

DEPARTMENT OF COMMUNITY HEALTH

Revised Controlled Substance Rules Pertaining to the MAPS Program

PART 1. GENERAL PROVISIONS

R 338.3101 Definitions; A to H.

Rule 1. As used in these rules:

- (a) "Act" means 1978 PA 368, MCL 333.1101 et seq.
- (b) "Deleterious drug" means a drug, other than a proprietary medicine, that is likely to be destructive to adult human life in quantities of 3.88 grams or less.
- (c) "Department" means the department of community health.
- (d) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures nonrepudiation so that the signature may not be rejected based on its validity.

R 338.3102 Definitions; I to P.

Rule 2. (1) As used in these rules:

- (a) "Inventory" means all stocks in finished form of a controlled substance that is manufactured or otherwise acquired by a licensee, whether in bulk or commercial containers or contained in pharmaceutical preparations in the possession of the licensee.
- (b) "Licensee" means a person who is licensed pursuant to section 7303 of the act.
- (c) "Michigan automated prescription system (maps) claim form" means a form, to be determined by the department, that is in the format and includes the information as specified by the American Society for Automation in Pharmacy (ASAP) and contains the information specified in R 338.3162b.
- (d) "National drug code number (ndc)" means a number that identifies the labeler/vendor, product, and package size and is assigned to each drug product listed under section 510, registration of producers of drugs and devices, of the federal food, drug, and cosmetic act.
- (e) "Officer" means a state, county, or local law enforcement officer who has a duty to enforce the laws of this state.
- (f) "Patient identifier" includes all of the following information about a patient:
 - (i) Full name.
 - (ii) Address, including zip code.
 - (iii) Date of birth.
 - (iv) Any 1 of the following:
 - (A) A Michigan driver's license number.
 - (B) An identification number obtained from a photo identification card issued by the state of Michigan.
 - (C) The number zero. Zeroes shall be entered as the identification number, if the positive identification presented by the patient or the patient's agent or caregiver does not include a license number or an identification number, as listed in subparagraphs (A) and (B) of this paragraph.

(g) "Positive identification" means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification shall include an identification card issued by a governmental agency, provided the identification card meets the requirements of this rule.

(2) As used in part 5 of these rules:

(a) "Medical institution" means an inpatient health facility which is licensed or approved by the state and which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services associated with the practice of pharmacy.

R 338.3104 Definitions; R, S.

Rule 4. As used in these rules:

(a) "Readily retrievable" means a record which is kept in such a manner that it can be separated from all other records within 48 hours and in which a listed controlled substance shall be marked with an asterisk, redlined, or in some other manner be visually identifiable apart from the other substances listed in the record.

(b) "Scientific investigator" means a person, other than a physician, who is licensed to conduct research with a controlled substance listed in schedules 1 to 5.

(c) "Sign" means to affix a signature manually in the same manner as signing a check or legal document or to use an electronic signature, as defined in subdivision (d) of R 338.3101. Stamped signatures are not valid for any controlled substance prescription.

(d) "Substance" means a controlled substance unless the context indicates otherwise.

PART 6. DISPENSING AND ADMINISTERING PRESCRIPTIONS

R 338.3161 Controlled substance prescriptions.

Rule 61. (1) A prescription that is issued for a controlled substance shall be dated and signed when issued and shall contain all of the following information:

(a) The full name and address of the patient for whom the substance is being prescribed.

(b) The prescriber's drug enforcement administration (dea) registration number, printed name, address, and professional designation.

(c) The drug name, strength, and dosage form.

(d) The quantity prescribed. For a prescription received in writing, the prescription shall contain the quantity in both written and numerical terms. A written prescription is in compliance if it contains preprinted numbers representative of the quantity next to which is a box or line the prescriber may check.

(e) The directions for use.

(f) In addition, if the prescription is for an animal, then the species of the animal and the full name and address of the owner.

(2) A written prescription for a controlled substance in schedules 2 to 5 shall be written legibly with ink or an indelible pencil, or prepared using a printer and shall be signed by the prescriber.

(3) An agent of the prescriber may prepare a prescription for the signature of the prescriber, but, pursuant to the act, the prescriber is liable if the prescription does not

conform to these rules. A pharmacist who dispenses a controlled substance pursuant to a prescription not prepared in the form required by these rules is liable pursuant to the act.

