AGENCY REPORT TO THE JOINT COMMITTEE ON ADMINISTRATIVE RULES (JCAR)

Under the Administrative Procedures Act (APA), 1969 PA 306, the agency that has the statutory authority to promulgate the rules must complete and submit this form electronically to the Michigan Office of Administrative Hearings and Rules (MOAHR) at MOAHR-Rules@michigan.gov.

1. Agency Information:

Agency name:	Department of Licensing and Regulatory Affairs
Division/Bureau/Office:	Bureau of Professional Licensing
Name, title, phone number, and e-mail of person completing this form:	Andria M. Ditschman Senior Policy Analyst 517-241-9255 DitschmanA@michigan.gov
Name of Departmental Regulatory Affairs Officer reviewing this form:	Liz Arasim Department of Licensing and Regulatory Affairs

2. Rule Set Information:

MOAHR assigned rule set number:	2019-057-LR
Title of proposed rule set:	Board of Pharmacy – Controlled Substances

3. Purpose for the proposed rules and background:

The purpose of the Pharmacy - Controlled Substances Rules is to regulate the schedules, licenses, security, records, dispensing and administering, prescriptions, distributions, and administrative and disciplinary procedures for controlled substances. The draft rules will: clarify R 338.3135, which requires an individual applying for a controlled substance license and 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, to complete a 1-time training on opioids and controlled substances awareness; and add requirements to R 338.3162b, which requires a pharmacist, dispensing prescriber, and veterinarian licensed in Michigan, to report data to an electronic drug monitoring system when they dispense schedule 2 to 5 controlled substances.

4. Summary of proposed rules:

R 338.3135: This proposed rule requires a prescriber or dispenser to delegate, allow by a practice agreement, or order the prescribing or dispensing of a controlled substance, as authorized by the Public Health Code to an individual only after he or she has complied with the training and timing requirements in the rule. The proposed rule deletes the training for individuals who are delegated the administering of controlled substances; provides an exemption for individuals who are licensed to prescribe or dispense controlled substances only for research on animals; extends the effective date of the rule to March 1, 2020 for all initial controlled substance license applicants, and for all individuals who are delegated to, allowed by a practice agreement, or ordered to prescribe or dispense a controlled substance by a prescriber or dispenser.

R 338.3162b: This proposed rule requires a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5, or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state to report the following information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by the American Society for Automation in Pharmacy (ASAP); number of

refills authorized; refill number of the prescription fill; prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; prescription payment type; electronic prescription reference number, if applicable; and patient's or client's location code when receiving pharmacy services, as specified by ASAP. In addition, beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, patient's representative, or client who is obtaining the dispensed controlled substance on behalf of the patient or animal will be required. The information being added to the list of information that must be reported will enhance the state Prescription Drug Monitoring Program, as collecting additional identifying information on a patient, their representative, or client (animal's owner) will decrease diversion and substance abuse, and allow users of the database to assess overdose risk.

5. List names of newspapers in which the notice of public hearing was published and publication dates (attach copies of affidavits from each newspaper as proof of publication).

Marquette Mining Journal – July 15, 2019
Flint Journal – July 14, 2019
Grand Rapids Press – July 14, 2019

6. Date of publication of rules and notice of public hearing in *Michigan Register:*

July 15, 2019, Issue No. 12

7. Time, date, location, and duration of public hearing:

July 29, 2019
9:00 a.m. – 9:25 a.m.
G. Mennen Williams Building Auditorium
525 W. Ottawa Street
Lansing, Michigan 48909

8. Provide the link the agency used to post the regulatory impact statement and cost-benefit analysis on its website*:*

https://dtmb.state.mi.us/ORRDocs/RIS/1953_2019-057LR_ris.pdf

9. List of the name and title of agency representative(s) attending public hearing:

Andria Ditschman, Senior Policy Analyst

10. Persons submitting comments of support:

11. Persons submitting comments of opposition:

Rose Baran, Pharm.D., MA, Assistant Professor, College of Pharmacy, Ferris State University
Adam Carlson, Senior Director, Government & Political Affairs, Michigan Health & Hospital Association (MHA)
Joel Kurzman, Director, State Government Affairs, National Association of Chain Drug Stores (NACDS)
Mary Anne McCoy, PhD, RN, ACNS, ACNP-BC, FAANP, President, Michigan Council of Nurse Practitioners (MICNP)

Michigan Office of Administrative Hearings and Rules
611 West Ottawa Street; 2nd Floor, Ottawa Building
Lansing, MI 48933
Phone: (517) 335-8658 FAX: (517) 335-9512

