Administrative Rules for Pharmacy – Controlled Substances
Public Comment on Rule Set 2022-6 LR
Rose Baran Pharm. D.

Rule	**Issue**	**Suggested Change**
Rule 338.3102(~~e~~**d**)	Issue	Suggested Change
"~~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~~)~~ 4.1 Standard for Prescription Drug Monitoring Programs and contains the information specified in R 338.3162b.	ASAP 4.1 Standard is outdated. The current Standard is 4.2B. The 2023 version 5.0 to be implemented January 2024.	MAPS claim form" means a form, determined by the department~~,~~ that is in the format and includes the information as specified by the ASAP 5.0 Standard for Prescription Drug Monitoring Programs and contains the information specified in R 338.3162b.
Rule 338.3102(d**f**)	Issue	Suggested Change
"NDC" means a ~~National~~ **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 (~~FDCA**,** ~~) of 2017, 21 USC 360~~**21 USC 360.**	The definition in the Code of Federal Regulations 21 USC 207.33(a) does not have vendor. "The NDC for a drug is a numeric code. Each finished drug product or unfinished drug subject to the listing requirements of this part must have a unique NDC to identify its labeler, product, and package size and type."	Delete vendor in the definition.
Rule 338.3102(**h**)(iv)	Issue	Suggested change
A tribal government identification is used at pharmacies at or near a tribal nation.	Residents of a tribal nation may only have a tribal government issued identification. To make it clear that a tribal government issued identification can be used for MAPS.	Add (D) to 338.3102(**h**)(iv)(D) A tribal government identification number obtained from a tribal government issued identification.
Rule 338.3141 (3)	Issue	Suggested Change

Within 15 days ~~of~~ **after** completion of an investigation regarding a suspected theft or significant loss of a controlled substance, a licensee shall notify the department of the suspected theft or significant loss of a controlled substance and submit a copy of the DEA theft and loss report form 106, or equivalent document, to the department, whether or not the controlled substance is recovered or the responsible ~~person~~**individual** is identified and action is taken against ~~him or her~~**the responsible individual**, and whether or not it is also reported to the DEA.	The DEA has set a time period when the registrant must file the 106 form which is different from the state requirement. "21 USC 1301.74 (c) ….The registrant must also file a complete and accurate DEA Form 106 with the Administration through the DEA Diversion Control Division secure network application within 45 calendar days after discovery of the theft or loss……."	To be less confusing for licensees change the 15 days to 45 days.
Rule 338.3153(1)	Issue	Suggested Change
(1) For 2 years, a licensee shall maintain in the pharmacy ~~responsible for the automated device,~~ for review by the department, an agency, or the board, all records for controlled substances, including invoices~~,~~ **and** acquisition records~~, and sales receipts,~~ as follows:	The 2 year record keeping requirement conflicts with the Rule 338.583a(1) which requires 5 years.	Both rule sets are open. Change 338.3153(1) to 5 years.
Rule 338.3153(3)	Issue	Suggested Change
~~The~~**A** licensee shall keep the original prescription record ~~on site~~ for 5 years ~~from~~**after** the last date of dispensing. However, ~~after~~ 2 years ~~from~~**after** the last date of dispensing, ~~if an electronic duplicate is made of the original paper prescription, which becomes the original prescription, the original prescription may be destroyed~~ **a licensee may make an**	Controlled substance prescriptions must be kept on site. 21 CFR 1304.04(h) states paper prescriptions for Schedule II, III, IV and V controlled substances shall be maintained at the registered location in a separate prescription file. Deleting the on site would conflict with federal rules.	Leave on site in the rule.

