

14 DEPARTMENT OF HEALTH AND HUMAN SERVICES

118 OFFICE OF SUBSTANCE ABUSE

**Chapter 11: RULES GOVERNING THE CONTROLLED SUBSTANCES PRESCRIPTION
MONITORING PROGRAM**

RULES GOVERNING THE CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

STATE OF MAINE



**DEPARTMENT OF HEALTH AND
HUMAN SERVICES
OFFICE OF SUBSTANCE ABUSE**

State House Station #11
Augusta, Maine 04333
(207) 287-2595

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SECTION 1. Introduction

Legal Basis: These rules are promulgated under the authority of 22 MRSA § 7252.

Severance Clause: The provisions of these rules are severable. If any provision of the rules is invalid, or if the application of the rules to any person or circumstances is invalid, such invalidity shall not effect other provisions or applications which can be given effect without the invalid provision or application.

SECTION 2. Purpose

These rules implement the controlled substances prescription monitoring program, established by the Legislature as a means to promote the public health and welfare and to detect and prevent substance abuse.

SECTION 3. Definitions

1. Authorized representative. A parent or guardian of a minor child, or a person who has been authorized pursuant to Article V of the Maine Probate Code to make health care decisions, or gain access to health care records, on behalf of another.
2. CFR. The Code of Federal Regulations. The Code of Federal Regulations is available at the State of Maine Law and Legislative Library, Maine State House, State Street, Augusta, Maine.
3. Controlled substance. A drug or other substance included in schedules II, III or IV of 21 USC § 812 (2004), or 21 CFR §1308 (2004).
4. Credentials. Information or a device provided by the office or their designee to a dispenser or prescriber that allows the dispenser or prescriber to electronically access prescription monitoring information. Credentials may include, but are not limited to, a username, password, or an identification device that generates a username or password.
5. Customer of the dispenser. A person seeking to have a prescription filled from a dispenser, has had a prescription partially filled by a dispenser, or has a prescription on file with the dispenser that has refills remaining.
6. Data requester. A prescriber, dispenser, or an individual duly authorized by a prescriber or dispenser, who registers with the Office or the Monitor, intending to search the prescription monitoring database for information regarding his or her own patients and customers.

7. Days Supply. Estimated number of days a prescription will last, based on the number of days a given prescription should last if taken according to the instructions.
8. Dispenser. A pharmacist who is licensed or registered under Title 32, Chapter 117 of Maine Revised Statutes Annotated or a licensed health care professional with authority to dispense or administer prescription drugs.
9. Dispenser identification number. The provider identification number issued to dispensing pharmacies by the National Council for Prescription Drug Programs or an equivalent, unique identification number assigned to a dispenser by the Office or the Monitor.
10. Generational suffix. An element of a patient name used to identify the patient by generation, such as but not limited to “junior,” “senior,” or “III.”
11. Monitor. The entity designated by the Office to implement and manage the prescription monitoring program under the direction and oversight of the Office.
12. MRSA. The Maine Revised Statutes Annotated.
13. Office. The Department of Health and Human Services, Office of Substance Abuse, as defined by 22 MRSA § 7246, as amended.
14. Patient. Either the person, or the owner or keeper of an animal, who is the ultimate user of a drug for whom a prescription is issued and/or for whom a drug is dispensed.
15. Patient address. The current geographic location of the patient’s residence. If the patient’s address is in care of another person or entity, the address of that person or entity must be provided in its entirety. When alternate addresses are possible, they must be recorded in the following order of preference:
 - A. the geographical location of the residence, as would be identified when a telephone is used to place a 9-1-1 call as described by Title 25, Chapter 352 of the Maine Revised Statutes Annotated, as amended;
 - B. a post office address issued by the United States Post Office;
 - C. the common name of the residence and town; or
 - D. The mailing address of the patient.
16. Patient date of birth. The date of birth of the ultimate user of the drug, as recorded by the Department’s Office of Vital Statistics.