12. Identify any changes made to the proposed rules based on comments received during the public comment period:

	Name & Organization	Comments Made at Public Hearing	Written Comments	Agency Rationale for Change	Rule Number & Citation Changed
1.	Rose Baran, Ferris State University	Same comments as sent in letter with email dated July 25, 2019.	Letter sent with email dated July 25, 2019: Modify (viii) and add (ix) to clarify that security features and disposal requirements both refer to controlled substance prescriptions, as follows: (viii) Security features of a controlled substance prescription.(ix) Proper disposal for dispensed controlled substance prescriptions. Delete (2) and (5) as the Board of Pharmacy does not have the authority to mandate this training of licensees who only administer controlled substances, who do not hold a controlled substance license under Article 7 and are not licensed by the Board of Pharmacy. Further, not all individuals who administer controlled substances are licensed under Article 15, such as emergency medical technicians who are licensed under Article 17 and unlicensed individuals who administer	To clarify that "security features" applies to both the prescription and opioids or other controlled substances, and "proper disposal" applies to opioids and other controlled substances and not a prescription. The burden of requiring all individuals that administer controlled substances to take the training does not outweigh the benefit when the alternatives to prescribing the controlled substance has already been evaluated by the prescriber. Article 15 licensees are not the only individuals that are delegated to, included in a practice agreement, or ordered to prescribe or dispense a controlled substance. There are	R 338.3135(1) R 338.3135(2) and (5)

			drugs in physician's offices. Section (2) can be read to limit a prescriber or dispenser from delegating, allowing by practice agreement, or ordering only to those licensed under Article 15. Modify the effective date from September 1, 2019, to January 4, 2021, to provide additional time to new applicants to comply with the rule. If left as currently drafted, those in the application process would have to stop their application process and obtain the training. Insert an "a" before pharmacist.	unlicensed individuals that may be delegated to as well as licensees under Article 17. Further the rule was not intended to limit delegation only to Article 15 licensees. Although applicants for a controlled substance license have been on notice even before the existing rule went into effect in January of 2019 that the training was required as of September 1, 2019, as there are individuals that will be delegated to that were not included in the existing rule, for consistency, the training will be required beginning March 1, 2020, except for renewal of controlled substances licensees. Typographical error.	R 333.3135(4) R 338.3162b(1)
2.	Mary Anne McCoy, MICNP		Letter dated July 23, 2019: The commenter is requesting that due to the addition of the language "prior to the application for licensure," that the September 1, 2019 date be modified to January 1, 2020 to provide adequate notice to licensure applicants that they must take the training.	Although applicants for a controlled substance license have been on notice even before the existing rule went into effect in January of 2019 that the training was required as of September 1, 2019, as there are individuals that will be delegated to that were not included in the existing rule, for consistency, the training will be required beginning March 1, 2020, except for renewal of controlled substances licensees.	R 333.3135(4)
3.	Adam Carlson,		Letter dated July 29, 2019:		

	MHA		There is confusion amongst licensees regarding the definition of “dispense” and “dispensing” as it relates to the requirement to report to MAPS. Section 7333a of the Code requires reporting of dispensing schedule II-V controlled substances, however, the definition of “dispense” in Article 7, Controlled Substances, of the Code, is defined as “to deliver or issue a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, or compounding necessary to prepare the substance for the delivery or issuance.” The Department requires reporting only for the preparation, compounding, packaging, or labeling with delivery to the ultimate user. The commenter is suggesting the addition of the following language: (3) As used in this rule, the term “dispense” or “dispensing” shall mean the preparation, compounding, packaging, or labeling of a controlled substance with delivery of the controlled substance to the ultimate user, pursuant to a prescription or other authorization issued by a prescriber, and shall not include the acts of prescribing controlled substance or administering controlled substance directly to a patient.	For clarification “dispense” and “dispensing” as used in this rule is defined so those regulated by the rule understand that it does not include administration or prescribing a controlled substance and they must report at the time the controlled substance is delivered, not at the time it is prepared, compounded, packaged, or labeled.	R 338.3162b(3)
4.	The rules				

	submitted in the report incorporate LSB edits.				

13. Date report completed:

August 14, 2019

STATE OF MICHIGAN)
County of Genesee ss Dawn Suttorp

Being duly sworn deposes and say he/she is Principal Clerk of

THE FLINT JOURNAL
DAILY EDITION

a newspaper published and circulated in the County of Genesee and otherwise qualified according to Supreme Court Rule; and that the annexed notice, taken from said paper, has been duly published in said paper on the following day(days)

July 14 A.D. 20 19

Sworn to and subscribed before me this 15th day of July 2019

Janice M. DeGraaf
JANICE M. DEGRAAF
NOTARY PUBLIC, STATE OF MI
COUNTY OF KENT
MY COMMISSION EXPIRES Oct 3, 2020
ACTING IN COUNTY OF Kent

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing

NOTICE OF PUBLIC HEARING

July 29, 2019 9:00 a.m.

Location: G. Mennen Williams Building Auditorium
525 W. Ottawa Street, Lansing, Michigan

The hearing is held to receive public comments on the following administrative rules:

Board of Pharmacy – Controlled Substances (ORR #2019-057 LR)

Authority: MCL 333.7301; MCL 333.7333a; MCL 338.3501; MCL 445.2001; MCL 445.2011; and MCL 445.2030.

