MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
AUGUST 6, 2019

The Michigan Board of Pharmacy Rules Committee Work Group, met on August 6, 2019, at 611 West Ottawa Street, Upper Level Conference Center Room 4, Lansing, Michigan 48933.

CALL TO ORDER

Andria Ditschman called the meeting to order at 2:04 p.m.

ATTENDANCE

Members Present: Charles Mollien, PharmD, JD
Kathleen Pawlicki, MS, FASHP
James Stevenson, PharmD

Members Absent: None

Staff Present: Andria Ditschman, Analyst, Boards and Committees Section
Douglas Padgett – Manager, MAPS Section
Stephanie Wysack, Board Support, Boards and Committees Section

Public Present: Adam Carlson – Michigan Health and Hospital Association
Nichole Cover – Walgreens Pharmacy
Deeb Eid – Self
Joe Osborne – Self
Sean Sorenson-Abbott – Michigan Health and Hospital Association

WELCOME

Ditschman stated that the public hearing for the Controlled Substance Rules was held on July 29, 2019. She indicated that only comments received from the public hearing can be discussed.

RULES DISCUSSION – A copy of the draft rules, revised pursuant to the meeting discussion, is attached.

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

Subrule (1)(viii): Ditschman read the comment made by Baran to clarify that security features and disposal requirements both refer to controlled substance prescriptions.

Pawlicki stated that security applied to both the drug product and the written prescriptions and didn't feel they should be separated into two provisions.

Stevenson stated that separating them could provide clarification.

Mollien asked where the list in section (1) came from. Ditschman stated that it came from the Department and was previously approved by the Board.

Mollien stated that security features applies to both the drug product and written prescriptions and proper handling applies to only the drug product.

The rule will read "Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.

The Rules Committee agreed with the proposed language.

Subrule (2): Ditschman read the comment made by Baran indicating (2) and (5) should be deleted.

Ditschman stated that the intent of the rule is not to limit the type of licensee who can dispense or prescribe, but to require a dispenser or prescriber from allowing others to take on the responsibility of dispensing or prescribing without having the training.

The Rules Committee disagreed with the comment to delete the provision for the reason that the training is in the best interest of the public. The rule does not authorize or limit the type of licensee who can dispense or prescribe.

Baran's comment was that not all individuals who administer controlled substance drugs are licensed under Article 15.

There was discussion regarding the delegation of dispensing and prescribing to other individuals who are licensed under other provisions of the Code, as well as those who are not licensed at all.

Mollien questioned who would be missed by using the term “individual” instead of individuals licensed under Article 15.

Pawlicki asked if who can be delegated to is defined or limited.

Ditschman stated that delegation can be to those licensed or unlicensed if the other requirements of delegation are met, and the Rules Committee can limit the rule to those licensed under Article 15 or broaden it.

Pawlicki stated that not all individuals will get something out of the training. Mollien and Stevenson agreed.

The Rules Committee agreed to change the language to broaden the requirement for the training to any “individual.” There was discussion regarding the rule and that the rule regulates those who have a controlled substance license. If a prescriber or dispenser with a controlled substance license does not follow the rule, they are subject to discipline for not checking to see that the person they delegated to had the training, not the unlicensed individual.

Provision (4)(b): Ditschman noted the comment made by McCoy and Baran, requesting a change in the effective date for additional time to comply with the rule.

Ditschman stated that the rule currently reads, “prior to applying” and it was not the intent that the applicant had to complete the training before filling out an application. She stated that the dates replaced the language in the existing rule.

Pawlicki stated that leaving the date of September 1, 2019 would cause panic as it is only a few weeks away.

Mollien suggested using language referencing the date of promulgation of the rule.

The language will read “Other than a license renewal under (a) of subsection (4), as of March 1, 2020, the department shall not issue a controlled substance license until an applicant provides proof of having completed the controlled substance training.

Subrules 5(a) and (b): Ditschman stated that the effective date for the individuals being delegated to should be reviewed. She asked the Rules Committee if they would like to use the effective date in the existing rule or use a longer timeframe.

The Rules Committee stated that (a) is fine as is.

Pawlicki pointed out that (b) is only for those individuals who are applying for licensure. A six-month timeframe should be provided.

It was suggested by the Rules Committee that the rule be simplified and not tied to licensure. Ditschman suggested using March 1, 2020 as providing an actual date provides clarity. Pawlicki and Stevenson agreed.

Pawlicki stated that the individuals being delegated to should have the same date as the individual delegating.

The Rules Committee agreed to use March 1, 2020.

Eid asked if the training currently existed. Ditschman stated that it is available so an individual could take it at any time. Ditschman also clarified that multiple trainings could be taken and combined to meet the requirement.

The Rules Committee recommended that the language read as follows: "beginning March 1, 2020, an individual who is a delegate, or allowed by a practice agreement or an order to prescribe or dispense a controlled substance by a prescriber or dispenser as authorized by the act, shall complete the controlled substance training required by subrule (1) of this rule.