17. Patient identification number. The unique number used to identify a particular person by the dispenser.
18. Patient name. The name of the patient for whom a prescription is ordered and must be recorded in the following format: Surname, first or given name, middle initial, generational suffixes if any.
19. Prescriber. As defined by 22 MRSA § 7246, a licensed health care professional with authority to prescribe controlled substances.
20. Prescriber identification number. The unique number issued to authorized prescribers of controlled substances by the Drug Enforcement Administration, United States Department of Justice, to authorized prescribers of controlled substances.
21. Prescriber's care. A patient is considered under a prescriber's care when that patient has had an in-person professional medical consultation with that prescriber within the past three years, or has an appointment for such a consultation.
22. Prescription monitoring information. As defined by 22 MRSA § 7246, information submitted to and maintained by the program.
23. Program. The Controlled Substances Prescription Monitoring Program established under 22 MRSA § 7248.
24. Public Health District. One of the eight public health districts defined and established by 22 M.R.S.A. §§411(5) & 412(3).
25. Surname. The family name of a patient, including hyphenated family names.
26. USC. The United States Code. The United States Code is available at the Law and Legislative Library, Maine State House, State Street, Augusta, Maine.
27. Valid photographic identification.
 - a. A valid Maine motor vehicle operator license;
 - b. A valid Maine identification card issued pursuant to Title 29-A M.R.S.A. § 1410;
 - c. A valid United States passport; or
 - d. A valid passport or motor vehicle operator's license issued by another state, U.S. territory, U.S. possession or a foreign country, provided the passport:

1. Contains a photograph of the traveler or licensee;
2. Is encased in tamper-resistant plastic, or otherwise possesses indicia of tamper-resistance; and
3. Identifies the date of birth of the traveler or licensee

SECTION 4. Waivers

1. The Office may grant a waiver of the electronic submission requirement to a dispenser for good cause. The dispenser requesting the waiver is responsible for establishing the basis for the requested waiver.
2. Waivers may be granted for the following circumstances:
 - A. The dispenser demonstrates that for any reason, including because the volume of controlled substances dispensed is low, financial hardship will result from being required to make electronic submissions of prescription monitoring information.
 - B. Other good cause.
3. Requests for a waiver shall be by application in writing on a form provided by the Office for such a purpose. The dispenser requesting the waiver may provide the Office with any reasonable supplemental materials in support of their request for a waiver, in addition to the written application. The Office may request additional information from the dispenser requesting the waiver as a condition of granting the waiver.
4. Requests for a waiver shall be granted or denied by the Office no later than 60 days from the date the written application for waiver is submitted to the Office, or the date the last supplemental written materials are received by the Office, including any additional information requested by the Office, whichever is later.
5. The decision of the Office to grant or deny a waiver shall constitute final agency action.

SECTION 5. Requirements for Dispensers

1. Dispensers must acquire and maintain an identification number issued to dispensing pharmacies by the National Council for Prescription Drug Programs (“NCPDP”), or request that an alternative number be assigned to them by the Monitor or the Office.
2. Dispensers must provide the information required by 22 MRSA § 7249(1) as follows:
 - A. electronically;
 - B. in the form required by the Office;
 - C. to the monitor; and
 - D. within Twenty Four hours ~~seven (7) days~~ of the controlled substance being dispensed.
 - E. The required information is
 - The dispenser identification number;
 - The date the prescription was filled;
 - The prescription number;
 - Whether the prescription is new or is a refill;
 - The National Drug Code (NDC) for the drug dispensed;
 - The quantity dispensed;
 - The dosage;
 - The patient identification number;
 - The patient name;
 - The patient address;
 - The patient date of birth;
 - The prescriber identification number; and
 - The date the prescription was issued by the prescriber.
3. A dispenser is immune from liability for disclosure of the above information made pursuant to 22 MRSA §7249 (4).
4. Dispensers must correct their own records and submit corrected copies of these records to the Program whenever they become aware of errors or omissions.

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SECTION 6. Requirements for Prescribers

1. Prescribers must acquire an individual prescriber identification number.

2. Prescribers must clearly indicate their individual prescriber identification number on every prescription for a controlled substance written by the prescriber.