Overview: The proposed changes include: requiring an opioid and controlled substances awareness training for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee; exempting an individual who is licensed under MCL 333.7303 to prescribe or dispense controlled substances only for research on animals from having to attend the opioid and controlled substances awareness training; and requiring a pharmacist, dispensing prescribers who dispense a controlled substance listed in schedules 2 to 5, or a pharmacy licensed by this state that dispenses in this state or to an address in this state to report the following information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; the patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by the American Society for Automation in Pharmacy (ASAP); the number of refills authorized; the refill number of the prescription fill; the prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; the prescription payment type; the electronic prescription reference number, if applicable; the patient's or client's location code when receiving pharmacy services, as specified by ASAP; and beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, the patient's representative, or the client who is obtaining the dispensed controlled substance on behalf of the patient or animal.

The rules will take effect immediately upon filing with the Secretary of State, unless specified otherwise in the rules. Comments on the proposed rules may be presented in person at the public hearing. Written comments will also be accepted from date of publication until **5:00 p.m. on July 29, 2019**, at the following address or e-mail address:

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing– Boards and Committees Section
P.O. Box 30670
Lansing, MI 48909-8170
Attention: Policy Analyst Email: BPL-BoardSupport@michigan.gov

A copy of the proposed rules may be obtained by contacting Board Support at (517) 241-7500 or the email address noted above. Electronic copies also may be obtained at the following link:

https://dtmb.state.mi.us/ORRDocs/ORR/1953_2019-057LR_orr-draft.pdf

The meeting site and parking are accessible to people with disabilities. Individuals attending the meeting are requested to refrain from using heavily scented personal care products, in order to enhance accessibility for everyone. People with disabilities requiring additional accommodations (such as materials in alternative format) in order to participate in the meeting should call (517) 241-7500.

RECEIVED
JUL 17 2019
LARA

STATE OF MICHIGAN)
County of Kent
and County of Ottawa

ss Dawn Sutton

RECEIVED
JUL 18 2019
LARA

Being duly sworn deposes and say he/she is Principal Clerk of

THE GRAND RAPIDS PRESS
DAILY EDITION

a newspaper published and circulated in the County of Kent and the County of Ottawa and otherwise qualified according to Supreme Court Rule; and that the annexed notice, taken from said paper, has been duly published in said paper on the following day(days)

July 14 A.D. 20 19

Sworn to and subscribed before me this 15th day of July 20 19

Janice M. DeGraaf
JANICE M. DEGRAAF
NOTARY PUBLIC, STATE OF MI
COUNTY OF KENT
MY COMMISSION EXPIRES Oct 3, 2020
ACTING IN COUNTY OF Kent

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing

NOTICE OF PUBLIC HEARING

July 29, 2019 9:00 a.m.

Location: G. Mennen Williams Building Auditorium
525 W. Ottawa Street, Lansing, Michigan

The hearing is held to receive public comments on the following administrative rules:

Board of Pharmacy – General Rules (ORR #2019-057 LR)

Authority: MCL 333.7801, MCL 333.7333a, MCL 338.3501, MCL 445.2001, MCL 445.2011, and MCL 445.2030.

Overview: The proposed changes include: requiring an opioid and controlled substances awareness training for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee; exempting an individual who is licensed under MCL 333.7303 to prescribe or dispense controlled substances only for research on animals from having to attend the opioid and controlled substances awareness training; and requiring a pharmacist, dispensing prescribers who dispense a controlled substance listed in schedules 2 to 5, or a pharmacy licensed by this state that dispenses in this state or to an address in this state to report the following information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; the patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by the American Society for Automation in Pharmacy (ASAP); the number of refills authorized; the refill number of the prescription fill; the prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; the prescription payment type; the electronic prescription reference number, if applicable; the patient's or client's location code when receiving pharmacy services, as specified by ASAP; and beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, the patient's representative, or the client who is obtaining the dispensed controlled substance on behalf of the patient or animal.

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Bureau of Professional Licensing– Boards and Committees Section
P.O. Box 30670
Lansing, MI 48909-8170
Attention: Policy Analyst Email: BPL-BoardSupport@michigan.gov

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RECEIVED
JUL 19 2019
DEPARTMENT OF LICENSING & REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARDS & COMMITTEES SECTION

The Mining Journal

Upper Michigan's Largest Daily Newspaper

249 W. Washington St., P.O. Box 430, Marquette, Michigan 49855. Phone (906)228-2500. Fax (906)228-3273

AFFIDAVIT OF PUBLICATION

STATE OF MICHIGAN

AFFIDAVIT OF PUBLICATION

For the County of **MARQUETTE**

In the matter of: Notice of Public Hearing
July 29, 2019
Department of Licensing and Regulatory Affairs
Board of Pharmacy – Controlled Substances

Size: 2 x 10

State of **MICHIGAN,** County of Marquette ss.

