diversion control, a documented history of take-home safety, and the submission of exception requests. Documentation of appropriateness shall be noted in the patient record.

B. During the first ninety (90) days of take-home privileges, the take-home supply shall be limited to a single dose each week. The individual shall ingest all other doses under appropriate supervision.

C. During the second ninety (90) days, the take-home supply shall be limited to two (2) doses per week.

D. During the third ninety (90) days, the take-home supply shall be limited to three (3) doses per week with no more than two (2) consecutive days supply of medication.

E. After one (1) year the individual may be permitted to reduce attendance to two (2) visits weekly and may be given no more than three (3) consecutive days supply of medication.

F. After two (2) years, the individual may be permitted to reduce program attendance to once weekly and may receive no more than six (6) days take-home supply of medication.

G. After three (3) years, the individual may be permitted to reduce program attendance to two (2) visits monthly and receive no more than a fourteen (14) day supply of medication.

H. After four (4) years, the individual may be permitted to reduce program attendance to once monthly. OTPs are required to inform the State Opioid Treatment Authority of all individuals advanced to this take-home phase.

45.16.2 In an emergency situation or severe illness, individuals may be given up to ten (10) days supply of medication based on the judgment of the OTP physician.

45.16.3 Prior to the initiation of take-home privileges, the following shall be confirmed and documented:

A. The individual shall receive instructions regarding safety. Such instructions shall include but not be limited to, child safety measures and the storage of medications.

B. The individual shall obtain an agency approved locked box for storage of take-home medication.

45.16.4 Take-home containers shall be labeled with the following:

A. Individual's name;

B. Name and amount of medication;

C. Directions for use, including route of administration;

D. Date issued and date medication is to be taken;

E. Program name and address;

F. Program's telephone number.

45.16.5 Childproof caps shall be used on all take-home bottles of opioid replacement medication.

45.16.6 The OTP physician shall document in the treatment record the rationale for authorizing take-home privileges.

45.16.7 The individuals shall return all take-home containers on their next day of Program attendance. Prior to the person's receiving his or her subsequent dose, bottles shall be inspected to ensure that they are coming from the appropriate person during the appropriate time-period.

45.16.8 The agency shall have a policy regarding the non-return of take-home bottles that includes the interventions to be taken. Should there be a violation of this policy, the documentation required for each incident shall include the following:

A. The person's treatment history at the agency

B. Reason for damage to the label on the container or the person's inability to produce the container

C. Number of repeated occurrences.

45.16.9 Take-home privileges are not allowed during long or short-term opioid detoxification.

45.16.10 Take-home privileges may be revoked by the OTP physician with the rationale documented in the person's treatment record.

45.16.11 Individuals may contest a revocation of take-home privileges through the Concern and Complaint Resolution Procedure.

45.16.12 An OTP must maintain a Diversion Control Plan to ensure quality care while minimizing the diversion of an opioid replacement medication from treatment to illicit use. The plan shall include, but not be limited to, the following:

A. Clinical and administrative continuous monitoring

B. Problem identification, correction, and prevention

C. Accountability to the person and to the community

45.16.13 When buprenorphine is given as a take-home medication, the medically indicated formulation shall be used.

45.17 Each OTP shall have policies and procedures regarding the discontinuation of any opioid replacement medication that include, at a minimum, the following:

45.17.1 The OTP physician shall approve all requests for voluntary withdrawal from an opioid replacement medication.

45.17.2 All withdrawal schedules shall be determined on an individual basis and each individual's progress shall be monitored by OTP staff.

A. Withdrawal schedules shall adhere to proper medical guidelines without consideration of financial concerns.

45.17.3 Written procedures that address the involuntary discharge from treatment shall include, but not be limited to the following:

A. At the inception of treatment, each person served shall be informed of his or her responsibilities associated with the program, including the policies related to involuntary withdrawal. The person shall be reminded of these policies and procedures at the time of an impending involuntary discharge.

B. Criteria shall be established for the involuntary withdrawal of treatment.

C. The OTP physician shall establish the withdrawal schedule in accordance with sound medical treatment and ethical considerations.

D. Dosage reduction schedules shall be individualized. No standardized dosage reduction schedule shall be established.

E. Withdrawal schedules shall be carefully monitored by all clinical personnel within the program.

F. When on-site withdrawal is determined to not be suitable for an individual, OTP staff shall assist the individual to transfer to another OTP.

45.17.4 Opioid treatment programs shall develop a written procedure establishing standards for "against medical advice" withdrawal. The withdrawal schedule shall be determined on an individual basis and completed under observation of the OTP staff.