SECTION 7. Access to Prescription Monitoring Information

1. By patients.
 - A. A patient, or a patients' authorized representative, may obtain a report listing all prescription monitoring information that pertains to the patient.
 - B. A patient or a patient's authorized representative seeking access to prescription monitoring information described above must submit a written request for information in person at the office of the Monitor, or at any other place specified by the Monitor or the Office. The written request shall be in a format established by the Office or the Monitor and shall contain at least, but not limited to, the following elements:
 - 1) the patient's name and the full name of the patient's authorized representative, if applicable;
 - 2) the patient's date of birth;
 - 3) the patient's address, and the complete physical address of the patient's authorized representative, if applicable;
 - 4) the patient's telephone number, if any, and the telephone number of the authorized representative, if applicable; and
 - 5) the time period for which information is being requested.
 - C. The patient or the patient's authorized representative must produce valid photographic identification prior to obtaining access to the information described above. The patient or the patient's authorized representative must allow photocopying of the identification.
 - D. Prior to obtaining access to the information described above, authorized representatives must produce either an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or in the case of parents of a minor child, a certified copy of the Birth Certificate of the minor child or other official documents establishing legal guardianship; or in the case of persons holding power of attorney, the original document establishing the power of attorney. The patient's authorized representative must allow photocopying of the documents described above. The Office or the Monitor may verify the

patient authorization by any reasonable means prior to providing the information to the authorized representative.

2. By dispensers.

- A. A dispenser, or a licensed pharmacy technician authorized by a supervising pharmacist, may obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Office, which may include, but is not limited to, delivery by electronic means, facsimile transmission, or telephonic communication.
- B. A dispenser who seeks access to the information described above must register as a data requester in a manner specified by the Monitor or the Office. The Office or Monitor shall issue credentials to authorized dispensers. Dispensers may use these credentials to access the online database and submit requests. If the credentials issued by the Office are lost, missing, or the security of the credentials is compromised, the dispenser shall cause the Office or Monitor to be notified by telephone and in writing as soon as reasonably possible. Information regarding more than one customer may be submitted in a single request. Requests shall be in a format established by the Office or the Monitor and shall contain at least, but not limited to, the following elements for each customer:
 - 1) The name and date of birth of the customer; and
 - 2) The time period for which information is being requested.
- C. The Office or the Monitor shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the dispenser or to an agent of the dispenser at a telephone number known to belong to the dispenser's place of business.

3. By prescribers.

- A. A prescriber, or any staff member duly authorized by a prescriber and the Office, may obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber's care. The information shall be provided in a format established by the Office, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.
- B. A prescriber, or any staff member duly authorized by a prescriber and the Office, who seeks access to the information described above must register

as a data requester in a manner specified by the Monitor or the Office. The Office or Monitor shall issue credentials to authorized prescribers or their designees. Data requesters may use these credentials to access the online database and submit requests. If the credentials issued by the Office are lost, missing, or the security of the credentials is compromised, the data requester shall cause the Office or Monitor to be notified by telephone and in writing as soon as reasonably possible. Requests shall be in a format established by the Office or the Monitor and shall contain at least, but not limited to, the following elements for each patient:

- 1) The name and date of birth of the patient; and
 - 2) The time period for which information is being requested.
 - C. The Office or the Monitor shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber and licensed health care practitioners duly authorized by prescribers, or to an agent of the prescriber at a telephone number known to belong to the prescriber's place of business.
4. By executive director, board investigator, or person authorized to discharge equivalent functions of a licensing board.
- A. An executive director, board investigator, or person authorized to discharge equivalent functions of a licensing board with jurisdiction over a dispenser or prescriber may obtain any prescription monitoring information as required for an investigation, with reasonable cause. The information shall be provided in a format established by the Office, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.
 - B. An executive director, board investigator, or person authorized to discharge equivalent functions of a licensing board with jurisdiction over a dispenser or prescriber who seeks access to prescription monitoring information described above must submit a request via mail, facsimile, or secure electronic transmission, to a location specified by the Monitor or the Office. The request shall contain identifying information regarding the licensee or patient and the time period for which the information is being requested. The data requester shall certify that each request is related to an investigation involving misuse of a Schedule II, III, or IV drug and provide a case number or other assurance that the request is related to the board representative's official duties.
5. By personnel of any vendor or contractor engaged by the Office.