GERALD NEWHOUSE

being duly sworn, says that he is

CIRCULATION MANAGER

of **THE MINING JOURNAL**

a newspaper published and circulated in said county and otherwise qualified according to Supreme Court Rule; that annexed hereto is a printed copy of a notice which was published in said newspaper on the following date, or dates, to-wit

July 15, 2019

Gerald Newhouse

GERALD NEWHOUSE

Subscribed and Sworn to before me this 16th day of July 2019.

Holly Gasman

HOLLY GASMAN
Notary Public for Marquette County, Michigan
Acting in the County of Marquette
My commission expires: May 25, 2025

cist.

"He was ready to end it," Bartley said. "I think this was a suicide. But then he was able to kind of do it in a way that spoke to his political beliefs. I know he went down there knowing he was going to die."

Van Spronsen was accused of assaulting a police officer during a protest outside the detention center in 2018, The News Tribune reported.

mostly immigrant.

While federal immigration officials were mum on details, agents had been expected to start a coordinated action Sunday targeting roughly 2,000 people, including families, with final deportation orders in 10 major cities, including Chicago, Los Angeles, New York and Miami.

Activists and city officials reported some U.S. Immigration and Customs Enforcement activity in New York

been routine since 2003, themselves sanctuaries.

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
NOTICE OF PUBLIC HEARING
July 29, 2019
9:00 a.m.

Location: G. Mennen Williams Building Auditorium
525 W. Ottawa Street, Lansing, Michigan
The hearing is held to receive public comments on the following administrative rules:

Board of Pharmacy – Controlled Substances
(ORR #2019-057 LR)

Authority: MCL 333.7301; MCL 333.7333a, MCL 338.3501; MCL 445.2001; MCL 445.2011; and MCL 445.2030.

Overview: The proposed changes include: requiring an opioid and controlled substances awareness training for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee; exempting an individual who is licensed under MCL 333.7303 to prescribe or dispense controlled substances only for research on animals from having to attend the opioid and controlled substances awareness training; and requiring a pharmacist, dispensing prescribers who dispense a controlled substance listed in schedules 2 to 5, or a pharmacy licensed by this state that dispenses in this state or to an address in this state to report the following information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; the patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by the American Society for Automation in Pharmacy (ASAP); the number of refills authorized; the refill number of the prescription fill; the prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; the prescription payment type; the electronic prescription reference number, if applicable; the patient's or client's location code when receiving pharmacy services, as specified by ASAP; and beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, the patient's representative, or the client who is obtaining the dispensed controlled substance on behalf of the patient or animal.

The rules will take effect immediately upon filing with the Secretary of State, unless specified otherwise in the rules. Comments on the proposed rules may be presented in person at the public hearing. Written comments will also be accepted from date of publication until **5:00 p.m. on July 29, 2019**, at the following address or e-mail address:

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing– Boards and Committees Section
P.O. Box 30670
Lansing, MI 48909-8170
Attention: Policy Analyst
Email: BPL-BoardSupport@michigan.gov

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STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BUREAU OF PROFESSIONAL LICENSING

PUBLIC HEARING

Re: Board of Pharmacy
Controlled Substances
ORR #2019-057 LR

July 29, 2019

9:00 - 9:25 a.m.

Location: G. Mennen Williams Building Auditorium
525 West Ottawa Street
Lansing, Michigan

REPORTED BY: Claudia W. Weekly, CSR-2963

MS. DITSCHMAN: Okay. We're going to open the public hearing. It's 9:00 o'clock. My name is Andria Ditschman. I'm an analyst for the Bureau of Professional Licensing in the Department of Licensing and Regulatory Affairs and I will be facilitating the hearing today.

This is a public hearing on proposed administrative rules entitled Board of Pharmacy, Controlled Substances. And the hearing is being conducted under the authority of the Administrative Procedures Act, Public Act 306 of 1969 on behalf of the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing.

The hearing is being held to order at 9:00 a.m. on July 29th, 2019 at the G. Mennen Williams Building auditorium located at 525 West Ottawa Street in Lansing, Michigan. The notice of a public hearing was published in three newspapers of general circulation, as well as the Michigan Register, Issue Number 12, published on July 15th, 2019.

We are here today for you to offer your data, views, questions, and comments on the proposed rules. If you wish to speak, please make sure that you have signed in and indicated your willingness to speak. You may use the cards provided in the lobby for that purpose. If you'd like to testify and have not signed in, please do

so now. For those of you who do not wish to sign in with a card, you may speak at the microphone once we have exhausted the stack of cards submitted.

If you have comments, please make sure that they relate directly to the proposed rules. If you have suggested changes to the proposed rules, please include specific reasons why you're making those changes and why they're in the public interest.

For the record, when you testify please identify yourself by name and organization, if any, that you may be speaking for today, and this will help the department prepare the hearing record that goes before the Board. Written statements can be submitted directly to me at the table if you have those today. The department will also accept written statements that are e-mailed or postmarked until 5:00 p.m. today.

The department staff from the Bureau includes myself and Stephanie Wysack, who's out in the hall assisting me today.

So, we're going to start with the cards. I think you probably want this on. We're using the microphone. So, the microphone is over on the table. I'll get that for you. And the first card I have is from Brian Sapita.

