Archived: Thursday, June 22, 2023 11:29:59 AM
From: Alisha Cottrell
Sent: Tuesday, June 6, 2023 10:10:33 AM
To: Ditschman, Andria (LARA)
Subject: Ascension Michigan Comment Letter
Sensitivity: Normal
Attachments:
Administrative Rules for Pharmacy-General Rules Comment Letter.pdf

---

Hi Andria,

Please let me know if this works for you.

Thanks!

Alisha
--
Alisha Cottrell
Chief Advocacy Officer
Ascension Michigan
110 W. Michigan Ave., Suite 1000 | Lansing, MI 48933
Office: 517-482-1422
Mobile: 517-392-5304

Executive Assistant: **Laurie Piekarski**

Ascension Michigan

Administration - Corporate Services Building

ascension.org/Michigan

T: (586) 753-0662

Located in Eastern Time Zone

Archived: Thursday, June 22, 2023 11:36:11 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 1:06:22 PM
To: Ditschman, Andria (LARA)
Subject: FW: Administrative Rules for Pharmacy-General Rules Comment Letter
Response requested: No
Sensitivity: Normal

Hi Andria,

Please see below.

From: Alisha Cottrell <alisha.cottrell@ascension.org>
Sent: Friday, June 2, 2023 12:11 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Cc: Jeffrey Thomas <jeffrey.thomas@ascension.org>; Gary Blake <gary.blake@ascension.org>; Douglas Apple <douglas.apple@ascension.org>
Subject: Administrative Rules for Pharmacy-General Rules Comment Letter

Dear Department Specialist:

Please see the attached letter submitted on behalf of Ascension Michigan as our official comment letter for the Administrative Rules for Pharmacy-General Rules. Thank you for your time and consideration in this matter.

Sincerely,

Alisha

--

Administrative Rules for Pharmacy-General Rules...

Alisha Cottrell
Chief Advocacy Officer
Ascension Michigan
110 W. Michigan Ave., Suite 1000 | Lansing, MI 48933
Office: 517-482-1422
Mobile: 517-392-5304

Executive Assistant: **Laurie Piekarski**
Ascension Michigan
Administration - Corporate Services Building

ascension.org/Michigan
T: (586) 753-0662
Located in Eastern Time Zone

Archived: Thursday, June 22, 2023 11:27:38 AM
From: Alisha Cottrell
Sent: Tuesday, June 6, 2023 10:10:33 AM
To: Ditschman, Andria (LARA)
Subject: Ascension Michigan Comment Letter
Sensitivity: Normal
Attachments:
Administrative Rules for Pharmacy-General Rules Comment Letter.pdf

---

Hi Andria,

Please let me know if this works for you.

Thanks!

Alisha
--
Alisha Cottrell
Chief Advocacy Officer
Ascension Michigan
110 W. Michigan Ave., Suite 1000 | Lansing, MI 48933
Office: 517-482-1422
Mobile: 517-392-5304

Executive Assistant: **Laurie Piekarski**

Ascension Michigan

Administration - Corporate Services Building

ascension.org/Michigan

T: (586) 753-0662

Located in Eastern Time Zone

Ascension

June 2, 2023

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Administrative Rules for Pharmacy-General Rules
2022-8 LR

Submitted via BPL-BoardSupport@michigan.gov

Dear Department Specialist:

Thank you for the opportunity to provide comments on the proposed changes to the Administrative Rules for Pharmacy-General Rules. Ascension Michigan has the following concerns identified below.

R 338.533 Compounding standards and requirements; outsourcing facilities; requirements.

Rule 33. (1) The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**.

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding, or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan~~,~~ 48909.

(3) A pharmacy that provides compounding services shall comply with all **applicable** current standards adopted in subrule (1) of this rule.

(4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state **shall** ~~must~~ be inspected and registered as an outsourcing facility by the ~~United States Food and Drug Administration (~~FDA~~)~~ ~~prior to~~ **before** applying for a pharmacy license in this state.

Suggestion: Delete the phrase “not limited to” and remove the reference to chapter version dates from USP 795 and 797. Update this section to adopt “current compendial chapters of USP 795 and 797”.

Rationale: It is anticipated that other regulatory and accrediting bodies (e.g. Joint Commission) will utilize the revised USP standards when evaluating Michigan pharmacies. This would result in state licensed pharmacies having to adopt the strict requirements in the updated chapters without realizing any of the corresponding benefits (e.g. extended BUDs) and leading to increased operational costs and waste. Also, the new standards are more in alignment with the FDA definition of compounding. For multi-state health-systems (like Ascension) attempting to standardize practice, state-specific compounding policies and metrics would need to be established for MI sites. Also, for MI pharmacies licensed outside of the state (e.g. home infusion), other states may not accept sterile products from MI pharmacies, which would result in a loss of business. Most recognized training programs (e.g. ASHP) will update their training and resources to reflect current USP standards, which will result in confusion for pharmacists licensed in the state of Michigan and both in-state and out-of-state pharmacy students/residents being trained at MI facilities.

R 338.591 Dispensing emergency supply of insulin.

Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:

(a) The requirements in section 17744f of the code, MCL 333.17744f.

(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.

(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.0

(2) If the smallest single package of insulin available exceeds a 30-day supply, dispensing the package of insulin that is available complies with this rule and section 17744f of the code, MCL 333.17744f.

Suggestion: Change to also include insulin analogs

Rationale: Since many patients are prescribed insulin analogs (e.g. lispro, as part), adding this language would clarify that the emergency supply also pertains to these agents.

Again, thank you for your time and consideration. Should you have any further questions or concerns, please contact me at (586) 753-1120 or douglas.apple@ascension.org.

Sincerely,

Douglas Apple

Douglas J. Apple, MD, MS, FHM
Chief Clinical Officer, Ascension Michigan

Archived: Thursday, June 22, 2023 11:45:58 AM
From: BPL-BoardSupport
Sent: Wednesday, May 31, 2023 9:24:49 AM
To: Ditschman, Andria (LARA)
Subject: FW: Comments on Pharmacy General Rules (MOAHR #2022-8 LR)
Response requested: No
Sensitivity: Normal
Attachments:
PharmacyGeneralRulesComment.docx

From: Rose M Baran <RoseBaran@ferris.edu>
Sent: Wednesday, May 31, 2023 9:11 AM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comments on Pharmacy General Rules (MOAHR #2022-8 LR)

Attention: Departmental Specialist
Please find attached comments on the Pharmacy General Rules (MOAHR #2022-8 LR) for the public hearing on these Rules scheduled for June 2, 2023 at 9:00 AM.
Sincerely,
Rose Baran Pharm.D.

Rose Baran

Comments on Administrative Rules for Pharmacy-General Rules
Rule Set 2022-8 LR
Rose Baran Pharm.D.

Rule 338.486	Issue	Suggested change
(d) **Furnishing medications for administration to registered patients under R 338.588 and 338.588c.** ~~Delegating the stocking of an automated device. Technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another board-approved error prevention technology that complies with R 338.3154.~~	There is no rule 338.588c in this rule set or the current rule set.	Delete **338.588c.**
Rule 338.501	Issue	Suggested change
(x)(~~k~~) "Virtual manufacturer" means a**n individual** ~~person~~ who engages in the manufacture of prescription drugs or devices and meets all of the following: (i) Owns either of the following: (A) The new prescription drug application or abbreviated new prescription drug application number. (B) The unique device identification number, as available, for a prescription device. (ii) Contracts with a contract manufacturing organization for the physical manufacture of the drugs or devices. (iii) Is not involved in the physical manufacture of the drugs or devices.	Individual means a natural person (333.1105(1)) while person is defined in 333.1106(4) as "(4) "Person" means an individual, partnership, cooperative, association, private corporation, personal representative, receiver, trustee, assignee, or other legal entity. Person does not include a governmental entity unless specifically provided." Using individual would restrict this to only a natural person and would not allow a partnership, cooperative, association, private corporation, personal representative, receiver, trustee, assignee, or other legal entity to be a virtual manufacturer.	Individual in this section (**x**) should be changed to "person".

(iv) At no time takes physical possession of or stores the drugs or devices. (v) Sells or offers for sale to other **individuals** ~~persons~~, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.		
Rule 338.511	Issue	Suggested change
Rule 338.511 lacks a time period the licensee needs to hold the documentation of completing the training for identifying the victims of human trafficking.	The current status of this rule would mean the licensee would have to retain documentation for as long as they are licensed in Michigan.	Add (3) *A licensee or registrant shall retain documentation of meeting the requirements of this rule for a period of 6 years after the date of applying for licensure, registration, or renewal.*
Rule 338.513	Issue	Suggested change
(6) An applicant for an educational limited license shall meet the requirements of R 338.511.	Rule 338.7004 requires an individual applying for licensure or registration under article 15 of the code, MCL 333.16101 to 333.18838, except those seeking to be licensed under part 188 of the code to obtain Implicit Bias Training.	Add at the end of (6) *and rule 338.7004*
Rule 338.517	Issue	Suggested change
In (3)(b) and (3)(c) it quotes rule 338.501(~~j~~**u).**	(**u**) is the definition for PIC, perhaps the **u** should be **v** the definition for practical experience.	Change the **u** to **v**
Rule 338.523	Issue	Suggested change
338.523(2)(b)~~ Pass the MPJE as required under R 338.519~~**Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.**	A pharmacist needs knowledge of both state and federal regulations to competently practice in this state as identified in the competency statements of the MPJE exam. This would allow an applicant who failed the Michigan MPJE to obtain a license in another state and then by endorsement get licensed in Michigan if they attest to the department that	Leave the language as is in 338.523(2)(b) *Pass the MPJE as required under R 338.519.*

	they have sufficient knowledge of the code and the board's rules even though they failed the MPJE. Also, there is no attestation here that the applicant is attesting to sufficient knowledge of the laws of the United States Code and Code of Federal Regulations relevant to the practice of pharmacy.	
Rule 338.525(4)	Issue	Suggested change
(f) ~~Examination: retake and pass the MPJE as provided in R 338.519519~~**Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state**.	A pharmacist needs knowledge of both state and federal regulations to competently practice in this state as identified in the competency statements of the MPJE exam.	Add this to 338.525(4)(f) *Must also attest to sufficient knowledge of the laws of the United States Code and Code of Federal Regulations relevant to the practice of pharmacy.*
Rule 338.532	Issue	Suggested change
(5) The board may rescind approval of an organization upon just cause. The rescission will not immediately affect the compliance of a pharmacy using the accreditation. Within 12 months ~~of~~ **after** the rescission date or by the next licensure renewal date, whichever is later, the accreditation is void, and a pharmacy shall obtain accreditation or an inspection from an organization that satisfies subrule (1) of this rule.	Need timely notice when the board the rescinds approval of a sterile compounding accrediting organization. This will give notice to the pharmacies involved so they may plan accordingly to obtain accreditation from an approved organization.	Add to 338.532(5) *(a) If the Board rescinds approval, the Board must indicate on the website that it has, with an effective date.* *(b) If the Board rescinds approval the accrediting organization or inspection entity must notify the pharmacies involved.*
Rule 338.537	Issue	Suggested change
(2) In addition to subrule (1) of this rule, a pharmacy that dispenses drugs shall maintain, at a minimum, all of the following equipment:	The rule needs clarification regarding the sink as proposed a bucket could be used to collect the effluent draining from the sink.	Change (2) to*: (2) In addition to subrule (1) of this rule, a pharmacy that dispenses drugs shall maintain, at a*