(4) If the controlled substance prescription or order in a medical institution is issued pursuant to delegation under R 338.2304, R 338.2305, R 338.108a, or R 338.108b then the printed name of the delegatee, the licensure designation, the delegating prescriber, and the signature of the delegatee shall be on the written prescription. In medical facilities, orders shall contain the signatures of the delegatee and the printed name of the delegating prescriber.

(5) A prescription shall not be issued by a prescriber to obtain a stock of a controlled substance for the purpose of dispensing or administering the substance to patients.

(6) A prescriber shall not prescribe a controlled and noncontrolled substance on the same prescription form.

R 338.3162 Dispensing by pharmacists; delivery of controlled substances.

Rule 62. (1) A controlled substance shall be dispensed by a pharmacist or a pharmacy intern in the presence, and under the immediate supervision, of a pharmacist.

(2) A pharmacist shall require positive identification of individuals to whom controlled substances are dispensed or delivered when the individual is not known to the pharmacist or pharmacy employees. The following provide for waiver of this requirement:

(a) When positive identification is not available and a pharmacist, who in exercising his or her professional judgment, determines that a delay in dispensing the controlled substance may be detrimental to a patient.

(b) Subdivision (a) of this subrule does not exempt a pharmacist from the requirement to submit a patient identifier, as defined in R 338.3102(1)(f).

(3) The dispensing pharmacist and pharmacy are responsible for compliance with this rule.

(4) Except as provided by R 338.3162a, a pharmacist may dispense a controlled substance which is listed in schedules 3 to 5 and which is a prescription drug pursuant to the provisions of the federal food, drug, and cosmetic act of 1991, 21 U.S.C. §201.100(b)(i) et seq., only pursuant to a written, electronically transmitted, or oral order of a prescriber that contains all of the required information under R 338.3161, except that the signature of the prescriber is not required if the controlled substance is obtained pursuant to an oral order.

(5) If an oral order for a controlled substance listed in schedule 3 to 5 is transmitted by the prescriber's agent under delegation then all of the following shall be recorded on the prescription generated at the pharmacy:

The information required by R 338.3161.

The transmitting agent's identity.

The individual who received the prescription at the pharmacy.

(6) Only an order that is issued in the usual course of professional treatment or in the course of legitimate and authorized research is a prescription.

R 338.3162a Electronic transmission of prescriptions; "electronically transmitted prescription drug order" defined.

Rule 62a. (1) As used in this rule, "electronically transmitted prescription drug order" means a prescription drug order that is communicated from the prescriber directly to the pharmacy by electronic means, so that the data cannot be altered, modified, extracted, viewed, or manipulated in the transmission process.

(2) An electronically transmitted prescription order shall be transmitted to the pharmacy of the patient's choice and shall occur only at the option of the patient.

(3) A pharmacist may dispense an electronically transmitted prescription drug order only if both of the following conditions are satisfied:

(a) The electronically transmitted prescription drug order includes all of the following information:

(i) The name and address of the prescriber.

(ii) An electronic signature or other board-approved means of ensuring prescription validity.

(iii) The prescriber's telephone number for verbal confirmation of the order.

(iv) The time and date of the transmission.

(v) The name of the pharmacy intended to receive the transmission.

(vi) All other information that is required to be contained in a prescription under the provisions of R 338.3161.

(b) The pharmacist exercises professional judgment regarding the accuracy or authenticity of the transmitted prescription. Technological devices shall not be used to circumvent any applicable prescription documentation and verification requirement.

(4) An electronically transmitted prescription drug order that meets the requirements of subrule (3) of this rule shall be deemed to be the original prescription.

(5) This rule does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical institutions.

R 338.3162b Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances.

Rule 62b. (1) A pharmacist, dispensing prescriber, and veterinarian licensed under Part 177 who dispenses a prescription drug which is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5 shall report to the department or the department's contractor by means of an electronic data transmittal process the following information for each prescription of a schedules 2 to 5 controlled substance prescription dispensed:

(a) The patient identifier, as defined in R 338.3102(1)(f). The following apply:

(i) An identification number, as specified in R 338.3102(1)(f)(iv)(A) or (B), is not required for patients under the age of 16.

(ii) If the patient is under 16 years of age, zeroes shall be entered as the identification number.

(iii) If the patient is an animal, positive identification of the animal's owner that meets the requirements of R 338.3102(1)(f)(iv).