MR. SAPITA: I was just filling one out in case

there was a discussion in groups.

MS. DITSCHMAN: You don't want to speak directly?

MR. SAPITA: No. Sorry about that.

MS. DITSCHMAN: So, Rose?

MS. BARAN: Good morning. Rose Baran. I'm a pharmacist and I'm representing myself, with all the experience I have as a pharmacist.

My comments are regarding Rule 338.3135(1)(a)(viii), which says security features and proper disposal requirements for prescriptions. This should be changed to read in (viii) security features of a controlled substance prescription, and then adding a (ix), proper disposal for dispensed controlled substance prescriptions.

The way this is currently written it refers to the actual paper prescription, electronic, or verbal prescription and not the prescription that's been dispensed to the patient. I think that's the intent here is for proper disposal information be given to a patient with what to do with Controlled Substances they no longer need.

In that same Rule 338.3135(2) that whole Section 2 should be deleted. And this reads a prescriber or dispenser shall only delegate, allow by practice

agreement, or order the prescribing, dispensing, or administering of a controlled substance as authorized by this act to an individual who is licensed under Article 15 of the Act, MCL 333.16101 to 333.18838, who has complied with Subrules 1 and 5 of this rule.

My argument is the Board of Pharmacy has no authority under MCL 333.7301 to mandate this training of licensees who only administer controlled substances. A licensee to be regulated and/or disciplined by the Board of Pharmacy would need to be licensed under the Board of Pharmacy. MCL 333.7301 states the administrator may promulgate rules relating to the licensure and control of the manufacture, distribution, prescribing of controlled substances included in Schedule 2, and dispensing of controlled substances in this State. Administering a controlled substance is not included in 333.7301, and neither is administering included in the definition of distribute in 333.7105, which means to deliver other than by administering or dispensing a controlled substance.

So, MCL 333.7303 states a person who manufacturers, distributes, prescribes, or dispenses a controlled substance in this state or who proposes to engage in the manufacture, distribution, prescribing, or dispensing of a controlled substance in this state shall obtain a license issued by the administrator in

accordance with the rules. So, a person who is only administering a controlled substance is not required to get a license issued by the Board of Pharmacy.

Also, not all individuals who administer controlled substances are licensed under Article 15. Emergency medical technicians are licensed under Article 17, not Article 15. And according to this draft rule, a prescriber or dispenser could only delegate to an individual licensed under Article 15. Thus, EMTs would not be able to administer controlled substances. This will be an issue for patients being treated by EMTs in ambulances and emergency rooms. And there may also be unlicensed individuals such as medical assistants in physicians' offices who administer controlled substances, and they also would not be able to continue to do so.

For these same very reasons Rule 338.3135(5) should also be deleted.

Rule 338.3135(4)(b) states after September 1st, 2019, an individual who is applying for an initial controlled substance license shall complete the controlled substance training prior to applying for licensure. Change this date to January 4th, 2021. This would give time to implement so new applicants that would know they have to have the training before they start the application process. If left as currently drafted, those

in the application process would have to stop their application process and obtain the training.

Rule 338.3162b(1). Except as otherwise exempt under Section 7333a of the Act, MCL 333.7333a, pharmacist. Insert a small A before pharmacist. It's just grammar.

My last comment is on Rule 338.3162b(1)(u), (v), and (w). I won't read those in detail. They are in my written comments. There are a number of reasons (1)(u), (v) and (w) from Rule 338.3162b should be deleted. The first of these, this is in conflict with the current rule 338.3162(2), which states a pharmacist shall require positive ID 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. When positive ID is not available and a pharmacist, who in exercising his or her professional judgment, determines that a delay in the dispensing the controlled substance may be detrimental to a patient.

Subdivision (a) of this rule does not exempt a pharmacist from the requirement to submit a patient identifier, as defined in Rule 338.3102(1)(f). This would have two rules that are in conflict with each other, causing confusion.

The second reason is this rule does not address or give an exemption for circumstances where the person who's obtaining the prescription for the patient is not known to the pharmacy at the time of dispensing. For example, when the patient is in a nursing home, assisted living, or hospice, or delivery to the patient address, or mailed to a patient address. At this point the pharmacist does not know who's obtaining the prescription on behalf of the patient.

The third reason these should be exempt or deleted is depending on the pharmacy software, pharmacies will be submitting this information to MAPS the day the prescription is dispensed. However, if the prescription is not picked up on the day the prescription is dispensed the pharmacy will have to go back and correct the information that was sent to MAPS. The pharmacy incurs an extra cost to make this correction.

According to MCL 333.7333a(1), the pharmacy is not to incur any additional costs solely related to the transmission of data to the department. Also, in the regulatory impact statement for these rules the department states there may be an additional cost to a user of the Prescription Drug Monitoring Program to modify their system to allow for collection of the additional information. The department is acknowledging

there will be an extra cost; thus, not in compliance with MCL 333.7333a(1).