45.17.5 Individuals who have completed a voluntary withdrawal from an opioid replacement treatment medication shall be eligible for aftercare counseling through outpatient services.

45.17.6 Individuals who have successfully completed the medically supervised withdrawal or detoxification phase and are being transferred to an outpatient program at the same organization, shall be transferred to the OTP's aftercare status in the Client Information System at the Division of Behavioral Healthcare Services no later than seven (7) days after the person's last dose.

45.17.7 Individuals who complete a medically supervised withdrawal shall be given priority for re-admission within thirty (30) days of leaving treatment.

45.18 A program shall not admit a person for more than two (2) detoxification treatment episodes in one (1) year. Individuals with two (2) or more unsuccessful detoxification episodes shall be evaluated by the OTP physician for other forms of treatment.

45.19 In addition to the security requirements of the DEA Regulations Governing Narcotic Treatment Programs (Parts 1301 - 1307 and 42 CFR part 2) and Rhode Island General Laws section 21-28-1 et seq. ("Controlled Substance Act"), the following requirements must be met:

45.19.1 Access to electronic alarm areas where drug stock is maintained shall be limited to a minimum number of authorized personnel. Each employee shall have his or her own individual code, which shall be erased upon the employee's termination. A list shall be maintained that identifies all persons with access to the stock/safe and dispensing station and the type of access each has.

45.19.2 All stored controlled substances (powdered, liquid, tablet and reconstituted) shall be clearly labeled with the following information:

A. Name of substance;

B. Strength of substance;

C. Date of reconstitution;

D. Lot number;

E. Reconstituted expiration date or manufacture date, whichever is earlier.

45.19.3 All stored poured doses shall have the following information:

A. Name of substance;

B. Strength of substance;

C. Date of reconstitution;

D. Lot number;

E. Reconstituted expiration date or manufacture date.

45.19.4 Containers shall be kept covered and stored in the appropriate locked safe with access limited through an electronic alarm system that conforms with the DEA requirements of 21 CFR Part 21, Section 1301.71.

45.19.5 Following the initial opioid replacement treatment medication inventory at each OTP, an authorized licensed staff member shall conduct a bi-annual written inventory and document the results. The record is to be maintained for a period of two (2) years. The inventory shall contain:

A. Name and address of the OTP;

B. Date of inventory;

C. Opening or closing of business day;

D. Quantity of opioid replacement treatment medications on hand, amount used, and amount received;

E. Total of all medications accounted for;

F. Signature of person performing the inventory and a co-signature.

45.19.6 The Department shall be notified of any occurrence of theft, suspected theft, or any loss of any opioid replacement treatment medication. The form, authorized by the Department for reporting adverse events/incidents, shall be completed for each occurrence and shall be sent to the Rhode Island BHDDH, along with a photocopy of DEA form 106.

45.19.7 OTPs shall have quality control procedures to track and trend all spillages of any medication.

45.19.8 The disposal of unused controlled substances shall be done in accordance with procedures provided by Federal DEA Regulations (Part 1307.21) and the Rhode Island Department of Health.

45.20 To ensure that appropriate rehabilitative and nursing services are provided, the Program Director of the OTP or his or her designee, shall assign the treatment of persons served according to best practice standards.

45.21 Each OTP shall have a designated medical director who has the responsibility for administering all medical services. He or she shall be licensed to practice medicine in Rhode Island, have Department of Health Controlled Substance Registration and be DEA registered.

45.21.1 The medical director or other authorized OTP physician shall assume the following responsibilities:

A. Evaluate each person to determine and to document his or her current physiological opioid addiction

B. Conduct the required physical evaluation and document the medical history for each person served

C. Ensure that the appropriate laboratory studies have been performed

D. Document and sign or counter-sign all medical orders

E. Review and sign treatment plans at least annually.

45.22 Each OTP shall have a registered nurse who shall be responsible for the general supervision of the nursing staff. The nurse shall participate in at least two (2) trainings per year in the area of substance abuse.

45.23 All pharmacists employed by an OTP shall be licensed in Rhode Island and must be authorized by the organization to dispense all opioid replacement treatment medications used by the program.

45.24 No less than fifty percent (50%) of staff providing direct therapeutic services shall have the qualifications listed in Regulation 9.12.1 or 9.12.2.

45.25 Medical, social, educational, and other services essential to meeting the basic human needs of persons served may be provided by case managers.

45.25.1 Case managers in OTPs are not required to have or work toward the qualifications listed in Regulation 9.12.