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

Provision (1): Ditschman indicated that the Legislative Services Bureau (LSB) indicated that patient identifier is already defined within the rule, so "patient" should be removed from (b), (c), and (f). The Rules Committee disagreed. For clarity, the term "patient" will remain in the rule.

Provisions (1)(u), (v), and (w): Ditschman read through the comments made by multiple commenters asking that (u), (v), and (w) be deleted for various reasons. Baran also indicated that these provisions conflict with R 338.3162(2).

Mollien stated that there is no conflict. The MAPS system requires a patient identifier as a reporting requirement. The rule being compared to these provisions is an identification rule, not a MAPS reporting

Pawlicki stated that a nurse picking up a prescription for a patient, in a hospital setting, may not have a state ID on them. Therefore, using zeros would be used as the identifier.

Carlson stated that the "zero" wording is not referenced. Ditschman stated that it is already included in provision (1)(w).

Baran's comment indicated that the required updates to the system would be costly to the user and the law doesn't allow for additional costs. Mollien agreed with putting tools in providers hands to stop diversion. However, the burden and cost of collecting the data

does not outweigh the predicted benefit as there does not appear to be a clear connection between collection of this information and reducing death or diversion.

Mollien stated that dispensing is placing the product in a bottle and sealing it. Whereas reporting to MAPS is done when the prescription is picked up.

Mollien suggested requiring the pharmacy to document who picked up the prescription, just not reporting it to MAPS.

Mollien stated that he did not want to divert from MAPS's purpose and agreed with deleting (u), (v), and (w).

Stevenson stated that the statistical component had a valid point and he wanted the provisions to remain in the rule.

Pawlicki agreed with Stevenson because it could help address problems with prescribers, not necessarily the patients.

Mollien stated that entering this information is not going to help identify the prescriber.

Pawlicki asked how this information is being used.

Padgett stated that Appriss, the vendor, uses the information to identify a NARx score. The information collected from these provisions would help make the score more accurate. The NARx score is used by providers when prescribing to reduce abuse and can be used by MAPS to recognize diversion.

Padgett stated that public members are not being targeted. Capturing information on the individual picking up the prescription helps identify that the patient is not picking it up.

Sorenson-Abbott asked if the NARx score was used to investigate. Padgett stated that it is not used to investigate but it could be used as a tool in an investigation.

Mollien stated that the NARx score is used to decide who to dispense to and did not feel that it was a valid number. There is no clinical evidence to show that the NARx score works. In a health care clinical situation, the NARx score is not good data.

Padgett stated that it can be used as an indicator of potential abuse, not diversion.

Eid asked if the MAPS system could ask if it was the patient picking up. Padgett indicated that all requirements are needed that are listed in provisions (u), (v), and (w).

Eid asked if the individual picking up the prescription would be aware, or notified, how their information was being used. Mollien stated that they would if it was in the law.

Stevenson stated that the data will be a standard requirement with the American Society for Automation in Pharmacy (ASAP). Mollien verified the information being requested is included in the ASAP standards.

Mollien stated that there is no value in leaving provisions (1)(u), (v), and (w). Pawlicki agreed.

The Rules Committee agreed with the commenters to remove provisions (1)(u), (v), and (w).

The Rules Committee agreed with the comment that adding a definition of dispense or dispensing would clarify the rule.

ADJOURNMENT

Ditschman adjourned the meeting at 3:59 p.m.

Prepared by:
Stephanie Wysack, Board Support August 16, 2019
Bureau of Professional Licensing

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 7301 and 7333a of the public health code, 1978 PA 368, MCL 333.7301 and 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) An individual who is applying for a controlled substance license or who is licensed to prescribe or dispense controlled substances pursuant to section 7303 of the act, MCL 333.7303, shall complete a 1-time training, 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 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 for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.

(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 delegate, allow by a practice agreement, or order the prescribing or dispensing of a controlled substance as authorized by the act to an individual only after the individual 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 first renewal cycle that begins after January 4, 2019.

(b) Other than a license renewal under subdivision (a) of this subrule, as of March 1, 2020, the department shall not issue a controlled substance license until an applicant provides proof of having completed the controlled substance training.

(5) Beginning March 1, 2020, an individual who is a delegatee, or allowed by a practice agreement or an order to prescribe or dispense a controlled substance by a prescriber or dispenser as authorized by the act shall complete the controlled substance training required by subrule (1) of this rule.

(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 of the act, MCL 333.17701 to 333.17780, who dispenses a prescription drug that 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 dispensed:

(a) The patient identifier. For purposes of this subdivision, all of 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 must be entered as the identification number.

(iii) If the medication being dispensed is for an animal, the patient identifier includes 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 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.

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

(i) The national drug code number (NDC) of the controlled substance dispensed.

(j) The date of issue of the prescription.

(k) The date of dispensing.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

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

(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.

(t) The DEA registration number of the prescriber and 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, a patient's representative, or client is correct.

(3) As used in this rule, the term “dispense” or “dispensing” means the preparation, compounding, packaging, or labeling of a controlled substance with delivery of the controlled substance pursuant to a prescription or other authorization issued by a prescriber, and does not include the acts of prescribing a controlled substance or administering a controlled substance directly to a patient.