The last reason. Pharmacies that need to change software, again an added extra cost, will not be able to have the ability to electronically send the information in (u), (v) and (w) by January 1, 2020 because reprogramming software takes time, and if time is an issue the reprogramming comes at a higher cost. Also, in the regulatory impact statement for these rules the department states there may be an additional cost to a user of the Prescription Drug Monitoring Program to modify their system to allow for collection of the additional information. And the department is acknowledging that there will be an extra cost; thus, not in compliance with 333.7333a(1).

Thank you.

MS. DITSCHMAN: Would anyone else like to comment on the rules?

All right. We're going to take a recess for the public hearing just to make sure that no one else appears to comment on the rules. If you have any questions -- do you have any questions about the rules?

MR. GAROFALO: I do. It doesn't pertain specifically to this, though. That's why -- the question I have is --

MS. DITSCHMAN: Just a second here. Go ahead and state your name.

MR. GAROFALO: I'm sorry. Anthony Garofalo. I live in Allegan, Michigan. And I have a question because it affects me personally. The Pharmacy Board I thought was going to be here today. And they passed a rule about three months ago about a certain drug that I take for an ailment that I have that now is a Schedule 5, and I wanted to know what the process is, how does the Pharmacy Board go about doing this to people that are innocent of any crimes to help the people who are taking illegal drugs. Do they ever have meetings where they're all here?

MS. DITSCHMAN: So, this is Andria on the record. And I think you're probably referring to Gabapentin.

MR. GAROFALO: I am.

MS. DITSCHMAN: And so, this is just a public hearing just for this small set of rules. The Board will meet again, it's August either 8th or the 5th. It's coming up. It's in about a week and-a-half. And if you want to leave your information for me I can get back in touch with you and give you details. And the whole Board will be there at that time and you can make a public comment at that time about your concerns and why you

think there should be a modification.

Also, there was some legislation regarding Gabapentin. I don't know if that's pending still or what happened with that. I think it is. So, there may be a change there as well. But you're right, that's not what today is for, but if you will leave me some information I will give you -- if you will leave it on the table there I will get you the information as to when you can come and talk to the Board.

MR. GAROFALO: Thank you very much.

MS. DITSCHMAN: Sure. All right. Any other comments on the Controlled Substances Rules?

All right. We're going to recess the public hearing for now for a few minutes and probably for about ten minutes to see if anybody else shows up. Thank you for attending.

(Short recess had from 9:16 AM to 9:24 AM.)

MS. DITSCHMAN: Okay. Any more public hearing, comments on the Controlled Substance Rules?

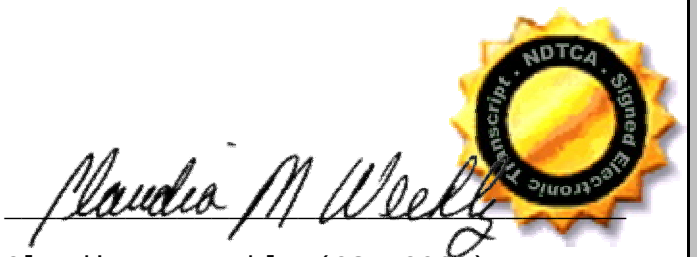
I don't see any here, so if there's no further comments at this time we'll close the hearing. The record will remain open until 5:00 p.m. today for any additional comments that anyone wishes to share. And thank you for coming.

(Hearing concluded at 9:25 AM.)

CERTIFICATE

STATE OF MICHIGAN)
)
COUNTY OF INGHAM)

I, Claudia M. Weekly, Certified Shorthand Reporter, do hereby certify that I reported stenographically the proceedings had in the above entitled matter, at 525 West Ottawa Street, Lansing, Michigan, on July 29, 2019; and do further certify that the foregoing transcript constitutes a true and correct record of my stenotype notes.



Claudia M. Weekly (CSR-2963)
Notary Public, Genesee County, MI
My commission expires: March 6, 2025

Dated: July 30, 2019

Ditschman, Andria (LARA)

From:	BPL-BoardSupport
Sent:	Thursday, July 25, 2019 2:42 PM
To:	Ditschman, Andria (LARA)
Subject:	FW: Comments on Rules Board of Pharmacy Controlled Substances (ORR #2019-057LR)
Attachments:	CSRuleCommentJune192019.docx

Thank you,
Stephanie Wysack
Departmental Technician
Boards and Committees Section
Bureau of Professional Licensing
Michigan Department of Licensing and Regulatory Affairs
Phone: 517-241-7500
Email: BPL-BoardSupport@michigan.gov

From: Rose M Baran <RoseBaran@ferris.edu>
Sent: Thursday, July 25, 2019 2:40 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comments on Rules Board of Pharmacy Controlled Substances (ORR #2019-057LR)

Department of Licensing and Regulatory Affairs

Bureau of Professional Licensing-Boards and Committees Section

P.O. Box 30670

Lansing, MI 48909-8170

Attention: Policy Analyst

Please find attached the comments on the Rules for the Board of Pharmacy - Controlled Substances (ORR#2019-057 LR).