(a) A sink with running water. **(b) A refrigerator for the exclusive use of prescription drugs. Personal or food items must not be stored in the refrigerator. Refrigeration must be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing. Temperatures must be monitored at all times for out-of-range temperatures during business closure.** **(c) A telephone.**	Most pharmacies now have frozen vaccines in inventory as well as refrigerated pharmaceuticals, including both prescription and over the counter drugs. Vaccine storage practice standards are given by the Centers for Disease Control (CDC) as well as Michigan Department of Health and Human Service, Division of Immunization. Telephone needs further clarification. Is the phone requirement a separate land line with the capacity to accept fax prescriptions, or can it be a cell phone that is carried by the pharmacist? Should there be a requirement for a type of telephone system (VoIP system, PBX, or multi-line system).	*minimum, all of the following equipment:* *(a) A functioning sink of adequate capacity, connected to running cold and hot water, with sanitary drainage.* *(b) A purpose-built or pharmaceutical-grade unit designed to either refrigerate or freeze, if frozen drugs are in the pharmacies inventory. Personal or food items must not be stored in the refrigerator or freezer. The units must be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing. Temperatures must be monitored at all times.* *(c) A telephone or telephone system that is HIPAA compliant for the exclusive use of the pharmacy.*
Rule 338.569	Issue	Suggested change
Rule lacks the requirement to maintain information required by the drug supply chain security act.	Records required to be kept.	Add to 338.569(1) a (d) *All information required under the drug supply chain security act, Public Law 113-54.*
Rule 338.583a(1)	Issue	Suggested change
(1) A pharmacy ~~must~~ **shall** keep and make available for inspection all acquisition and distribution records for prescription and non-prescription drugs and devices, ~~such as~~**including** invoices, packing slips or receipts, for 5 years. All records, which may be electronic, must be readily retrievable within 48 hours.	It places a burden on pharmacies that sell non-prescription drugs that it doesn't place on other retailers that sell non-prescription drugs that are not a pharmacy. It doesn't require the retailer to keep the records for non-prescription drugs as it does the pharmacy. This will increase cost for pharmacies.	Delete "and non-prescription" from (1).

Rule 338.583a(1)	Issue	Suggested change
(1) A pharmacy ~~must~~ **shall** keep and make available for inspection all acquisition and distribution records for prescription and non-prescription drugs and devices, ~~such as~~**including** invoices, packing slips or receipts, for 5 years. All records, which may be electronic, must be readily retrievable within 48 hours.	Also, rule 383.583a conflicts with the Pharmacy controlled substance rule 338.3153(k). The controlled substance rule states "Except for controlled substance prescriptions pursuant to subdivision (h) of this rule, a licensee shall maintain controlled substances records for 2 years." Also conflicts with Rule 338.3154(5) "If a controlled substance is dispensed from an automated device, then documentation of all of the following must be maintained on-site in the pharmacy responsible for the automated device for 2 years for review by the department, an agency, or the board:" So this would mean noncontrolled acquisition and distribution records would have to be kept for 5 years whereas controlled substance records, other than prescriptions need only be retained for 2 years." This will cause confusion and uncertainty.	Change rule 338.583a(1) to read "Except for prescriptions, ~~a~~**A** pharmacy ~~must~~ **shall** keep and make available for inspection all acquisition and distribution records for prescription ~~and non-prescription~~ drugs and devices, ~~such as~~**including** invoices, packing slips or receipts, for **2** ~~5~~ years. All records, which may be electronic, must be readily retrievable within 48 hours.
Rule 338.588	Issue	Suggested change
Rule 338.588 states "(~~7~~**3**) Records and electronic data ~~kept~~ **maintained** by automated devices must meet all of the following requirements: (a) All events involving access to the contents of the automated devices must be recorded electronically. (b) Records must be maintained for 5 years by the pharmacy or dispensing	Rule 338.3154 states "(5) If a controlled substance is dispensed from an automated device, then documentation of all of the following must be maintained on-site in the pharmacy responsible for the automated device for 2 years for review by the department, an agency, or the board:…."	These two rules are inconsistent on how long to maintain the records. Rule 338.3154 is undergoing revision, recommend changing the time period in Rule 338.3154 to 5 years to maintain consistency

prescriber and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:……..	These two rules are inconsistent on how long to maintain the records.	
Rule 338.589	Issue	Suggested change
(5) "Pharmacist delegation of acts, tasks, or functions ~~shall be in compliance~~ **must comply** with section 16215 of the code, MCL 333.16215, and **be** under the personal charge of the delegating pharmacist, except as provided in R 338.486. A pharmacist ~~who~~ **that** delegates acts, tasks, or functions to a licensed or unlicensed **individual** ~~person~~ shall do all of the following:….."	A technician at a remote pharmacy is not under the personal charge of a pharmacist.	Add to (5) Pharmacist delegation of acts, tasks, or functions ~~shall be in compliance~~ **must comply** with section 16215 of the code, MCL 333.16215, and **be** under the personal charge of the delegating pharmacist, except as provided in R 338.486 *and 17742b of the code MCL 333.17742b*. A pharmacist ~~who~~ **that** delegates acts, tasks, or functions to a licensed or unlicensed **individual** ~~person~~ shall do all of the following:……..
Rule 338.591(1)(c)	Issue	Suggested change
(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.0	Typo at end of sentence.	Delete 0.

Archived: Thursday, June 22, 2023 11:32:28 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 2:45:02 PM
To: Ditschman, Andria (LARA)
Subject: FW: 23_Pharmacy proposed rules comment
Response requested: No
Sensitivity: Normal
Attachments:
23_Pharmacy proposed rules comment.docx

From: Belding, Todd <Todd.Belding@sparrow.org>
Sent: Friday, June 2, 2023 1:46 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Cc: Shaski, John <John.Shaski@sparrow.org>
Subject: FW: 23_Pharmacy proposed rules comment

Pharmacy proposed rules comments

Todd Belding, PharmD.
Director of Pharmacy
Sparrow Health System
1215 E Michigan Ave.
Lansing, MI 48912
(517)253-2376

Sparrow

Improving the health of the people in our communities by
providing quality, compassionate care to everyone, every time

June 2, 2023

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

Submitted electronically to: BPL-BoardSupport@michigan.gov

Thank you for the opportunity to submit comments on the proposed revisions to the pharmacy general rules.

> Related to section **R 338.533 Compounding standards and requirements; outsourcing facilities.**

The current rule mandates compliance with United States Pharmacopeia (USP) 795 and 797 to versions revised in 2014 and 2008, respectively. We understand there is a new version of USP effective November 2023. USP needed to update the chapters because there are inconsistencies between the existing chapters and other chapters they have been updated. For example, we are required to follow USP to handle hazardous medications and several conflicts exist between chapters 800 and 797. The Joint Commission will require compliance with the new standards, and it will be impossible to be compliant with both the old and the new standards simultaneously.

> Related to section **R 338.534a In-state initial pharmacy license inspections.**

An in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and, within 6 months, an inspection to assess USP compliance or accreditation. We believe the second inspection is redundant as we are required to have all rooms and hoods certified semi-annually as well as conducting monthly testing for surface growth. The standards for an IV room are far stricter than other sterile areas, like surgery.

We appreciate this opportunity, and we appreciate revisions to the specific sections referenced.

Sincerely yours,

1200 E. Michigan Avenue
P.O. Box 30480
Lansing, Michigan 48909-7980

T 517.364.1000
T 1.800.SPARROW
F 517.364.5050
sparrow.org

Sparrow

Improving the health of the people in our communities by
providing quality, compassionate care to everyone, every time

Todd Belding, PharmD
Director of Pharmacy

1200 E. Michigan Avenue
P.O. Box 30480
Lansing, Michigan 48909-7980

T 517.364.1000
T 1.800.SPARROW
F 517.364.5050
sparrow.org

Archived: Thursday, June 22, 2023 11:36:49 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 1:05:57 PM
To: Ditschman, Andria (LARA)
Subject: FW: Comment on Proposed Revisions to Pharmacy General Rules
Response requested: No
Sensitivity: Normal
Attachments:
MI BOP Proposed Rule- Comment 6-1-23.pdf

Hi Andria,

Please see below.

From: Ryan Bickel <ryan.bickel@ascension.org>
Sent: Friday, June 2, 2023 12:58 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Cc: Ryan Bickel <rjbickel@hotmail.com>
Subject: Comment on Proposed Revisions to Pharmacy General Rules

Departmental Specialist,

I have attached a letter, which shares my comments regarding one of the proposed changes to the Pharmacy General Rules. Please let me know if you have any questions or wish to discuss this further.

Sincerely,

--
Ryan J. Bickel, Pharm.D., MHA, FASHP
Director, Pharmacy Services
Ascension Borgess
Ascension.org/Michigan
Phone: 269-226-6645
Fax: 269-226-8173
Ryan.Bickel@Ascension.org

June 2, 2023

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

Dear Departmental Specialist,

Thank you for the opportunity to provide comments on the proposed change to the Administrative Rules for Pharmacy - General Rules. As a Michigan-licensed Registered Pharmacist, I have identified a couple of concerns below.

R 338.533 Compounding standards and requirements; outsourcing facilities; requirements.
Rule 33. (1) The board approves and adopts by reference the compounding standards of the ~~United States Pharmacopeia (USP)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland, 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008).**
(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding, or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909.

Suggestion 1: Delete the phrase “not limited to” and remove the reference to chapter version dates from USP 795 and 797 in subrule (1). Update this section to adopt “current compendial chapters of USP Chapter 795 and 797.”

Rationale: It is anticipated that most regulatory and accrediting bodies (e.g. The Joint Commission) will adopt the most current compendial chapters when evaluating Michigan hospitals and pharmacies. This would result in state licensed pharmacies having to adopt the strict requirements in the updated USP chapters without appreciating any of the benefits (e.g. extended beyond use dating) and lead to increased operational costs and waste. This rule also creates obstacles for MI pharmacies, who dispense medications to patients in neighboring states, thus resulting in a loss of business. Conversely, some out-of-state pharmacies (e.g. 503B pharmacies) may not be able to send compounded medications to MI customers. This may result in exacerbating medication shortages for health-systems and, potentially, adversely impact patient care. Finally, most national professional pharmacy organizations (e.g. ASHP) accept the current compendial standards of the USP and base their training programs on them,

which will result in confusion for pharmacists license in the State of Michigan and both in-state and out-of-state pharmacy students and residents training at MI facilities.

Suggestion 2: Strike “at no cost” in subrule (2).

Rationale: The United States Pharmacopeia (USP) no longer provides copies of these chapters for free of charge, as they have transitioned to an online platform.

Thank you for your time and consideration. Please feel free to contact me should you have any further questions or concerns.

Sincerely,

Ryan J. Bickel, PharmD, MHA, FASHP
rjbickel@hotmail.com
C: (269) 303-1664

Archived: Thursday, June 22, 2023 11:34:04 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 1:08:06 PM
To: Ditschman, Andria (LARA)
Subject: FW: Comment on Proposed Revisions to Pharmacy General Rules
Response requested: No
Sensitivity: Normal

Hi Andria,

Please see below.

From: GARY BLAKE <gdb42@aol.com>
Sent: Friday, June 2, 2023 11:32 AM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comment on Proposed Revisions to Pharmacy General Rules

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing

Thank you for the opportunity to comment on the proposed revisions to the Pharmacy General Rules.

I would like to comment on 2 of the proposed rules changes:

Michigan BOP Proposed Revision

R 338.533 Compounding standards and requirements; outsourcing facilities; requirements.

Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland, 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**.

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding, or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909.

(3) A pharmacy that provides compounding services shall comply with all **applicable** current standards adopted in subrule (1) of this rule.