electronic duplicate of the original paper prescription, which becomes the original prescription.		
Rule 338.3153(6)	Issue	Suggested Change
(6) A pharmacy that holds an additional license for an automated dispensing system that dispenses controlled substances shall store inventories and schedule 2 order forms at the licensed location of the automated device.	Schedule 2 order forms and controlled substance inventories are required by federal law to be stored at the pharmacy. Controlled substances in the automated dispensing system (ADS) belong to the pharmacy because the drugs are not considered dispensed until the ADS provides them, thus drugs in the ADS are counted as pharmacy inventory. Schedule 2 order forms (DEA 222 form) used to order the 2s for the ADS location belong to the pharmacy. The ADS at a different address than the pharmacy is not a pharmacy. See LARA's licensing guide for Controlled Substance Automated Device License.	Delete (6). The pharmacy is already required to maintain executed DEA 222 forms and controlled substance inventories. See Rule 338.3151(5) and 338.3153(1)
Rule 338.3161(6)	Issue	Suggested Change
(6) The professional designation for the prescribing practitioner must be stored electronically.	Stored electronically is vague. It could be stored in a separate computer or in a separate word file from the pharmacy's automated data processing system.	The professional designation for the prescribing practitioner must be stored electronically in the pharmacy's automated data processing system.
Rule 338.3162a	Issue	Suggested change
	Section 333.17754 no longer applies. Rule revised to meet 333.17754a.	See attached Rule 338.3162a in Attachment A.
Rule 338.3162b	Issue	Suggested Change
(a) The patient identifier identification number. ~~For purposes of~~**As used in** this subdivision, all of the following apply:	To add tribal government identification	(a) The patient identifier identification number. ~~For purposes of~~**As used in** this subdivision, all of the following apply:

(i) An identification number, as specified in R 338.3102~~(1)~~(f)(iv)(A) to (C), is not required for patients under the age of 16.		(i) An identification number, as specified in R 338.3102~~(1)~~(~~f~~**h**)(iv)(A) to (~~C~~**E**), is not required for patients under the age of 16.
Rule 338.3162c	Issue	Suggested Change
(2) The data must be transmitted in the format established by the ASAP 4.1 Standard for Prescription Drug Monitoring Programs	To bring it current with ASAP standard	(2) The data must be transmitted in the format established by the ASAP ~~4.1~~ 5 Standard for Prescription Drug Monitoring Programs.
Rule 338.3165(1)	Issue	Suggested change
(a) The prescriber shall deliver to the dispensing pharmacist a written prescription **postmarked within 7 days after the date the prescription was dispensed,** or electronically transmit the prescription ~~pursuant to~~**under** R 338.3162a. (c) The pharmacy shall notify the department if the prescriber fails to deliver to ~~him or her~~ **the pharmacy** either a written prescription or a prescription transmitted electronically.	DEA under 1306.11(d) only allows a written prescription for an oral emergency prescription not an electronic prescription.	(a) The prescriber shall deliver to the dispensing pharmacist a written prescription **postmarked within 7 days after the date the prescription was dispensed,** ~~or electronically transmit the prescription pursuant to~~**under** R 338.3162a. (c) The pharmacy shall notify the department if the prescriber fails to deliver to ~~him or her~~ **the pharmacy** ~~either~~ a written prescription ~~or a prescription transmitted electronically~~.
Rule 338.3183	Issue	Suggested Change
Delete entire rule.	The rule is confusing. If the intent of this rule is to allow a licensee to return controlled substances from whom they obtained the drug lawfully it is already allowed under rule 338.3153.	Delete entire rule.

Attachment A

R 338.3162a Electronic transmission of prescription; waiver of electronic transmission.

Rule 62a. (1) ~~Until the enforcement date established by the federal Centers for Medicare and Medicaid Services~~**CMS** ~~for the Medicare electronic transmission requirement, a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted~~

~~prescription, if all of the following conditions are satisfied:~~ **Effective on January 1, 2023 prescribers shall, unless an exception under section 17754a of the code, MCL 333.17754a, applies, electronically transmit a prescription and a pharmacist may dispense the electronically transmitted prescription, if all of the following conditions are satisfied:**

(a) The prescription is transmitted to the pharmacy of the patient's choice and occurs only at the option of the patient.

(b) The electronically transmitted prescription 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 electronic transmission.

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

(vi) Unless otherwise authorized under section 17754(1)(b) of the code, MCL 333.17754, the full name of the patient for whom the prescription is issued.

(vii) All other information that must be contained in a controlled substance prescription under R 338.3161.

(c) The pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

(d) All requirements in section 17754**a** of the code, MCL 333.17754**a**, are met.

(2) An electronically transmitted prescription that meets the requirements of subrule (1) of this rule is the original prescription.