Sincerely,

Rose Baran

Rose Baran PharmD, MA
Assistant Professor, College of Pharmacy
Ferris State University,
25 Michigan NE, Suite 7000
Grand Rapids, MI 49503
Phone: 231-349-8065 Fax: 616-454-2108

Comments on Board of Pharmacy Rules 2019-057-LR Pharmacy Controlled Substances
Rose Baran Pharm.D.

Rule 338.3135(1)(a)(viii) Security features and proper disposal requirements for prescriptions.

Change this to read:
(viii) security features of a controlled substance prescription.
(ix) Proper disposal for dispensed controlled substance prescriptions.

The way it is currently written, it refers to the actual paper, electronic, or verbal prescription and not the proper disposal of the controlled substance drugs dispensed to a patient.

Rule 338.3135(2) should be deleted.
(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.

The Board of Pharmacy has no authority under MCL 333.7301 to mandate this training of licensees who only administer controlled substances. A license to be regulated and/or disciplined by the Board of Pharmacy would need to be licensed under the Board of Pharmacy. MCL 333.7301 states "the administrator may promulgate rules relating to the licensure and control of the manufacture, distribution, prescribing of controlled substances included in schedule 2, and dispensing of controlled substances in this state." Administering a controlled substance is not included in 333.7301 and neither is administering included in the definition of "distribute" in 333.7105 "means to deliver other than by administering or dispensing a controlled substance." MCL 333.7303(1) states "A person who manufactures, distributes, prescribes, or dispenses a controlled substance in this state or who proposes to engage in the manufacture, distribution, prescribing, or dispensing of a controlled substance in this state shall obtain a license issued by the administrator in accordance with the rules."…. A person who is only administering a controlled substance is not required to get a license issued by the Board of Pharmacy.

Also, not all individuals who administer controlled substances are licensed under Article 15. Emergency Medical Technicians (EMT) are licensed under Article 17 not Article 15. According to this draft rule, a prescriber or dispenser could only delegate to an individual licensed under Article 15 thus EMTs would not be able to administer controlled substances. This will be an issue for patients being treated by EMTs in ambulances and emergency rooms. There also may be unlicensed individuals such as medical assistants in physician's offices who administer controlled substances and they also would not be able to continue to do so.

Rule 338.3135(5) should be deleted.
(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.....

Rule 338.3135(5) should be deleted for the same reasons Rule 338.3135(2) should be deleted.

Rule 338.3135(4)(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.**

Change this date to January 4, 2021. This would give time to implement so new applicants would know they have to have the training to before they start the application process. If left as currently drafted, those in the application process would have to stop their application process and obtain the training.

Rule 338.3162b(1) **Except as otherwise exempt under section 7333a of the act, MCL 333.7333a,** ~~A~~ pharmacist, ...

Insert a small a before pharmacist.

Rule 338.3162b(1)**(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.

There are a number of reasons (1)(u), (v), and (w) from Rule 338.3162b should be deleted.
1. Rule 338.3162b(1) (u), (v), and (w) are in conflict with the current rule 338.3162 (2) which states "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)." This would have two rules that are conflict with each other causing confusion.

2. Does not address or give an exemption for circumstances where the person who is obtaining the prescription for the patient is not known to the pharmacy at the time of dispensing, for example when the patient is in a nursing home, assisted living, or hospice, delivery to the patient address, or mailed to a patient address. It is not known who is obtaining the prescription on behalf of the patient.

3. Depending on the pharmacy software, pharmacies will be submitting this information to MAPS the day the prescription is dispensed. However, if the prescription is not picked up the day the prescription is dispensed the pharmacy will have to go back and correct the information that was sent to MAPS. The pharmacy incurs an extra cost to make this correction. According to MCL 333.7333a(1) the pharmacy is not to incur any additional costs solely related to the transmission of data to the department. Also, in the Regulatory Impact Statement for these rules the department states "There may be an additional cost to a user of the Prescription Drug Monitoring Program to modify their system to allow for collection of the additional information." The department is acknowledging there will be an extra cost thus not in compliance with 333.7333a(1).

4. Pharmacies that need to change software, again an added extra cost, will not be able to have the ability to electronically send the information in (u), (v), and (w) by January 1, 2020 because reprogramming software takes time and if time is an issue the reprogramming comes at a higher cost. Also, in the Regulatory Impact Statement for these rules the department states "There may be an additional cost to a user of the Prescription Drug Monitoring Program to modify their system to allow for collection of the additional information." The department is acknowledging there will be an extra cost thus not in compliance with 333.7333a(1).

MHA Michigan Health & Hospital Association | Leading Healthcare

July 29, 2019

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Rules for Controlled Substances
ORR #2019-057 LR

Attention: Policy Analyst
P.O. Box 30670
Lansing, MI 48909
BPL-BoardSupport@michigan.gov

Dear Policy Analyst:

On behalf of the Michigan Health & Hospital Association, we respectfully submit the following comments on the Rules for Controlled Substances. Due to inconsistent legislative drafting, we are respectfully requesting a clarification related to direct administration of controlled substances (CS) to a patient and reporting to the Michigan Automated Prescription System (MAPS).