(4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state **shall** must be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to **before** applying for a pharmacy license in this state.

Comment/Response

Suggestion: Delete the phrase “not limited to” and remove the reference to chapter version dates from USP 795 and 797. Update this section to adopt “current compendial chapters of USP 795 and 797”.

Rationale: It is anticipated that other regulatory and accrediting bodies (e.g. Joint Commission) will utilize the revised USP standards when evaluating Michigan pharmacies. This would result in state licensed pharmacies having to adopt the strict requirements in the updated chapters without realizing any of the corresponding benefits (e.g. extended BUDs) and leading to

increased operational costs and waste. Also, the new standards are more in alignment with the FDA definition of compounding. For multi-state health-systems (like Ascension) attempting to standardize practice, state-specific compounding policies and metrics would need to be established for MI sites. Also, for MI pharmacies licensed outside of the state (e.g. home infusion), other states may not accept sterile products from MI pharmacies, which would result in a loss of business. Most recognized training programs (e.g. ASHP) will update their training and resources to reflect current USP standards, which will result in confusion for pharmacists licensed in the state of Michigan and both in-state and out-of-state pharmacy students/residents being trained at MI facilities.

Michigan BOP Proposed Revision

R 338.591 Dispensing emergency supply of insulin.
Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:
(a) The requirements in section 17744f of the code, MCL 333.17744f.
(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.
(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.0
(2) If the smallest single package of insulin available exceeds a 30-day supply, dispensing the package of insulin that is available complies with this rule and section 17744f of the code, MCL 333.17744f.

Comment/Response

Suggestion: Change to also include insulin analogs
Rationale: Since many patients are prescribed insulin analogs (e.g. lispro, aspart), adding this language would clarify that the emergency supply also pertains to these agents.

Thank you, again, for the opportunity to comment.

Gary Blake, R.Ph.
Michigan Registered Pharmacist

Archived: Thursday, June 22, 2023 11:46:28 AM
From: BPL-BoardSupport
Sent: Tuesday, May 30, 2023 7:05:11 AM
To: Ditschman, Andria (LARA)
Subject: FW: Michigan Board of Pharmacy General Rules Public Comments
Response requested: No
Sensitivity: Normal

From: Randy Burke <burke.randy88@gmail.com>
Sent: Tuesday, May 30, 2023 7:00 AM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Michigan Board of Pharmacy General Rules Public Comments

To: Michigan Board of Pharmacy Members
From: Randy Burke
Subject: Public Comments for MI Pharmacy Rules

Dear MI BOP,

The rules I am writing to comment publicly on are 338.519 (Rule 19) through 523 (Rule 23).

The main topic is to suggest removal of the MPJE law exam requirement from the rules governing pharmacy licensure. I, along with many others in the state and outside of the state believe removing this exam would simplify the licensing process and maintain patient safety.

I would like the Board to consider the following points to remove the MPJE requirement:

- Schools of pharmacy are required to have a law course and students are required to memorize, practice, and pass multiple assessments. This has been required for some time now in all states, including Michigan.
- Our technology has become so advanced and will continue to advance. Even programs such as ChatGPT have shown the ability to pass standardized tests. Pharmacies have technology in place these days that help with ensuring laws/rules are generally followed and pharmacists are healthcare professionals who are held to a high standard. They can look things up in a split second as needed these days.
- The exam is expensive and costs students who take on an average of $170,000 of debt for pharmacy school yet another expense. NABP is really who profits and gets the financial gain from making students take this meaningless test.
- If NABP submits comments, there is a direct conflict of interest as they have financial gains from keeping the test as a state requirement (so those should not be considered by the board to be fair).
- Doctors, nurses, PAs, and almost all other healthcare professionals do not require a law exam to become licensed. Why are they not held to the same "standard" if the exam is so important for patient safety and to truly protect patients?

- Even Colleges of Pharmacy are calling for removal of the law exam at the national conferences.

Furthermore, I would like to bring your attention to a published literature article titled "The Impact of Jurisprudence Exams on Pharmacy Licensure and Patient Safety". The article underscores the need to reassess the role of law exams in pharmacy licensure, focusing on competency assessment and meaningful measures of patient care. It provides great examples of how a state like Idaho logically thought through the process and provides rationale and level headed insights as to why.

In light of successful examples set by other states, such as Idaho and Vermont, which have removed the MPJE requirement without compromising patient safety, I am asking the Michigan BOP to consider this change.

Thank you for your attention to this matter. I hope you will consider my points in your discussions, as well as the insights provided by the literature.

Sincerely,

Randy

Archived: Thursday, June 22, 2023 11:30:27 AM
From: BPL-BoardSupport
Sent: Monday, June 5, 2023 7:04:26 AM
To: Ditschman, Andria (LARA)
Subject: FW: feedback on the Administrative Rules for Pharmacy-General Rules.
Response requested: No
Sensitivity: Normal

From: Michelle Dehoorne <dehoornesmith@gmail.com>
Sent: Friday, June 2, 2023 4:57 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: feedback on the Administrative Rules for Pharmacy-General Rules.

June 2, 2023
Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Administrative Rules for Pharmacy-General Rules
2022-8 LR
Submitted via BPL-BoardSupport@michigan.gov

Dear Department Specialist:

As a pharmacist who practices in the role of a Director at a hospital, I appreciate the opportunity to provide feedback on the Administrative Rules for Pharmacy-General Rules. Thank you for the opportunity to provide comments on the proposed changes.

1. R 338.533 Compounding standards and requirements; outsourcing facilities;
requirements.
Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland, 20852-1790. This includes, but is not limited to, USP Chapters 795 (revised 2014) and 797 (revised 2008).
(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding, or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909.
(3) A pharmacy that provides compounding services shall comply with all applicable current standards adopted in subrule (1) of this rule.
(4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state shall must be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to before applying for a pharmacy license in this state.

Recommedation:

- Remove the phrase “not limited to”
- Remove the reference to chapter version dates from USP 795 and 797

- Update this section to adopt “current compendial chapters of USP 795 and 797”.

Rationale: The administrative rules going foward would encourage utilizattion of the most current and up to date USP standards. This likely will establish standards that align with other accreditating bodies such as the Joint Commission. Lastly, this will decrease confusion for Michigan pharmacies and promote best practice.

2. R 338.591 Dispensing emergency supply of insulin.
Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:
(a) The requirements in section 17744f of the code, MCL 333.17744f.
(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.
(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.0
(2) If the smallest single package of insulin available exceeds a 30-day supply, dispensing the package of insulin that is available complies with this rule and section 17744f of the code, MCL 333.17744f.

Recommendation;

- Expand definition of insulin to include insulin analogs such as lispro and aspart.

Rationale: Many patients are prescribed insulin analogs (e.g. lispro, as part) and are a standard of care. By clarifying the scope of insulin to include insulin analogs, we would improve patient safety and accessibility resulting in improved patient care. .

3 R 338.588a Automated devices in non-inpatient settings.
Recommendation:

- Remove(a) The automated device may only deliver non-controlled drugs.
- Remove(b) the restriction that automated devices can only be used to deliver non-narcotics
- Remove limitation prohibiting a remote pharmacy from operating an automated device as long as a pharmacist is available

4. R 338.588b Automated devices in medical institutions.
Rule 88b. (1) An automated device used by staff to administer[1] store medications to registered patients[1] in any hospital, county medical care facility, nursing home, hospice, or another skilled nursing facility, as defined in section 20109(4) of the code, MCL 333.20109, must comply with all of the following:
(a) The automated device must be supplied stocked, maintained, and controlled by a pharmacy that is licensed in this state.

(b) If *a pharmacist delegates*[3] the stocking of the automated device is performed [4] then technologies must be in place and utilized to ensure that the correct

drugs are stocked in their appropriate assignment utilizing bar-coding or another board-approved error-prevention technology that complies with R 338.3154.

Recommendation:

- [1]Remove *administe*r from "to administer store medications"
- [2]Remove "to registered patients" and adjust to intended for patient administration
- [3] Remove a pharmacy delegates
- [3] Add is performed by non-pharmacist personnel

Rational: currently there is confusion as to who stocking may be delegated to.

Respectfully Submitted,

Michelle Dehoorne, PharmD, BSPharm

Archived: Thursday, June 22, 2023 11:31:21 AM
From: Eid, Deeb D
Sent: Friday, June 2, 2023 4:57:54 PM
To: Ditschman, Andria (LARA); BPL-BoardSupport
Subject: RE: Public Comments for MI General Rules (Pharmacy)
Sensitivity: Normal
Attachments:
CVS Health Comments on General Rules-MI 2023.pdf

Andria,

Please see the attached pdf for public comments from CVS Health on the Pharmacy General Rules. Thanks so much!

Thank you for your time!

Upcoming PTO: ***I will be out of the office with no access to work email and phone from 5/24 to 6/4 .***

DEEB D. EID, PHARMD, RPH
Sr. Advisor, Pharmacy Regulatory Affairs
1 CVS Drive, Mail Code 2325, Woonsocket, RI 02895
Located: *Grand Rapids, MI*
Cell: (W) 616-490-7398 | (P) 419-508-1669
Fax: *401-652-2302*
Email: *Deeb.Eid@CVSHealth.com*

CVSHealth

Deeb D. Eid, PharmD, RPh | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 616-490-7398

May 30th, 2023

Andria Ditschman, JD
Senior Policy Analyst
Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs (LARA)
611 W. Ottawa St. PO Box 30670 Lansing, MI 48909
Telephone: 517-241-9255
DitschmanA@michigan.gov

Re: CVS Health Comments Rules Public Hearing for Pharmacy General Rules (2022-8 LR)

Dear Andria and Board Members:

I am writing to you in my capacity as Senior Advisor of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in Michigan through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the proposed rules for Pharmacy General Rules. We would also like to thank the Department and Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns, and pharmacy technicians serving Michigan's patients.

After review, CVS Health has comments for the Department and Board to consider strengthening and better align with national trends, improve patient safety, and overall outcomes. These recommended changes are in the **Appendix section below** which highlights the rules, comments, proposed language, and any citations or additional information or questions to consider.

CVS Health appreciates the opportunity to submit comments for the Board's review. Please contact me directly at 616-490-7398 if you have any questions.

Sincerely,

Deeb D. Eid, PharmD, RPh
Sr. Advisor, Pharmacy Regulatory Affairs
CVS Health
deeb.eid@cvshealth.com

Deeb D. Eid, PharmD, RPh | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 616-490-7398

Appendix

1. Suggested Rule Language Changes:

Rule 88a

R338.588a

(2) A pharmacy licensee may locate a non-dispensing storage and pick up device inside of ~~on~~ the premises of the pharmacy that is used for a patient or agent of the patient to pick up prescription medication if the pharmacy meets both of the following:

(a) The automated device is secured, lockable, and privacy enabled.

~~**(b) The automated device is located on the inside of the premises of the licensed pharmacy.**~~

Comments: CVS Health supports the Board's efforts to simplify and create access to care for non-dispensing storage and pick up devices. These efforts will continue to allow Michigan patients to access medications and join along 29 other states that have had jurisdictional successes in allowing this type of access. Furthermore, we recommend simplifying (2) by adding the word *"inside of"* after "device" as shown above and deleting the word "on", along with letter (b) for clarity and simplification.

Archived: Thursday, June 22, 2023 11:32:00 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 3:46:07 PM
To: Ditschman, Andria (LARA)
Subject: FW: Public Comment - General Rules
Response requested: No
Sensitivity: Normal

From: Rony Foumia <ronyfoumia10@gmail.com>
Sent: Friday, June 2, 2023 3:40 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Cc: Rony Foumia <ronyfoumia10@gmail.com>
Subject: Public Comment - General Rules

Good Afternoon - My name is Rony Foumia and I am a pharmacist in the State of Michigan. Even though I am a regional leader for a pharmacy chain and a Michigan Board of Pharmacy Member, my comments are those of my own and don't represent the views of my organization or the BOP.