(3) ~~Effective~~ **on** ~~the enforcement date established by the federal Centers for Medicare and Medicaid Services~~**CMS** ~~for the Medicare electronic transmission requirement, prescribers shall, unless an exception under section 17754a of the Code,~~ **code**, ~~MCL 333.17754a, applies, electronically transmit a prescription for a controlled substance consistent with both of the following requirements:~~

~~(a) All the requirements in section 17754a of the code, MCL 333.17754a, are met.~~

~~(b) All the requirements in R 338.3161 are met.~~

A prescriber applying for a waiver from section 17754a of the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and satisfy either of the following requirements:

(a) The prescriber provides evidence satisfactory to the department that the prescriber has received a waiver of the Medicare requirement for the electronic transmission of controlled substances prescriptions from the ~~federal Centers for Medicare and Medicaid Services~~**CMS**.

(b) The prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code, MCL 333.17754a, and the prescriber meets 1 of the following:

(i) ~~The prescription is dispensed by a dispensing prescriber.~~ The prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber.

(ii) The prescriber demonstrates by attesting to exceptional circumstances, including, but not limited to, the following:

(A) Prescribing fewer than 100 controlled substances prescriptions per year or the number of controlled substances prescriptions used in the ~~Federal Centers for Medicare and Medicaid Services~~**CMS** waiver for electronic transmission of prescriptions for controlled substances, whichever is more.

(B) **The prescriber has or intends within the next 12 months to no longer regularly practice their licensed profession for financial gain or as a means of livelihood**~~Intention to cease practice within the next twelve months~~.

(C) Limited practice due to an illness or other unforeseen event.

~~(iv)~~**(iii)** The prescriber issues prescriptions from a ~~non-profit charitable~~ **not-for-profit** medical clinic **that provides free or low-cost services to the public**.

(5) A waiver is valid for 2 years and ~~is applicable~~**applies** to the specific circumstances included in the application. A waiver may be renewed by application to the department.

Przybylo, Kerry (LARA)

From: BPL-BoardSupport
Sent: Thursday, October 5, 2023 3:29 PM
To: Shaltry, Jennifer (LARA); Przybylo, Kerry (LARA)
Subject: FW: Comments on proposed Pharmacy – Controlled Substances rule set

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From: Chludzinski, Paul <pchludz1@hfhs.org>
Sent: Thursday, October 5, 2023 3:19 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comments on proposed Pharmacy – Controlled Substances rule set

Comments on proposed Pharmacy – Controlled Substances rule set

For schedules:

Regarding the proposal to remove gabapentin as a Schedule 5 drug (R338.3111) to align with the federal scheduling and the majority of the states in the Great Lakes Region:

If the Public Health Code requires the board to schedule a substance if it has a potential for abuse (333.7203), and gabapentin presents a potential for abuse, shouldn't it remain a scheduled drug in Michigan?

- *Gabapentin Presents High Potential for Misuse* (November 2022). https://www.pharmacytimes.com/view/gabapentin-presents-high-potential-for-misuse
- *Gabapentin Abuse Potential* (June 2023), https://americanaddictioncenters.org/neurontin-abuse

For controlled substance prescriptions:

R338.3161(1)(b) does not require the prescriber's professional designation to be on a prescription, but R338.3161(6) states that the professional designation must be stored electronically.
If the prescriber isn't required to supply a professional designation on a prescription, how will a pharmacy identify and store it?

Thank you.
Paul Chludzinski, RPh
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Dear BPL:

I have reviewed the Controlled Substances rules and have the following suggestions:

1. **R 338.3111: Schedules; federal controlled substance schedules adopt by reference; exceptions.**

Subrule (3)(d) pertains to the definition of isomers. It needs clarification to avoid confusion with the chart.

Suggested language:

(d) Isomers:

The definition of the term "isomer" used in 21 CFR 1308.11, schedule 1, is modified to include any optical, positional, or geometric isomer. The definition of "isomer" used in 21 CFR 1308.12 to 1308.15, schedules 2 to 5, remains as set forth in 21 CFR 1300~~, which includes the optical, position, and geometric isomers~~.

2. **R 338.3132 pertains a controlled substance license.**

There are revisions to the protocol required for licensure for CS research and analytical labs. References to some of the CFR's are not needed as these do not apply and the inclusion causes confusion.

The suggested edits are below to eliminate confusion of what is required:

(5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with ~~his or her~~**the** application required under subrule (1) of this rule:

(a) The applicant's credentials to conduct the proposed research.

(b) The protocol and description of the nature of the proposed research that **contains the following information:** ~~is filed and approved by the FDA and the Federal Drug Enforcement Administration (DEA) pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~:

(i) Investigator:

(a) Name, address, and DEA registration number; if any.