- A. Personnel of any vendor or contractor engaged by the Office may obtain any prescription monitoring information insofar as the information is necessary for establishing and maintaining the program's electronic system.
 - B. The Office, the monitor, and program vendors or contractors engaged by the Office, shall purge all prescription monitoring information more than six years old.
6. By the units within the Department of Health and Human Services that administer the MaineCare program.
- A. Subject to the requirements of 22 M.R.S.A. §7250(4)(F), the authorized representative of those units of the Department of Health and Human Services which oversee, administer, or otherwise supervise MaineCare programs which determine eligibility for and use of prescription drugs, and the appropriate utilization of prescription drugs, for the purposes of managing the care of MaineCare members, monitoring the purchase of controlled substances by MaineCare members, and avoiding duplicate dispensing of controlled substances to MaineCare members.
 - B. The person or persons authorized pursuant to Section 7(6)(A) must submit a request via mail, facsimile, or secure electronic transmission, to a location specified by the Monitor or the Office. The request shall contain surname, first name, and date of birth of the member and the time period for which the information is being requested. An intervention approach shall be undertaken with MaineCare members who are determined to be accessing controlled substances in a quantity or with a frequency beyond the norm for persons with similar medical conditions or diagnoses and the intervention approach shall not include terminating the member from MaineCare services.
7. By the Office of the Chief Medical Examiner.
- A. The Chief Medical Examiner or a designee may obtain any prescription monitoring information as required for an investigation or inquiry into the cause, manner and circumstances of death in a medical examiner case. The information shall be provided in a format established by the Office of Substance Abuse, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication.
 - B. The Chief Medical Examiner or a designee must submit a request via mail, facsimile, or secure electronic transmission, to a location specified by the Monitor or the Office. The request shall contain the surname, first name, and date of birth of the decedent and the time period for which the information is being requested.

SECTION 8. Confidentiality

1. Pursuant to 22 MRSA § 7250(1), prescription monitoring information is confidential and not a public record as defined in Title 1, section 402, subsection 3. Breaches of the confidentiality may result in criminal prosecution and/or administrative sanctions.
2. Pursuant to 22 MRSA § 7250(3), the Office may provide de-identified copies of prescription monitoring information to researchers who have signed written agreements restricting the use of the data for research, policy, or educational purposes. The Office may make aggregate information based on prescription monitoring information available to the public.
3. The Office shall periodically conduct an audit review of the Monitor for compliance with the terms of the contract regarding confidentiality of information concerning the prescription drug, prescriber, pharmacy, patient and dispenser.
4. The Monitor shall fully cooperate with the Office in any audit review conducted pursuant to Subsection 3.
5. The Office and the Monitor shall purge from the database all prescription monitoring information that is older than six (6) years old.

SECTION 9. Review of information

1. Pursuant to 22 MRSA § 7250, the Office and the Monitor shall review the information in the database on at least a quarterly basis to determine whether there are cases in which there has been questionable activity by patients or prescribers.
2. Patient Review
 - A. The Office shall review prescription monitoring information related to individual patients to determine which patients have surpassed threshold levels of controlled substances. These threshold levels may include any of the following –
 - high number of prescribers in a short time period, as determined by the Office;
 - high number of doses during a short time period, as determined by the Office;
 - Days Supply of prescriptions for the same drug overlapping by more than a few days;

- unhealthy combinations of controlled substances, as determined by the Office;
- more than one method of payment within a short time period;
- more than one out of state prescriber for the same patient, during a short time period, as determined by the Office;
- more than one pharmacy on the same day;
- more than one pharmacy in different public health districts within one month; AND/OR
- dangerous levels of specific drugs, as determined by the Office.

B. Notification – When a patient surpasses the threshold levels established by the Office, the office shall notify the prescriber(s) and the dispenser(s) of the controlled substance(s) and provide all relevant prescription monitoring information to those persons through an established letter of notification.

SECTION 10. Penalties and Sanctions

1. Criminal Penalties. A person who intentionally or knowingly uses or discloses prescription monitoring information in violation either of Title 22, M.R.S.A. Ch. 1603 or these rules, unless otherwise authorized by law, shall be subject to the criminal penalties established in 22 MRSA § 7251(2).
2. Administrative Sanctions. A dispenser who knowingly fails to submit prescription monitoring information to the Office as required by these rules and by statute is subject to discipline by the Maine Board of Pharmacy or other applicable licensing entity as set forth in 22 M.R.S.A. § 7251(1).

STATUTORY AUTHORITY: 22 MRSA Ch. 1603, Resolve 2005 ch. 36

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