1. R 338.531 Pharmacy license; remote pharmacy license; applications; requirements.
Rule 31. (1) An applicant for a pharmacy license or a remote pharmacy license shall submit to the department a completed application on a form provided by the department together with the requisite fee.
(2) An applicant shall submit all of the following information:
(a) Certified copies of articles of incorporation or partnership certificates and certified copies of assumed name certificates, if applicable.
(b) Submission of fingerprints for the purpose of a criminal history background check required under section 17748(6) of the code, MCL 333.17748.
(c) A ~~federal employer identification number (~~FEIN~~)~~ certificate.
(d) The name and license number of the pharmacist in this state designated as the ~~pharmacist in charge (~~PIC~~)~~ ~~pursuant to~~**under** section 17748(2) of the code, MCL 333.17748, who must have a valid and unrestricted license. **If a PIC is unable to fulfill his or her duties for 120 consecutive days, the pharmacy shall appoint a new PIC and notify the department as required in section 17748(4) of the code, MCL 333.17748.**

Comment: We also require that a PIC works on average 8 hours a week in a pharmacy to be compliant as a PIC. Are we saying that if a pharmacist in charge goes on a leave of absence i.e., are we forgoing the requirement for them to maintain the 8 hours a week average?

R 338.533 Compounding standards and requirements; outsourcing facilities;
requirements.
Rule 33. (1) The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**.
(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding,

or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan~~,~~ 48909.

Comment: USP 795 and 797 (2022 revisions are set to be implemented on 11-1-23, has this been taken into account? Furthermore, I am hearing that the rule website listed above (USP.org) is no longer free to obtain.

R 338.588a Automated devices in non-inpatient settings.

Rule 88a. (1) A pharmacy that operates an automated device to deliver prescription medication directly to an ultimate user that is not included in R 338.588(2)(a) to (h) shall comply with all of the following requirements:

(a) The automated device may only deliver non-controlled drugs.

Comment: Have we added a definition of an "Automated Device"? I think we need to clearly define what that is.

R 338.538 Closing pharmacy.

Rule 38. (1) A pharmacy that is ceasing operations shall return to the department the pharmacy license and the controlled substance license, if applicable, and provide the department with written notification of all of the following ~~at least~~**not less than** 15 days ~~prior to~~ **before** closing:

Comment: Pharmacies are now allowed to print and download copies of their pharmacy licenses. I don't think it is necessary to have closed pharmacies return these licenses as many times they are not even originally printed by the department.

Archived: Thursday, June 22, 2023 11:42:55 AM
From: Ditschman, Andria (LARA) Ditschman, Andria (LARA)
Sent: Thursday, June 1, 2023 4:05:51 PM
To: Ditschman, Andria (LARA) Ditschman, Andria (LARA)
Subject: FW: FW: State of Michigan Board of Pharmacy National Accrediting Organization Approval List
Response requested: No
Sensitivity: Normal
Attachments:
compendial-applicability-of-usp-800.pdf

For Pharmacy General Rules Comments.

Andria M. Ditschman, JD
Department Specialist
Boards and Committees Section

From: Denise Frank <denise.frank@gatesconsult.com>
Sent: Thursday, June 1, 2023 2:47 PM
To: Ditschman, Andria (LARA) <DitschmanA@michigan.gov>
Cc: Dan Parisi <dan.parisi@gatesconsult.com>
Subject: Re: FW: State of Michigan Board of Pharmacy National Accrediting Organization Approval List

Sure!

When the revised USP Chapters 795 and 797 become official on November 1, 2023, because they reference USP 800, then USP 800 will become compendially required (and enforceable) for compounding. I don't know if you will need to specifically reference USP Chapter 800, (although it would be prudent to specifically point out that it is now required!!) because you do not also point out and specifically approve all the other chapters referenced in USP 795 and 797 when the compounding chapters say you must perform an activity according to another chapter of USP. An example would be USP 797 references USP Chapter 71, Sterility Tests and USP 795 references Chapter 51, Antimicrobial Effectiveness Testing.
And, would you want to adopt USP 800 in its entirety (not limited to only those pharmacies only when they are compounding) to protect all pharmacy personnel? I would think, in the spirit of protecting the public, that this would make sense!

For reference:

I included the information from USP about applicability of 800 when the new 795 and 797 that reference 800 are made official in the email above.

This is an excerpt directly from the USP document that addresses USP 800 from this link: https://www.usp.org/sites/default/files/usp/document/our-work/compounding/compendial-applicability-of-usp-800.pdf
You could supply them with the document itself (it's a PDF). I have also attached a copy to this email.

This is the excerpt:

" On December 1, 2019, USP's standard on the safe handling of hazardous drugs, General Chapter <800>, became official. General Chapter <800> is informational and not compendially applicable. USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings describes practice and quality standards for handling hazardous drugs. USP is committed to maintaining patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs (hazardous drugs) in healthcare facilities."

"USP General Chapters, monographs, and related programs are intended to help protect and improve the health of people, in part by facilitating access to high quality, safe, and beneficial medicines. A general chapter numbered below 1000 becomes compendially applicable and thus is considered a required standard only when:

1. the chapter is referenced in a monograph;

2. the chapter is referenced in another General Chapter below 1000; or

3. the chapter is referenced in General Notices.

General Chapter <800> is informational and not compendially applicable because it is not referenced in General Notices, a monograph, or another applicable general chapter numbered below <1000>.

Revisions to General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations and <797> Pharmaceutical Compounding—Sterile Preparations, published on June 1, 2019, include cross-references to <800>. This would have made <800> compendially applicable for facilities that are required to implement <795> and <797>. Due to the appeals received on certain provisions in revised USP <795> and <797>, the chapters have been remanded to the Compounding Expert Committee with the recommendation for further engagement on the issues raised in the appeals (see Compounding Appeals).

This means that the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) remain official. These currently official compounding chapters do not reference USP <800>.

In the future, if the revised USP <795> and <797> contain reference to USP <800>, <800> would be applicable and compendially required only to the extent to which USP General Chapters <795> and <797> apply. For hazardous drugs, this means only when a practitioner is "compounding" (as that term is defined in USP <795> and <797>) <800> would be applicable and compendially required. Since administration is out of scope of USP <795> and <797>, General Chapter <800> would not be applicable or compendially required in this context."

Warm regards,

Denise

(she/her/hers)

Denise M. Frank, RPh, FACA, FAPC
Senior Associate
Gates Healthcare Associates, Inc.
Innovative Healthcare Solutions
1 Central Street, Suite 201, Middleton, MA 01949
Phone: 978-646-0091
Cell: 612-860-1705

Please consider the environment before printing this email

Sign Up for our Newsletter!

Role and Applicability of USP General Chapter <800> Related to Safe Handling of Hazardous Drugs

Summary

On December 1, 2019, USP's standard on the safe handling of hazardous drugs, General Chapter <800>, became official. General Chapter <800> is **informational** and not compendially applicable. USP General Chapter *<800> Hazardous Drugs – Handling in Healthcare Settings* describes practice and quality standards for handling hazardous drugs. USP is committed to maintaining patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs (hazardous drugs) in healthcare facilities.

Compendial Applicability

USP General Chapters, monographs, and related programs are intended to help protect and improve the health of people, in part by facilitating access to high quality, safe, and beneficial medicines.

A general chapter numbered below 1000 becomes compendially applicable and thus is considered a required standard only when:

1. the chapter is referenced in a monograph;
2. the chapter is referenced in another General Chapter below 1000; or
3. the chapter is referenced in General Notices.

General Chapter <800> is informational and not compendially applicable because it is not referenced in *General Notices*, a monograph, or another applicable general chapter numbered below <1000>.

Revisions to General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations*, published on June 1, 2019, include cross-references to <800>. This would have made <800> compendially applicable for facilities that are required to implement <795> and <797>. Due to the appeals received on certain provisions in revised USP <795> and <797>, the chapters have been remanded to the Compounding Expert Committee with the recommendation for further engagement on the issues raised in the appeals (see Compounding Appeals). This means that the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) remain official. These currently official compounding chapters do not reference USP <800>.

In the future, if the revised USP <795> and <797> contain reference to USP <800>, <800> would be applicable and compendially required **only to the extent to which USP General Chapters <795> and <797> apply**. For hazardous drugs, this means only when a practitioner is "compounding" (as that term is defined in USP <795> and <797>) <800> would be applicable and compendially required. Since administration is out of scope of USP <795> and <797>, General Chapter <800> would not be applicable or compendially required in this context.

March 12, 2020

Enforcement

State agencies (e.g., State Boards of Pharmacy), other regulators (e.g., Occupational Safety and Health Administration), and oversight organizations (e.g., The Joint Commission) may make their own determinations regarding the applicability and enforceability of <800> for entities within their jurisdiction. USP continues to engage and inform regulators, accreditation organizations, and stakeholders about the compendial status of the chapter. USP plays no role in enforcement.

USP Standards for the Handling and Compounding of Hazardous Drugs

The known risks associated with hazardous drug exposure present a compelling public health challenge. General Chapter <800> was developed based on public health need and potential exposure of approximately 8 million U.S. healthcare workers to hazardous drugs each year. There were also published reports of adverse effects in healthcare personnel from occupational exposure to hazardous drugs. Although General Chapters <795> and <797> contained some information on handling of hazardous drugs, there was no public standard aimed to minimize the potential risk of exposure. To meet this need, the Compounding Expert Committee sought to expand on the principles of hazardous drug compounding established in USP <795> and <797> and to develop a general chapter specific to the handling of hazardous drugs through the development of USP <800>. USP is committed to maintaining patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs (hazardous drugs) in healthcare facilities.

Additional Resources

For additional information on General Chapter <800>, see:

- USP <800> FAQs
- FAQs on the Compounding Appeals

Archived: Thursday, June 22, 2023 11:32:51 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 2:44:37 PM
To: Ditschman, Andria (LARA)
Subject: FW: Comments for proposed Pharmacy General Rules
Response requested: No
Sensitivity: Normal
Attachments:
Comment MI BOP Proposed Revisions 6.2.23.pdf

From: Marc Guzzardo <marc.guzzardo@ascension.org>
Sent: Friday, June 2, 2023 2:32 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comments for proposed Pharmacy General Rules

Please accept these comments to the proposed revisions to the Pharmacy General Rules.