(b) Institutional affiliation.

(c) Qualifications, including a curriculum vitae and an appropriate list of publications.

(ii) Research project:

(a) Title of project.

(b) Statement of the purpose.

(c) Name of the controlled substance or substances involved and the amount of each needed.

(d) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(e) Location where the research will be conducted.

(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143 and for dispensing the controlled substances in order to prevent diversion.

(g) If the investigator desires to manufacture any controlled substance, a statement of the quantity to be manufactured and the sources of the chemicals to be used.

(iii) Authority:

(a) Institutional approval.

(b) Approval of a Human Research Committee for human studies.
(c) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).
(d) Indication of an approved funded grant (number), if any.

(7) An applicant who intends to conduct chemical analysis involving controlled substances shall submit all of the following information with ~~his or her~~**the** application required under subrule (1) of this rule:
(a) The applicant's credentials to conduct the proposed chemical analysis.
(b) The protocol and description of the nature of the chemical analysis that **contains the following information:** ~~is filed and approved by the FDA and the DEA pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~

(1) Investigator:
(a) Name, address, and DEA registration number, if any.
(b) Institutional affiliation.
(c) Qualifications, including a curriculum vitae and an appropriate list of publications.
(2) Chemical analysis project:
(a) Title of project.
(b) Statement of the purpose.
(c) Name of the controlled substance or substances involved and the amount of each needed.
(d) Description of the chemical analysis and instructional activity to be conducted, and the duration of the project.
(e) Location where the chemical analysis will be conducted.
(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143.
(g) If the investigator desires to manufacture any controlled substance for analytical or instructional purposes, a statement of the quantity to be manufactured and the sources of the chemicals to be used.
(3) Authority:
(a) Institutional approval.
(b) Approval of a Human Research Committee for human studies.
(c) Indication of an approved funded grant (number), if any.

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

Due to the federal requirement of 8 hours of training for substance abuse and controlled substances, and the state's direction to accept the 8 hours training in lieu of the training required in this rule until the rule is modified, the rule language needs to be corrected to edit the training content for those licensees who are required to obtain a DEA registration in subrule(1)(a) to include only utilizing the MAPS and State and federal laws regarding prescribing and dispensing controlled substances.

The rule also needs to require others who do not get the DEA registration to meet all the subjects in the current rule and require the training for each cycle, not just a 1-time training.

Suggested Edits are in red.

Rule 35. (1) An individual who is applying for **or renewing** a controlled substance license ~~or who is licensed to prescribe or dispense controlled substances pursuant to~~**under** ~~section 7303 of the code, MCL 333.7303,~~ shall complete a ~~1 time~~ training in opioids and controlled substances awareness **before applying for the license or renewal. The training must meet** ~~that meets~~ the following standards:

(a) Training content must cover ~~all~~**both** 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 MAPS.

~~(vii)~~ **(ii)** 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 code, 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 code, 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~~**may** ~~not~~ delegate, allow by a practice agreement, or order the prescribing~~,~~ or dispensing of a controlled substance as allowed by the code to an individual, other than a physician's assistant, only after the individual has complied with ~~subrules~~ **subrule** ~~(1) and~~ (5) of this rule. A physician's assistant is subject to subrules (1), (3), and (4) of this rule.

(3) The department may select and audit licensees and request documentation of proof of completion of training. A licensee shall maintain proof of completion of training for 3 renewal periods plus 1 additional year. If audited, an individual shall provide an acceptable proof of completion of training, including ~~either~~**1** 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~~**under** section 7303 of the code, 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~~**a** 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, beginning September 1, 2019, the department shall not issue a controlled substance license until an applicant provides proof of having completed the controlled substance training.

(5) ~~Beginning December 31, 2021,~~ **Except as exempted under subrule (6) of this rule, veterinarians and an** individual, other than a physician's assistant, 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 allowed by the code, shall complete ~~the~~ **a** controlled substance training ~~required by subrule (1) of this rule.~~ **The training must be taken 1 time during the current license cycle. The training must cover ~~that covers~~ all of the following topics:**

(a) Use of opioids and other controlled substances.

(b) Integration of treatments.

(c) Alternative treatments for pain management.

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

(e) The stigma of addiction.

(f) Utilizing the MAPS.

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

(h) Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.

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

Sincerely,

Martha O'Connor