(b) The name of the controlled substance dispensed.

(c) The metric quantity of the controlled substance dispensed.

(d) The national drug code number (ndc) of the controlled substance dispensed.

(e) The date of issue of the prescription.

(f) The date of dispensing.

(g) The estimated days of supply of the controlled substance dispensed.

(h) The prescription number assigned by the dispenser.

(i) The dea registration number of the prescriber and the dispensing pharmacy.

(j) The Michigan license number of the dispensing pharmacy.

(2) A pharmacist, dispensing prescriber, or veterinarian may presume that the patient identification information provided by a patient or a patient's representative is correct.

R 338.3162c Format for electronic transmission of data; waiver.

Rule 62c. (1) A pharmacist, dispensing prescriber, or veterinarian who dispenses a prescription drug which is a controlled substance listed in schedules 2 to 5 shall transmit the data, as specified under R 338.3162b, by electronic media or other means as approved by the department or the department's contractor.

(2) The data shall be transmitted in the format established by the American Society for Automation in Pharmacy (ASAP) telecommunications format for controlled substances.

(3) A pharmacist, dispensing prescriber, or veterinarian who dispenses controlled substances and who does not have an automated record-keeping system capable of producing an electronic report in the format established by subrule (2) of this rule may request a waiver from electronic reporting. The request shall be made in writing to the department.

(4) A pharmacist, dispensing prescriber, or veterinarian may be granted a waiver, if he or she demonstrates an inability to report as required by R 338.3162b and he or she agrees in writing to report the data to the department or the department's contractor by submitting a completed maps claim form as defined in R 338.3102(c) or transmitting data via an internet web portal that is provided by the Department or the Department's contractor for this purpose.

R 338.3162d Required reporting of prescription data; error reporting.

Rule 62d. (1) A pharmacist, pharmacy, dispensing prescriber, or veterinarian shall report all schedules 2 to 5 controlled substances dispensed beginning on the date that these amendatory rules take effect.

(2) The data required by R 338.3162b shall be forwarded by on-line transmission, computer diskette, compact disk, or other approved medium, as specified in R 338.3162c to the department or the department's contractor twice monthly, by the first calendar day and the 15th calendar day of each month immediately following the month in which the prescription was dispensed, and shall include the data for all controlled substances dispensed since the previous transmission or report. A pharmacist, pharmacy, dispensing prescriber, or veterinarian may choose 2 different dates to report each month, provided that they are within 2 calendar days of the first calendar day and the 15th calendar day of each month and they include all controlled substances dispensed since the previous transmission or report.

(3) For each pharmacist, pharmacy, dispensing prescriber, or veterinarian who does not have the capacity to forward the information as specified in R 338.3162b, the information shall be mailed or delivered to a location specified by the department or the department's contractor twice monthly by the first calendar day and the 15th calendar day of the month following the month in which the prescription was dispensed, and shall include the data for all controlled substances dispensed since the previous transmission or report. The pharmacist, pharmacy, dispensing prescriber, or veterinarian may choose 2 different dates to report each month provided they are within 2 days of the first calendar day and the 15th calendar day of each month and they include all controlled substances dispensed since the previous transmission or report.

(4) The department or the department's contractor shall notify a pharmacist, pharmacy, dispensing prescriber, or veterinarian of an error in data reporting. Upon receiving notification of an error in data reporting, a pharmacist, pharmacy, dispensing prescriber, or veterinarian shall take appropriate measures to correct the error and transmit the corrected data to the department or the department's contractor within 15 days of being notified of the error.

(5) A pharmacist, pharmacy, dispensing prescriber, or veterinarian who fails to report the dispensing of a prescription for a controlled substance listed in schedules 2 to 5 as

required, beginning on the date that these amendatory rules take effect, shall be subject to the penalty provisions in sections 16221, 17741, or 17768 in article 15 of the act.

R 338.3162e Exemption from reporting requirements.

Rule 62e. A pharmacist, dispensing prescriber, or veterinarian shall be exempt from the reporting requirements under the following circumstances:

- (a) When a controlled substance in schedules 2 to 5 is administered directly to a patient.
- (b) When a controlled substance in schedules 2 to 5 is dispensed from a health facility or agency licensed under article 17 of the act by a dispensing prescriber in a quantity adequate to treat a patient for not more than 48 hours.