Thank you
--
Marc Guzzardo

t: 810-606-6095

Comment : Proposed Revisions to Michigan Pharmacy General Rules

Michigan BOP Proposed Revision	Proposed Ascension Michigan Response
R 338.533 Compounding standards and requirements; outsourcing facilities; requirements. Rule 33. (1) The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**. (2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding, or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan~~,~~ 48909. (3) A pharmacy that provides compounding services shall comply with all **applicable** current standards adopted in subrule (1) of this rule. (4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state **shall** ~~must~~ be inspected and registered as an outsourcing facility by the ~~United States Food and Drug Administration (~~FDA~~)~~ ~~prior to~~ **before** applying for a pharmacy license in this state.	Suggestion: Delete the phrase "not limited to" and remove the reference to chapter version dates from USP 795 and 797. Update this section to adopt "current compendial chapters of USP 795 and 797". Rationale: It is anticipated that other regulatory and accrediting bodies (e.g. Joint Commission) will utilize the revised USP standards when evaluating Michigan pharmacies. This would result in state licensed pharmacies having to adopt the strict requirements in the updated chapters without realizing any of the corresponding benefits (e.g. extended BUDs) and leading to increased operational costs and waste. Also, the new standards are more in alignment with the FDA definition of compounding. For multi-state health-systems (like Ascension) attempting to standardize practice, state-specific compounding policies and metrics would need to be established for MI sites. Also, for MI pharmacies licensed outside of the state (e.g. home infusion), other states may not accept sterile products from MI pharmacies, which would result in a loss of business. Most recognized training programs (e.g. ASHP) will update their training and resources to reflect current USP standards, which will result in confusion for pharmacists licensed in the state of Michigan and both in-state and out-of-state pharmacy students/residents being trained at MI facilities.
R 338.591 Dispensing emergency supply of insulin. **Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:** **(a) The requirements in section 17744f of the code, MCL 333.17744f.** **(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.** **(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.0** **(2) If the smallest single package of insulin available exceeds a 30-day supply, dispensing the package of insulin that is available complies with this rule and section 17744f of the code, MCL 333.17744f.**	Suggestion: Change to also include insulin analogs Rationale: Since many patients are prescribed insulin analogs (e.g. lispro, aspart), adding this language would clarify that the emergency supply also pertains to these agents.

Archived: Thursday, June 22, 2023 11:45:29 AM
From: BPL-BoardSupport
Sent: Thursday, June 1, 2023 6:42:07 AM
To: Ditschman, Andria (LARA)
Subject: FW: Comment Submission for April 2023 Pharmacy General Rules
Response requested: No
Sensitivity: Normal
Attachments:
UMH Comments on BOP General Rules Revisions 2023 copy.docx

From: Lisa Herz <lisamarieherz@gmail.com>
Sent: Wednesday, May 31, 2023 3:45 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comment Submission for April 2023 Pharmacy General Rules

Hello,

I am a Board Certified Sterile Compounding Pharmacist and have been a Compounding Supervisor for over 10 years at an acute care hospital in Michigan.

I support the general and specific comments submitted by Jamie Tharp on May 26, 2023. Please review and revise as described in the attached document.

Thank you,
Lisa Herz, PharmD, BCSCP
586-524-3039

Archived: Thursday, June 22, 2023 11:44:48 AM
From: BPL-BoardSupport
Sent: Thursday, June 1, 2023 1:41:25 PM
To: Ditschman, Andria (LARA)
Subject: FW: Public comment on proposed revisions to Pharmacy General Rules
Response requested: No
Sensitivity: Normal

From: King, Lee <Lee.King@Sparrow.Org>
Sent: Thursday, June 1, 2023 1:00 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Public comment on proposed revisions to Pharmacy General Rules

Questioning the undue burden and redundancy that would be caused by enforcement of the two proposed changes:

- An in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and, within 6 months, an inspection to assess USP compliance or accreditation.

  - We all understand that there is not complete alignment in rules between the State of Michigan and USP compliance. In the many areas that rules are conflicting, which source would prevail? In any situation where the expectation that the State of Michigan rule were to be followed as opposed to USP, any Joint Commission accreditation would be in immediate noncompliance for not conforming with USP standards.

  - Additional burden of record keeping and standard compliance with having to maintain two separate sterile compounding surveys

  - From a safety perspective, I would suggest that compliance with the USP standards are sufficient to attain sterile compounding compliance.

  - A suggestion would be to consider the dual inspection for any site that previously failed inspection by the accrediting body as the first path back towards compliance with sterile compounding standards.

- Mandates compliance with USP 795 and 797 to versions revised in 2014 and 2008, respectively.

  - I would question if the recommendation to hold pharmacies accountable to both the 2008 and 2014 versions of USP 795 and 797 came from USP themselves? What is the purpose in enforcing both versions simultaneously?

  - There is significant overlap and even contradicting standards between the 2008 and 2014 versions. It will be extremely difficult to enforce both versions at the same time.

- Having to maintain compliance with two separate versions of USP puts our patients at risk when there are standards that are in disagreement.

I have no other additional feedback on other public comment changes at this time.
Thank you for your time and consideration.

Regards,

Lee M. King, PharmD

Medication Safety Officer | **Sparrow Health System** | lee.king@sparrow.org |Phone: 517/ 364-5564

"Quality's core is Safety. Safety's core is reliability. Reliability's core is culture. Culture's core is fairness, justice, teamwork and transparency." – Barbara Balik

Archived: Thursday, June 22, 2023 11:43:54 AM
From: BPL-BoardSupport
Sent: Thursday, June 1, 2023 2:51:52 PM
To: Ditschman, Andria (LARA)
Subject: FW: Comments for Proposed Rules for 6/2/23 Public Hearing
Response requested: No
Sensitivity: Normal

From: Bradley McCloskey <brad@univrx.com>
Sent: Thursday, June 1, 2023 2:51 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comments for Proposed Rules for 6/2/23 Public Hearing

Hello, please find my comments below regarding the Proposed Draft Rule Language and our Requests for Change. I agree with proposed changes suggested by the MPA

Proposed Language	Comment
R 338.533 (1) The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**. R 338.555 (1) The board approves and adopts by reference the current good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR 211.1 to 211.208 (~~2021~~**2022**).	MPA opposes the addition of dates to this rule language. We second this opposition. The proposed language creates a situation in which pharmacies are required to comply with outdated standards rather than the most current versions. Pharmacies may also be put in a situation where they might need to comply with the latest versions under federal law or for the purpose of accreditation by a non-governmental entity. This may not be possible as revised standards may conflict sufficiently with older versions that simultaneous compliance with both old and new versions is not feasible. Additionally, adding these dates punishes pharmacies that have sought to become compliant with upcoming versions of the standards in advance of official publication. **Suggested Revision:** Do not specify the revision dates for USP 795 and 797 in R 338.533(1). Remove the 2021 revision date for cGMP in R 338.555 (1), but do not replace it with the 2022 date.

Thank you,

Brad McCloskey, PharmD
President/CEO
University Compounding Pharmacy
6054 Livernois Rd.
Troy, MI 48098
Phone: 877-531-1147
Fax: 866-531-1826
www.univrx.com

Helping one patient at a time live their best life

Archived: Thursday, June 22, 2023 11:46:55 AM
From: BPL-BoardSupport
Sent: Monday, May 29, 2023 8:20:17 PM
To: Ditschman, Andria (LARA)
Subject: FW: Comment regarding your USP law language
Response requested: No
Sensitivity: Normal

From: David Medina <dmedinarph@gmail.com>
Sent: Monday, May 29, 2023 9:44 AM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comment regarding your USP law language

Good morning,

I am a NYS pharmacist and I became aware of your recent updates to your pharmacy law via a post on LinkedIn from a Michigan based based pharmacist. Upon reading the language in the law, as it's written, professionally speaking, you are putting your patient population, and even the livelihood of your Compunding pharmacists on the line.

If you are specifically stating in law that your standards for compounding will be based on the old rules, as a Board of Pharmacy you are willfully stating that increased protection for the public as a whole is not a vital concern.

For years now stakeholders have been meeting to discuss the revisions to USP 797. These revisions are now final and serve as the benchmark for any compounding pharmacist in the country as a gold standard.

If you are going to hold your pharmacies to an outdated standard, what will happen to them when they pursue JCAHO, ACHC, or URAC accreditation? Failing those could mean loss of business. That aside, if you hold pharmacies to less than the standard, what will the board be saying to the public at large should harm come to them as a result of this? What would happen to the business or Pharmacist in charge if the FDA decides to come into a 503a pharmacy and sees way less than they should be seeing as a result of this law?

I urge you as a Board of Pharmacy to reconsider your language on this. Remove your specificity to the old years and just state the the Board will uphold the mist current revisions to the USP standards as they come. Not doing this could have dramatic consequences for your pharmacists and your people.

Sincerely

David Medina R.ph

Archived: Thursday, June 22, 2023 11:45:06 AM
From: BPL-BoardSupport
Sent: Thursday, June 1, 2023 1:41:14 PM
To: Ditschman, Andria (LARA)
Subject: FW: Board of Pharmacy Comments on Rules
Response requested: No
Sensitivity: Normal

From: Jasmin Mehta <jasminmehta43@gmail.com>
Sent: Thursday, June 1, 2023 12:30 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Board of Pharmacy Comments on Rules

Hello Michigan Board,

My name is Jasmin and I am writing to you about the pharmacy rules that are open for public comments. I have been reading your meeting minutes over the past year as part of a project I am working on and noticed you have had many discussions on the topic of removing the state law exam or MPJE.

In looking at your proposed rules, I am suggesting you look at rule 19, 21, 23 and any others that mention the MPJE or law exam as a requirement. My comment is to remove the law exam as a requirement for licensure.

You all have had some great discussions based on your meeting minutes in the past on this topic. Don't let the opinion of just 1 or 2 board members change your minds and you had some great arguments for why to remove this exam.

Other states have removed the exam and talked about this based on researching the topic.

Please consider removal of the exam from your rules as it is a pointless exam that is outdated.

Best,

Jasmin Mehta

Sent from my iphone

Archived: Thursday, June 22, 2023 11:37:40 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 7:07:55 AM
To: Ditschman, Andria (LARA)
Subject: FW: Comments to proposed changes to R338.533(1)
Response requested: No
Sensitivity: Normal
Attachments:
smime.p7s

From: Dr. Dave <drdave@keystonepharm.com>
Sent: Thursday, June 1, 2023 7:06 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Cc: Eric Roath <eroath@michiganpharmacists.org>; Lawrence Curtis <lcurtis@centerforcompounds.com>; jPritchett@revpharmacorp.com
Subject: Comments to proposed changes to R338.533(1)

Dear board of pharmacy members,

I oppose the addition of dates to this rule language. The 2014 and 2008 revisions for USP<795> and USP<797> respectively are antiquated and about to officially change on November 1, 2023. The proposed language creates a situation in which pharmacies are required to comply with outdated standards rather than the most current versions. This will put compounding pharmacies at odds with accrediting bodies. Public Act 280 of 2014 requires pharmacies to receive PCAB, or equivalent accreditation for sterile compounding. Accreditation cannot be obtained unless the most current chapters of USP are followed. This revision will also put compounding pharmacies at odds with the Food and Drug Administration who will require the most current revisions of the USP chapters to be followed. Additionally, adding these dates punishes pharmacies that have sought to become compliant with upcoming versions of the standards in advance of official publication.

Suggested Revision:
Do not specify the revision dates for USP 795 and 797 in R 338.533(1). Simply state:

R 338.533 (1) The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (USP)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 and 797.

Thank you for considering my comments when considering the proposed revisions.

David J Miller, RPh, PhD, FAPC, FACA
Keystone Pharmacy
4021 Cascade Rd SE, STE 50
Grand Rapids, MI 49546
616-974-9792
616-464-3469 fax
www.keystonerx.com

From: Jessica Morris
Mail received time: Wed, 24 May 2023 03:35:47
Sent: Tuesday, May 23, 2023 11:35:47 PM
To: BPL-BoardSupport
Cc: Ditschman, Andria (LARA)
Subject: Michigan General Rules Pharmacy Public Comments
Importance: Normal
Sensitivity: None
Archived: Wednesday, May 24, 2023 10:57:14 AM

Dear Members of the Michigan Board of Pharmacy,

I hope this letter finds you well. This letter is in relation to the Pharmacy General Rules you have open for public comments. On behalf of myself, I am writing to respectfully request the removal of the MPJE (Multistate Pharmacy Jurisprudence Examination) law exam requirement from the rules governing pharmacy licensure in Michigan. After careful consideration and review of the relevant statutes and regulations, I believe that eliminating this exam would be a progressive step towards streamlining the licensing process without compromising patient safety. Your Board has also discussed this topic in the past and has had ample and colorful discussions on why the exam is baseless and no longer relevant.

