DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BOARD OF PHARMACY

PHARMACY – CONTROLLED SUBSTANCES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the board of pharmacy by ~~sections 7201, 7219,~~ **sections** 7301~~,~~ and ~~16204e~~ **7333a of the public health code,** 1978 PA 368, MCL ~~333.7201, 333.7219,~~ 333.7301~~,~~ and ~~333.16204e~~ **333.7333a** and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3135 and R 338.3162b of the Michigan Administrative Code are amended, as follows:

R 338.3135 Opioids and other controlled substances awareness training standards for prescribers and dispensers of controlled substances; requirements.

Rule 35. (1) Pursuant to section ~~7301~~ **7303** of the act, MCL ~~333.7301~~ **333.7303**, an individual **who is applying for** ~~seeking~~ a controlled substance license or who is licensed to prescribe or dispense controlled substances shall complete a 1-time training, ~~offered after promulgation of this rule,~~ in opioids and controlled substances awareness that meets the following standards:

(a) Training content must cover all of the following topics:

(i) Use of opioids and other controlled substances.

(ii) Integration of treatments.

(iii) Alternative treatments for pain management.

(iv) Counseling ~~patients~~ on the effects and risks associated with using opioids and other controlled substances.

(v) The stigma of addiction.

(vi) Utilizing the Michigan Automated Prescription System (MAPS).

(vii) State and federal laws regarding prescribing and dispensing controlled substances.

(viii) Security features and proper disposal requirements for prescriptions.

(b) Topics covered under subrule (1)(a) of this rule may be obtained from more than 1 program.

(c) Acceptable providers or methods of training include any of the following:

(i) Training offered by a nationally recognized or state recognized health related organization.

(ii) Training offered by, or in conjunction with, a state or federal agency.

(iii) Training offered by a continuing education program or activity that is accepted by a licensing board established under article 15 of the act**, MCL 333.16101 to 333.18838**.

(iv) Training obtained in an educational program that has been approved by a board established under article 15 of the act**, MCL 333.16101 to 333.18838,** for initial licensure or registration, or by a college or university.

(d) Acceptable modalities of training include any of the following:

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

(2) A prescriber or dispenser shall ~~not~~ **only** delegate**, allow by a practice agreement,** or order the prescribing, dispensing, or administering of a controlled substance as authorized by this act to ~~an advanced practice registered nurse, registered professional nurse, or licensed practical nurse~~ **an individual who is licensed under article 15 of the act, MCL 333.16101 to 333.18838,** ~~unless the nurse complies~~ **who has complied** with **subrules (1) and (5) of** this rule.

(3) The department may select and audit licensees and request documentation of proof of completion of training. If audited, an individual shall provide an acceptable proof of completion of training, including either of the following:

(a) A completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name.

(b) A self-attestation by the individual that includes the date, provider name, name of training, and individual's name.

(4) **An individual who has been issued a controlled substance license, pursuant to section 7303 of the act, MCL 333.7303, shall complete the controlled substance training required by subrule (1) of this rule as follows:**

(a) A licensee who is renewing his or her controlled substance license shall complete the controlled substance training by the end of ~~The requirements specified in this rule apply to controlled substance license renewals beginning with~~ the first renewal cycle **that begins** after ~~the~~ **January 4, 2019**. ~~promulgation of this rule and for initial licenses issued after September 1, 2019~~.

(b) After September 1, 2019, an individual who is applying for an initial controlled substance license shall complete the controlled substance training prior to applying for licensure.

(5) An individual who is licensed under article 15 of the act, MCL 333.16101 to 333.18838, **who is a delegatee, or allowed by a practice agreement or an order to prescribe, dispense, or administer a controlled substance by a prescriber or dispenser as authorized by this act shall complete the controlled substance training required by subrule (1) of this rule as follows:**

(a) An individual who is renewing his or her license under article 15 of the act, MCL 333.16101 to 333.18838, shall complete the controlled substance training by the end of the first renewal cycle that begins after January 4, 2019.

(b) After September 1, 2019, an individual who is applying for an initial license under article 15, MCL 333.16101 to 333.18838, shall complete the controlled substance training prior to applying for licensure.

(6) An individual who is licensed under section 7303 the act, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals is exempt from this rule.

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

Rule 62b. (1) **Except as otherwise exempt under section 7333a of the act, MCL 333.7333a,** ~~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 **medication being dispensed is for** ~~patient is~~ an animal, positive identification of the animal's owner **(client)** that meets the requirements of R 338.3102(1)(f)(iv)**, and the animal's name**.

(b) ~~The name of the controlled substance dispensed.~~ **The patient's or client's name, including first name, middle name, or middle initial, if available, and last name.**

(c) The patient's or client's address, including street, city, state, and zip code.

(d) The patient's or client's phone number.

(e) The patient's or client's gender.

(f) The patient's or client's date of birth.

(g) The species code, as specified by asap.

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

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

~~(e)~~ **(j)** The date of issue of the prescription.

~~(f)~~ **(k)** The date of dispensing.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

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

~~(h)~~ **(o)** The prescription number assigned by the dispenser.

(p) The prescription transmission form code, as specified by asap, that indicates how the pharmacy received the prescription.

(q) The prescription payment type.

(r) The electronic prescription reference number, if applicable.

(s) The patient's or client's location code when receiving pharmacy services, as specified by asap.

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

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

(u) Beginning January 1, 2020, the first and last name of the patient, patient's representative, or client who is obtaining the dispensed controlled substance on behalf of the patient.

(v) Beginning January 1, 2020, the relationship of the patient, patient's representative, or client who is obtaining the dispensed controlled substance to the patient or animal who was prescribed the controlled substance.

(w) Beginning January 1, 2020, the identifier of the patient, patient's representative, or client who is obtaining the dispensed controlled substance on behalf of the patient. Any of the following may serve as an acceptable identifier:

(i) A Michigan driver's license number.

(ii) An identification number obtained from a photo identification card issued by this state.

(iii) The number zero. Zeroes shall be entered as the identification number if the positive identification presented by the patient, patient's representative or client who is obtaining the dispensed controlled substance on behalf of the patient does not include a license number or an identification number, as listed in this subdivision.

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