Hospital members have raised questions about the obligation to report dispensing of schedule II-V controlled substances to MAPS as required under MCL 333.7333a. Section 333.7333a(1) of the Michigan Public Health Code (Code) which requires a veterinarian, a pharmacist, a dispensing prescriber (i.e., physician/dentist with a drug control license) and a licensed pharmacy to report all "dispensing" of schedule II-V CS to MAPS. This reporting requirement includes the dispensing (and prescribing) of buprenorphine or methadone to a patient in a licensed substance use disorder services program (defined term), unless the reporting is prohibited under federal law — MCL 333.7333a(11).

Section 333.7333a(1) of the Code provides exceptions to this MAPS dispensing reporting requirement for: (i) certain veterinary situations, (ii) when the CS is both dispensed and administered to an inpatient in a licensed hospital; and (iii) when the dispensing occurs in a licensed health facility by a dispensing prescriber in a quantity adequate to treat the patient for not more than 48 hours. Public Act 252 of 2017 amended MCL 333.7333a to remove the reporting exemption that had been in place for "the administration of a controlled substance directly to a patient," and replaced it with the exemption for hospital inpatient dispensing and administration described above. PA 252 also rescinded the MAPS reporting rule which contained the general administration exception, Mich. Admin. Code R 338.3162e. MCL 333.7333a(12).

The Article 15, 333.17703(3), definition does *not* include the acts of prescribing or administration, which are generally understood as separate acts from dispensing for purposes of licensing pharmacies, veterinarians, pharmacists and dispensing prescribers.

LARA has not required the reporting of CS prescribing or administration to MAPS, and LARA staff have advised stakeholders that reporting of CS prescribing or administration is not required. Further, MAPS does not appear to be designed to accept reports of CS prescribing or administration. This situation has created uncertainty among those who prescribe and/or administer CS outside the confines of a hospital or licensed health facility regarding exactly what their MAPS reporting obligations are under Section 333.7333a.

The MHA recommends a distinction for all in house administration. CS may be administered and used for the patient on the premises of a health facility, and the CS are administered directly to patients during the course of treatment. The delivery of such a prescription drug is for immediate use by lawful order of a prescriber, and the provider is monitoring both the use of medication and the patient in the healthcare setting.

To help clarify the MAPS reporting requirements under MCL 333.7333a, the MHA is respectfully recommending revising Mich. Admin. Code R 333.3162b to add the following text as a new subsection (3):

> **Rule 62b (3) As used in this rule, the term "dispense" or "dispensing" shall mean the preparation, compounding, packaging, or labeling of a controlled substance with delivery of the controlled substance to the ultimate user, pursuant to a prescription or other authorization issued by a prescriber, and shall not include the acts of prescribing controlled substance or administering controlled substance directly to a patient.**

Thank you for your consideration of our comments. Please reach out to Paige Fults (pfults@mha.org) with questions.

Respectfully submitted,

Adam Carlson
Senior Director, Government & Political Affairs
Michigan Health & Hospital Association
Desk: (517) 886-8245 | Cell: (269) 757-2479
acarlson@mha.org

July 23, 2019

Attention: Policy Analyst
Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing– Boards and Committees Section
P.O. Box 30670
Lansing, MI 48909-8170

Dear Policy Analyst:

Thank you for the opportunity to submit comments on the recent work of the **Board of Pharmacy – Controlled Substances** on ORR #2019-057 LR. Specifically, we have concerns regarding the proposed changes to R 338.3135 that would require opioid and controlled substances awareness training for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee.

In Rule 35, the proposed revisions state that a prescriber or dispenser shall only delegate, allow by a practice agreement, or order the prescribing, dispensing, or administering of a controlled substance to an individual licensed under article 15 who has complied with opioid and controlled substance awareness training. Further, in Rule 35 (5) (a), the draft rules specify that an individual who is renewing his or her license who is a delegate, or allowed by a practice agreement or an order to prescribe, dispense, or administer a controlled substance by a prescriber or dispenser shall complete said training by the end of the first renewal cycle after January 4, 2019, or (b) After September 1, 2019, shall complete the controlled substance training **prior to the application for licensure** (*emphasis added*). Given the next meeting date of July 29, 2019 and taking into consideration any further delays before finalization or posting of revised rules, it would seem that a September 1, 2019 date for initial applicants for a license would not provide them with adequate notice to comply. We respectfully request that the September 1, 2019 date as currently stated in Rule 35 5 (a) & 5 (b) be changed to January 1, 2020 to provide more time for compliance.

We greatly appreciate your consideration of this change. The Michigan Council of Nurse Practitioners stands ready to answer any questions or assist you in any way as you continue to discuss these revisions.

Sincerely,

Mary Anne McCoy

Mary Anne McCoy, PhD, RN, ACNS, ACNP-BC, FAANP
President, Michigan Council of Nurse Practitioners

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