Upon conducting an in-depth analysis of the existing laws and regulations, it is evident that there is no explicit requirement for the MPJE in the statutes pertaining to pharmacy licensure in Michigan.

Therefore, I present the following arguments in favor of removing the MPJE requirement within your current proposed rules. Relevant rules are: R338.519, R 338.521, R 338.523 and anywhere else in these rules that require this exam.

Pharmacy is among a minority of health professions that impose a jurisprudence exam as a prerequisite for licensure. It is worth considering which other health professions require a similar exam and if it is truly necessary for ensuring public safety. What evidence or published literature shows that an individual passing this exam one time improves patient safety or outcomes? There are none to my knowledge. When asked, even NABP can not produce an answer to this day-old question.

Some arguments in favor of a law exam may stem from conflicts of interest, such as individuals or entities that benefit financially from creating study materials (such as state associations or colleges), generating exam questions, or providing educational content related to the exam. It is important to question the motivations behind such arguments and consider whether they truly contribute to

public safety or simply serve vested interests. In addition, NABP has a vested financial interest in making this exam a requirement to ensure they are receiving revenue each year from students and licensees who are taking the test in multiple states.

The historical belief that a law exam is required due to the complexity of pharmacy laws may not be entirely applicable today. Technological advancements and electronic pharmacy dispensing systems have greatly facilitated adherence to professional practice standards. Many of the specific details, such as information on prescription labels or permissible refills, are now automatically checked and enforced by these systems, alleviating the burden on pharmacists to memorize every minute aspect of the laws.

It is worth noting that there are currently no published articles demonstrating a direct correlation between jurisprudence competence exams and patient safety. Without concrete evidence that passing such an exam leads to safer care provided by pharmacists, the burden of cost and time associated with the MPJE becomes difficult to justify.

The COVID-19 pandemic serves as a poignant example of how additional examinations can exacerbate delays in equipping the pharmacy workforce and addressing staffing shortages. Executive orders were required to waive regulations and increase access to pharmacists during this critical time. By removing the MPJE requirement, Michigan can ensure a more efficient and timely process for licensing pharmacists.

To address potential counterarguments, I offer the following responses:

The argument that pharmacists need to know the law when other healthcare professionals may not overlooks the fact that each profession has its own set of laws and rules that its members must adhere to. If passing an exam directly equates to comprehensive knowledge of the laws and rules, then why don't other health professions impose a similar requirement?

Technological advancements have significantly improved compliance with laws and regulations. Many aspects of pharmacy practice that previously required manual vigilance are now automated and integrated into computer software and systems. This reduces the reliance on individual pharmacists to memorize every detail, as the technology itself enforces compliance.

Removing the MPJE requirement does not necessarily lower the bar for licensure or allow anyone to become a pharmacist. On the contrary, it could attract highly qualified candidates who are seeking a more efficient pathway to licensure and practice. Incompetence exists in every profession, and passing an exam does not guarantee competence. A comprehensive evaluation of candidates' qualifications, including their educational background and performance in pharmacy school, remains critical in ensuring the competency of licensed pharmacists.

Concerns about NABP's opinion and potential loss of support should not overshadow the primary objective of protecting public safety. While NABP may experience financial losses due to the removal of the exam, it is the responsibility of the Board of Pharmacy to prioritize

patient safety and outcomes over financial considerations. If patient safety remains unaffected by the removal of this administrative requirement, then it should not hinder progress.

The responsibility of ensuring pharmacy graduates' competence in state and federal laws lies with the colleges and schools of pharmacy. Accreditation standards set by the Accreditation Council for Pharmacy Education (ACPE) require educational institutions to adequately prepare graduates in this regard. The role of the Board of Pharmacy is to evaluate whether passing one exam equates to sufficient competence in all state laws and rules, thus protecting public safety.

Last July, the American Association of Colleges of Pharmacy (AACP) which is the association that houses all colleges of pharmacy and faculty as members passed a national emerging resolution in which the academy supports removal of a stand alone examination of federal and/or state pharmacy laws as a requirement for licensure. This was endorsed by members from neighboring states such as WI, OH, IL, and IA.

It is also worth considering the examples set by other states that have revised their requirements:

Idaho (ID): Since 2018, Idaho has operated without an MPJE requirement and has transitioned to an enforcement approach based on the standard of care. They have reported no increase in complaints to the board and no known patient safety issues resulting from the removal of the exam.

Vermont (VT): Vermont recently voted to remove the MPJE requirement, aligning itself with the evolving trends in pharmacy licensure.

Ohio (OH): Ohio does not require license transfer applicants to maintain their license by original examination. However, license transfer applicants must have a license in good standing from a member board and transfer their license through the NABP clearinghouse. This approach prioritizes evaluating the equivalence and thoroughness of the examination taken in another state.

Wisconsin (WI): Wisconsin currently has a bill being heard by the legislature that would remove unnecessary and unproven licensure requirements for healthcare professionals. The MPJE is amongst those exams/requirements. The state association in WI has publically supported this bill and removal of the MPJE.

In conclusion, I urge the Michigan Board of Pharmacy to carefully consider the arguments presented in favor of removing the MPJE requirement. Doing so would represent a progressive and forward-thinking approach to pharmacy licensure without compromising patient safety. By streamlining the licensing process, Michigan has the opportunity to attract highly qualified candidates and ensure a competent pharmacy workforce that can meet the evolving healthcare needs of the state. This move also ensures that the Board and staff are utilizing evidence and logical thinking to remove undue barriers while protecting the public.

Thank you for your time and consideration. I trust that you will

carefully evaluate this request, keeping in mind the ultimate goal of protecting public safety while fostering an efficient and effective pharmacy licensing process.

Sincerely,

Jessica Morris

Archived: Thursday, June 22, 2023 11:37:13 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 7:08:12 AM
To: Ditschman, Andria (LARA)
Subject: FW: Michigan Pharmacists Association - Pharmacy General Rules Comments
Response requested: No
Sensitivity: Normal
Attachments:
Pharmacy General Ruels Comments 05-2023.docx

From: Eric Roath <eroath@michiganpharmacists.org>
Sent: Thursday, June 1, 2023 5:36 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Cc: Farah Jalloul <fjalloul@michiganpharmacists.org>; Mark Glasper <mark@michiganpharmacists.org>
Subject: Michigan Pharmacists Association - Pharmacy General Rules Comments

Department Specialist,

Please see the attached letter for MPA's formal comments on the Pharmacy General Rules. I can be reached at this email address if you have any questions.

Sincerely,

Eric Roath, PharmD, MBA
Director of Government Affairs
Michigan Pharmacists Association
408 Kalamazoo Plaza, Lansing, MI 48933
Cell (906) 282-8930
Direct (517) 377-0254

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

Thank you for the opportunity to provide comments on the Pharmacy General Rules. Michigan Pharmacists Association (MPA) represents pharmacy practitioners across the state of Michigan. We represent pharmacists and pharmacy technicians in all practice areas, from community outpatient practice to inpatient health systems.

The areas of the proposed rules we wish to comment on are outlined in the following table:

Proposed Language	**Comment**
R 338.513 (1) An applicant for an educational limited license shall submit to the department a completed application on a form provided by the department with the requisite fee. In addition to satisfying the requirements of sections 16174 and 17737 of the code, MCL 333.16174 and ~~MCL~~ 333.17737, the applicant shall establish ~~either~~ **1** of the following: (a) That the applicant is actively enrolled in, or is within 180 days of completing, an approved educational program. (b) That the applicant has received a ~~Foreign Pharmacy Graduate Examination Committee (~~FPGEC~~)~~ certification from the ~~National Association of Boards of Pharmacy (~~NABP~~)~~ Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr**ive.**~~.~~, Mount Prospect, Illinois, 60056, https://nabp.pharmacy/programs/fpgec/.~~)~~ (2) The educational limited license must be renewed annually as follows: (a) At the time of renewal, the applicant shall submit verification to the department that ~~he or she~~ **the applicant** is actively enrolled in, or is within 180 days of completing, an approved educational program. The educational limited license is valid for 1 year.	The phrase "or is within 180 days of completing" seems redundant. If an individual is within 180 days of completing a program, it would stand to reason they are actively enrolled in the program. We believe that this phrasing may have been an oversight, and that the original intent of the rule was to allow individuals who had *recently* completed an education program to secure an educational limited license. This grace period is important for allowing new graduates from out of state to work in the pharmacy while their full license is pending. **Suggested revision:** "(1)(a) That the applicant is actively enrolled in an approved educational program or has completed an approved educational program within the past 180 days." "(2)(a) At the time of renewal, the applicant shall submit verification to the department that the applicant is actively enrolled in an approved educational program, or has completed an approved educational program within the past 180 days."

Proposed Language	Comment
R 338.523 (2)(ii)(C)(b) ~~Pass the MPJE as required under R 338.519~~**Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.**	MPA is opposed to removing the requirement to pass the MPJE if seeking licensure via endorsement. We believe an applicant must demonstrate competency in pharmacy practice law in the State. Failure to demonstrate this competency increases the likelihood that pharmacists may inadvertently practice outside of Michigan's state-specific regulations. This represents not only a risk to patient safety but also increases liability exposure for the practitioner. **Suggested Revision:** Retain the old language for R 338.532 (2)(ii)(C)(b): "Pass the MPJE as required under R 338.519."
R 338.533 (1) The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**. R 338.555 (1) The board approves and adopts by reference the current good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR 211.1 to 211.208 (~~2021~~**2022**).	MPA opposes the addition of dates to this rule language. The proposed language creates a situation in which pharmacies are required to comply with outdated standards rather than the most current versions. Pharmacies may also be put in a situation where they might need to comply with the latest versions under federal law or for the purpose of accreditation by a non-governmental entity. This may not be possible as revised standards may conflict sufficiently with older versions that simultaneous compliance with both old and new versions is not feasible. Additionally, adding these dates punishes pharmacies that have sought to become compliant with upcoming versions of the standards in advance of official publication. **Suggested Revision:** Do not specify the revision dates for USP 795 and 797 in R 338.533(1). Remove the 2021 revision date for cGMP in R 338.555 (1), but do not replace it with the 2022 date.

Proposed Language	Comment
R 338.588a Automated devices in non-inpatient settings. **Rule 88a. (1) A pharmacy that operates an automated device to deliver prescription medication directly to an ultimate user that is not included in R 338.588(2)(a) to (h) shall comply with all of the following requirements:** **(a) The automated device may only deliver non-controlled drugs.** **(b) The automated device is operated as an extension of a pharmacy, under the control of a pharmacist, however, a remote pharmacy may not operate an automated device.** **(c) A pharmacist shall be available for the automated device to be operable.** **(d) The automated device is secured, lockable, and privacy enabled.** **(e) Prescriptions must contain a label that identifies the automated device where the medication was dispensed.** **(f) A pharmacist shall be available to provide patient consultation through real-time audio and visual communication. The pharmacist may provide consultation from a remote location.**	MPA advocates for removing the restriction that automated devices only be used to deliver non-controlled drugs in subsection (1)(a). Current technology allows for the capture of positive identification of a patient at the point of dispensing via an automated device. We suggest that rather than prohibit dispensing controlled medications via an automated device, the board introduces language requiring positive verification of a patient's ID at the point of delivery. Additionally, MPA advocates for removing the limitation prohibiting a remote pharmacy from operating an automated device in subsection (1)(b). If a pharmacist is available, as required by subsection (1)(c), and a pharmacist may be available for real-time consult in subsection (1)(f), then a remote pharmacy should be permitted to operate an automated device. Further, the added safety features implemented by an automated device stocked and maintained by a pharmacist will enhance the safe delivery of medications in a remote pharmacy. **Suggested Revision:** R 338.588a (1) A pharmacy that operates an automated device to deliver prescription medication directly to an ultimate user that is not included in R 338.588(2)(a) to (h) shall comply with all of the following requirements: ~~(a) The automated device may only deliver non-controlled drugs.~~ (b) The automated device is operated as an extension of a pharmacy, under the control of a pharmacist~~, however, a remote pharmacy may not operate an automated device~~. (c) A pharmacist shall be available for the automated device to be operable. (d) The automated device is secured, lockable, and privacy enabled. (e) Prescriptions must contain a label that identifies the automated device where the medication was dispensed. (f) A pharmacist shall be available to provide patient consultation through real-time audio and visual communication. The pharmacist may provide consultation from a remote location.

Proposed Language	Comment
R 338.588a Automated devices in non-inpatient settings. **(3) If an automated device is used in a dispensing prescriber's office, and the automated device is not affiliated with a pharmacy, the device must be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. All of the following apply to the use of an automated device in a dispensing prescriber's office:** **(a) If a dispensing prescriber delegates the stocking of the automated device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that complies with R 338.3154.** **(b) A dispensing prescriber operating an automated device is responsible for all medications that are stocked and stored in that device, as well as removed from that device.** **(c) If any medication or device is dispensed from an automated device in a dispensing prescriber's office, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the dispensing prescriber for review by an agent of the board. This documentation must include all of the following information:** **(i) Manufacturer name and model.** **(ii) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.** **(iii) Policy and procedures for system operation that addresses, at a minimum, all of the following:** **(A) Accuracy.** **(B) Patient confidentiality.** **(C) Access.** **(D) Data retention or archival records.** **(E) Downtime procedures.** **(F) Emergency procedures.** **(G) Medication security.** **(H) Quality assurance.**	MPA advocates for parity in the requirements for automated devices operated by pharmacies and automated devices managed by dispensing prescribers. In addition to the recommended revisions noted below, if the Board believes it necessary to continue the prohibition of dispensing controlled substances from an automated device controlled by a pharmacy, a similar prohibition should be put in place for the offices of a dispensing prescriber. **Suggested Revision:** MPA recommends adding the following language: R 338.588a (3) (d) The dispensing prescriber shall be available for the automated device to be operable. (e) The automated device is secured, lockable, and privacy enabled. (f) Prescriptions must contain a label that identifies the automated device where the medication was dispensed.

Proposed Language	Comment
R 338.591 Dispensing emergency supply of insulin. **Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:** **(a) The requirements in section 17744f of the code, MCL 333.17744f.** **(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.** **(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.**	MPA recommends the addition of language to clarify that although an emergency supply of insulin may only be dispensed once per qualified prescription, this does not change the ability of a pharmacy to issue three such emergency supplies per patient per year (MCL 333.17744f (2)). **Suggested Revision:** Add R338.591 (d) a pharmacist may dispense an emergency supply of insulin for up to three qualified prescriptions within a calendar year for an individual patient.

Thank you again for the opportunity to provide comments on these rules. If you have any questions or require clarification regarding our remarks, please do not hesitate to reach out.

Respectfully submitted,

Eric Roath, PharmD, MBA
Director of Government Affairs
Michigan Pharmacists Association
(906) 282-8930
eroath@michiganpharmacists.org

Archived: Thursday, June 22, 2023 11:43:23 AM
From: BPL-BoardSupport
Sent: Thursday, June 1, 2023 3:26:53 PM
To: Ditschman, Andria (LARA)
Subject: FW: R 338.521 and 338.523 of the Pharmacy – General Rules
Response requested: No
Sensitivity: Normal

From: Colleen Ryan <cryan4710@gmail.com>
Sent: Thursday, June 1, 2023 3:07 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: R 338.521 and 338.523 of the Pharmacy – General Rules

My comment pertains to R 338.521 and 338.523 of the Pharmacy – General Rules.

The rules should allow licensure by examination by new grads even though they may be licensed in another state with a score transfer.

Thank you,
Colleen Ryan

Archived: Thursday, June 22, 2023 11:33:36 AM
From: BPL-BoardSupport
Sent: Friday, June 2, 2023 1:08:24 PM
To: Ditschman, Andria (LARA)
Subject: FW: MHA Comments - Administrative Rules for Pharmacy-General Rules 2022-8 LR
Response requested: No
Sensitivity: Normal
Attachments:
MHA Comments Pharmacy-General Rules 2022-8 LR.pdf

Hi Andria,

Please see below.

From: Renee Smiddy <rsmiddy@mha.org>
Sent: Friday, June 2, 2023 11:58 AM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: MHA Comments - Administrative Rules for Pharmacy-General Rules 2022-8 LR

Good morning,

On behalf of Michigan hospitals, the MHA appreciates the opportunity to provide comments on the Administrative Rules for Pharmacy – General Rules 2022-8 LR. Please see our attached feedback.

Thank you,

Renée Smiddy, MS | Senior Director, Finance Policy
Michigan Health & Hospital Association
110 W. Michigan Avenue, Suite 1200 | Lansing, MI 48933
(517) 285-0881 | rsmiddy@mha.org

MHA Michigan Health & Hospital Association | Leading Healthcare

June 2, 2022

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Administrative Rules for Pharmacy – General Rules
2022-8 LR

Submitted via BPL-BoardSupport@michigan.gov

Dear Departmental Specialist:

On behalf of Michigan hospitals, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to provide comments on the Administrative Rules for Pharmacy – General Rules.

The MHA has significant concerns related to the automated device sections and how the draft rules try to delineate practices between different types of facilities, specifically related to inpatient and non-inpatient settings. Some hospital settings are not considered inpatient but reside within the hospital footprint. The MHA has received multiple questions from members requesting clarification related to hospital emergency departments and distinct part units, are these areas considered inpatient or non-inpatient?

Please see our feedback and commentary below:

R 338.533 Compounding standards and requirements; outsourcing facilities; requirements.

Rule 33. (1) The board approves and adopts the latest available ~~by reference the~~ compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention.~~12601 Twinbrook Parkway, Rockville, Maryland, 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**.~~

…

(6) An outsourcing facility shall do all of the following:

(a) Compound drugs by or under the supervision of a licensed pharmacist.

(b) Compound drugs ~~pursuant to~~ **under** current good manufacturing practices for finished pharmaceuticals ~~set forth in 21 CFR 211.1 to 211.208 (2021~~**2022**~~).~~

The MHA recommends removing date references to avoid confusion and pharmacies inadvertently using outdated guidance. Clear and concise language should be adopted.

R 338.588a Automated devices in non-inpatient settings. *Please define and clarify areas of impact. The MHA recommends using definitions such as, outpatient clinics, infusion centers, etc., rather than the term non-inpatient settings.*

Rule 88a. (1) A pharmacy that operates an automated device to deliver prescription medication directly to an ultimate user that is not included in subdivision (a) to (h) of subrule (2) of R 338.588 shall comply with all of the following requirements:

(a) The automated device may ~~only deliver non-controlled drugs~~ not be used to deliver controlled substances.

The MHA recommends striking R 338.588a or updating to the suggested language above.

(b) The automated device is operated as an extension of a pharmacy, under the control of a pharmacist, however, a remote pharmacy may not operate an automated device.

(c) A pharmacist shall be available for the automated device to be operable.

The MHA has received direct feedback from hospitals that this section is unclear and they're not sure this would apply to their non-inpatient units. Would the pharmacist need to be onsite, available by phone or virtually?

(d) The automated device is secured, lockable, and privacy enabled.

Please clarify 'privacy enabled', is the intent to ensure patient privacy? If patient privacy is the intent, the MHA recommends clarifying language that ensures the privacy of the end-user.

(e) Prescriptions must contain a label that identifies the automated device where the medication was dispensed.

Please clarify if this would be in-addition to the dispensing pharmacy. For non-inpatient settings within a hospital, would this be satisfied by a room number if the dispensing pharmacy and automated device share the same address.

(f) A pharmacist shall be available to provide patient consultation through real-time audio and visual communication. The pharmacist may provide consultation from a remote location.

The MHA suggests combining (f) and (c) subsections.

(g) Before the automated device is put into service, the pharmacy shall notify the department of the location of the automated device on a form provided by the department.

Please clarify who the department is?

(h) Dispensing activities through the automated device must comply with all recordkeeping, drug utilization review, and patient counseling requirements that are applicable to a pharmacy.

(2) A pharmacy licensee may locate a non-dispensing storage and pick up device on the premises of the pharmacy that is used for a patient or agent of the patient to pick up prescription medication if the pharmacy meets both of the following:

(a) The automated device is secured, lockable, and privacy enabled.

(b) The automated device is located on the inside of the premises of the licensed pharmacy.

Please clarify if acute care hospitals, critical access hospitals, specialty hospitals, inpatient psychiatric facilities, etc. are excluded from R 338.588a 2(b).

R 338.588b Automated devices in medical institutions.

Rule 88b. (1) An automated device used by staff to ~~administer~~ store medications ~~to registered patients~~ intended for patient administration in any hospital, county medical care facility, nursing home, hospice, or another skilled nursing facility, as defined in section 20109(4) of the code, MCL 333.20109, must comply with all of the following:

(a) The automated device must be ~~supplied~~ stocked, maintained, and controlled by a pharmacy that is licensed in this state.

(b) If ~~a pharmacist delegates~~ the stocking of the automated device is performed by non-pharmacist personnel, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another board-approved error-prevention technology that complies with R 338.3154.

The suggested modifications attempt to reduce confusion related if the pharmacist is the default standard for stocking the automated device, since there is not an explicit language referencing stocking by a pharmacist. Above statements reference 'controlled by a pharmacy', not controlled by a pharmacist.

Please contact me at rsmiddy@mha.org if you have any questions regarding these comments or if you need additional information.

Respectfully submitted,

Renée Smiddy
Senior Director, Finance Policy

Archived: Thursday, June 22, 2023 11:47:19 AM
From: BPL-BoardSupport
Sent: Friday, May 26, 2023 3:11:21 PM
To: Ditschman, Andria (LARA)
Subject: FW: Attention Departmental Specialist- BOP General Rules Comments
Response requested: No
Sensitivity: Normal
Attachments:
UMH Comments on BOP General Rules Revisions 2023.docx

Hi Andria,

Please see below and attached.

-Kimmy

From: Tharp, Jamie <jcburke@med.umich.edu>
Sent: Friday, May 26, 2023 3:07 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Cc: Tharp, Jamie <jcburke@med.umich.edu>
Subject: Attention Departmental Specialist- BOP General Rules Comments

Attention Departmental Specialist-
I am writing to submit comments and suggested revisions to the Board of Pharmacy General Rule draft revisions. Please see attached for a copy of the changes suggested by me as the Assistant Director of Compounding Compliance for the University of Michigan Health.

Deadline for comment: 6/2/23 17:00

Thoughtfully, *Jamie Tharp*

Jamie Tharp, PharmD, BCSCP | *she/her/hers*
Assistant Director, Compounding Compliance | Department of Pharmacy
jcburke@med.umich.edu |page:7730 | 734-678-7933 *(prefer texts)*

Comment Submission for: April 2023 Pharmacy-General Rules

Comment Deadline: June 2, 2023

Comments Submitted: May 26, 2023

Commenter's Name:	**Position:**	**Full Contact Details:**
Jamie Tharp, PharmD, BCSCP	Assistant Director of Pharmacy- Compounding Compliance University of Michigan Health	jcburke@med.umich.edu

General Comments:

- The 2023 revisions to the Pharmacy-General Rules that restrict the applicable compounding standards to fixed version dates will result in
  - disparities with standards adherence for pharmacies and outsourcing facilities that are surveyed/inspected for out-of-state licenses, federal entities (FDA, CMS, etc) and other accrediting agencies who will update their evaluation criteria to be aligned with revised USP standards.
  - licensees will also find it difficult to obtain continuing education that aligns with past versions of USP and may become confused by learning opportunities that reflect the revised standards.
- USP chapters are periodically revised to reflect changing expert consensus and scientific advancements. The chapter revisions are led by expert committees made up of individuals with significant expertise in the field and also include FDA representatives.[1] Revisions undergo public comment period review and subsequent revisions. Chapter revisions are generally released 6-12 months before their official dates. USP provides guidance about their recommendations if the revised chapters should be early adopted. In the case of the 2022 revisions of USP 797/795, USP encouraged compounders to early adopt the chapters.[2]
- It is my recommendation that the Michigan Board of Pharmacy allow the adoption of revised versions of USP chapters, with the adoption to early adopt before the official date if so recommended by USP. Additionally, I recommend that revisions to cGMP standards be allowed for outsourcing facilities.

References: [1] USP and FDA Working Together to Protect Public Health https://www.usp.org/public-policy/usp-fda-roles accessed 5/11/23;

[2] USP Chapter Revision announcement and encouragement to early adopt https://go.usp.org/Revisions_Announcement_USP_GC_USP_795_and_797 accessed 5/11/23

Specific Comments:

Section(s)	**Suggested change:** (Provide the revised suggestion to replace the existing text.)	**Comment/Rationale**
R 338.533 Rule 33. (1)	Suggest deleting the chapter version dates from USP 795 and 797 and adding a statement to allow adoption of future revisions as follows: The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 and 797.Revisions to USP chapters shall be adopted by the official date or earlier as encouraged by USP, unless otherwise stated by the Board.	Allowing pharmacies to adopt USP standards as they are revised will minimize confusion between state and federal inspections and accrediting bodies. It is expected that most other states and federal agencies will recognize revised USP standards and will expect Michigan licensed pharmacies and licensees to adhere to the current versions of USP Chapters. Michigan licensed pharmacies will likely have to adopt the strictest standards of all chapter versions to ensure compliance with Michigan General Pharmacy Rules and external state licenses and federal agencies. This will disadvantage Michigan Pharmacies and likely cause undue financial and labor resources to maintain compliance with multiple versions of USP.

Section(s)	Suggested change: (Provide the revised suggestion to replace the existing text.)	Comment/Rationale
R 338.533 Rule 33. (2)	(2) The standards adopted by reference in subrule (1) of this rule are available for purchase at http://www.usp.org/compounding, or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan~~,~~ 48909.	USP no longer provides free copies of compounding chapters. Pharmacies and licensees must purchase or subscribe to USP to gain access the chapters.
R 338.533 Rule 33. (3)	(3) A pharmacy that provides compounding services shall comply with all **applicable** current standards adopted in subrule (1) of this rule.	The use of the phrase "current standards" is in conflict with the proposed fixed versions of USP being proposed in subrule (1) of this rule. I support leaving "current standards" in this sentence if my proposed changes to subrule (1) are adopted.
R 338.533 Rule 33. (4)	(4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state **shall** ~~must~~ be inspected and registered as an outsourcing facility by the ~~United States Food and Drug Administration (~~FDA~~)~~ ~~prior to~~ **before** applying for a pharmacy license in this state.	It may not be possible for an outsourcing facility to coordinate an FDA inspection before applying for a pharmacy license in the state if they are operating within the state of Michigan. Consider aligning this standard with the Sterile Compounding Pharmacy Licensing requirement R 338.534a (2) An applicant for an in-state pharmacy license that intends to compound sterile pharmaceutical products shall complete both of the following: (a) Obtain an inspection from the department or its designee for the purpose of meeting R 338.536 and R 338.537 for initial licensure. (b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess adherence to cGMP
R 338.533 Rule 33. (5)	Suggest deleting a fixed reference date to cGMP standards (b) Compound drugs ~~pursuant to~~**under** current good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208 ().	Similar to USP standards, cGPM standards are revised through rigorous processes. Holding outsourcing facilities to outdated cGMP standards will cause significant issues with their ability to meet expectations from out of state and federal entities, who will likely require adherence to future standards revisions. Per the FDA 503B Registration FAQ(LINK)- it is the FDAs intention to visit newly registered 503B entities within 2 months of registration.

Archived: Thursday, June 22, 2023 11:30:57 AM
From: BPL-BoardSupport
Sent: Monday, June 5, 2023 7:04:12 AM
To: Ditschman, Andria (LARA)
Subject: FW: Administrative Rules for Pharmacy - General Rules Comments
Response requested: No
Sensitivity: Normal

From: Jeffrey Thomas <jeffrey.thomas@ascension.org>
Sent: Friday, June 2, 2023 4:16 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Administrative Rules for Pharmacy - General Rules Comments

Dear Departmental Specialist,

Thank you for the opportunity to comment on the proposed revisions to the Pharmacy General Rules. Please see my comments below. Thank you for your time and consideration.

Michigan BOP Proposed Revision	Comments
R 338.533 Compounding standards and requirements; outsourcing facilities; requirements. Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland, 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**. (2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding, or	Suggestion: Delete the phrase "not limited to" and remove the reference to chapter version dates from USP 795 and 797. Update this section to adopt "current compendial chapters of USP 795 and 797". Rationale: It is anticipated that other regulatory and accrediting bodies (e.g. Joint Commission) will utilize the revised USP standards when evaluating Michigan pharmacies. This would result in state licensed pharmacies having to adopt the strict requirements in the updated chapters without realizing any of the corresponding benefits (e.g. extended BUDs) and leading to increased operational costs and waste. Also, the new standards are more in alignment with the FDA definition of compounding. For multi-state health-systems (like Ascension) attempting to standardize practice, state-specific compounding policies and metrics would need to be established for MI sites. Also, for MI pharmacies licensed outside of the state (e.g. home infusion), other states may not accept sterile products from MI pharmacies, which would result in a loss of business. Most recognized training programs (e.g. ASHP) will update their training and resources to reflect current USP standards, which will result in confusion for pharmacists licensed in the state of Michigan and both in-state and out-of-state pharmacy

at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909. (3) A pharmacy that provides compounding services shall comply with all **applicable** current standards adopted in subrule (1) of this rule. (4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state **shall** must be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to **before** applying for a pharmacy license in this state.	students/residents being trained at MI facilities.
R 338.591 Dispensing emergency supply of insulin. **Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:** **(a) The requirements in section 17744f of the code, MCL 333.17744f.** **(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.** **(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.0** **(2) If the smallest single package of insulin available exceeds a 30-day supply, dispensing the package of insulin that is available complies with this rule and section 17744f of**	Suggestion: Change to also include insulin analogs Rationale: Since many patients are prescribed insulin analogs (e.g. lispro, aspart), adding this language would clarify that the emergency supply also pertains to these agents.

the code, MCL 333.17744f.	

Jeffrey Thomas, BS, PharmD
Area Clinical Operations Manager - MI & NY Markets
Pharmacy Clinical Operations
t: 734-560-5071

Ascension Rx

Appreciation | Belongingness | Inclusivity | Diversity | Equity

Archived: Thursday, June 22, 2023 11:44:23 AM
From: BPL-BoardSupport
Sent: Thursday, June 1, 2023 2:50:31 PM
To: Ditschman, Andria (LARA)
Subject: FW: Comments for Proposed Rules for 6/2/23 Public Hearing
Response requested: No
Sensitivity: Normal

From: Chad Whitefield <chad@univrx.com>
Sent: Thursday, June 1, 2023 2:36 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Comments for Proposed Rules for 6/2/23 Public Hearing

Hello, please find our comments below regarding the Proposed Draft Rule Language and our Requests for Change.

Proposed Language	Comment
R 338.533 (1) The board approves and adopts by reference the compounding standards of ~~the United States Pharmacopeia (~~USP~~)~~, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 **(revised 2014)** and 797 **(revised 2008)**. R 338.555 (1) The board approves and adopts by reference the current good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR 211.1 to 211.208 (~~2021~~**2022**).	MPA opposes the addition of dates to this rule language. We second this opposition. The proposed language creates a situation in which pharmacies are required to comply with outdated standards rather than the most current versions. Pharmacies may also be put in a situation where they might need to comply with the latest versions under federal law or for the purpose of accreditation by a non-governmental entity. This may not be possible as revised standards may conflict sufficiently with older versions that simultaneous compliance with both old and new versions is not feasible. Additionally, adding these dates punishes pharmacies that have sought to become compliant with upcoming versions of the standards in advance of official publication. **Suggested Revision:** Do not specify the revision dates for USP 795 and 797 in R 338.533(1). Remove the 2021 revision date for cGMP in R 338.555 (1), but do not replace it with the 2022 date.

Thank you,
Chad Whitefield, RPh, BCSCP
Pharmacist-In-Charge
University Compounding Pharmacy
6054 Livernois Rd.
Troy, MI 48098
Phone: 877-531-1147
Fax: 866-531-1826
www.univrx.com

Helping one patient at a time live their best life

Archived: Thursday, June 22, 2023 11:33:14 AM
From: Maria Young
Sent: Friday, June 2, 2023 2:14:34 PM
To: Ditschman, Andria (LARA)
Subject: Public Comments for Pharmacy General Rules
Sensitivity: Normal

Andria,

These comments for the Pharmacy General Rules are submitted in my individual capacity as a pharmacist licensed to practice Pharmacy in the state of Michigan and are not being offered in my official capacity as a member of the Board of Pharmacy and do not represent the views of the Board.

Below are areas I wish to review for the Rules Committee and Board to address.

- R 338.517 – Modify references to R 338.501(1)(u) in the rules to R 338.501(1)(v).
  - There is a Typo
- R 338.525(1)(f) and (4)(g)– Delete reference to English language requirement
  - English language only required with initial licensure.
- R 338.533 –
  - (1) – If the new versions of USP 795 and 797 are adopted, provide an exception for flavoring, and review the range for monitoring relative humidity in cleanrooms
  - Review the adoption of USP 800.
  - (2) – Delete the statement that the public can request a copy of the USP from the Department as it is no longer available except to review in person.
- R 338.589 – there is a line in the word “prescription” in (2).
- R 338.589 – Add the exception for pharmacy technicians doing remote work for performing certain prescription processing functions, if the pharmacy establishes controls to protect the privacy and security of confidential records.
- R 338.589 – Add ability for the licensed Pharmacist to access pharmacy database from home or other remote location for remote order entry verification including performing a drug regimen review. If the pharmacy establishes controls to protect the privacy and security of confidential records.

R 338537 – update Rule 37 (1)(b) Most recent printed, and or unabridged computerized versions of the Michigan pharmacy laws and rules, plus at least 2 comprehensive pharmaceutical reference text(s). Which will encompass the general practice of pharmacy that pertains to pharmacology, drug interactions, drug composition, or other information necessary for the delivery of safe and effective practice of pharmacy.

- Reason for unabridged computerized version is to ensure that the licensed pharmacy is using the most complete version of the reference text versus the shortened “google” reference text and to make sure the reference material is pertinent to the practice setting.

Thank you
Maria Young,
University Pharmacy

Sent from my tether...
excuse my brevity and any spelling errors.