MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
JANUARY 21, 2022

The Michigan Board of Pharmacy Rules Committee Work Group met on January 21, 2022. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman, Departmental Specialist, called the meeting to order at 7:00 a.m.

ATTENDANCE

Members Present: Pierre Boutros, R.Ph. (arrived 7:17 a.m.)
Charles Mollien, PharmD, JD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph.
Maria Young, R.Ph.

Members Absent: None

Staff Present: Andria Ditschman, Departmental Specialist,
Boards and Committees Section
Jacob Poynter, Manager, Licensing Division
Stephanie Wysack, Board Support Technician,
Boards and Committees Section

Public Present: Jessica Adams – Cardinal Health

RULES DISCUSSION

Ditschman stated that the Pharmacy Technician Rules would not be worked on today. The goal of the meeting was to get through the Pharmacist Continuing Education and Central Fill Pharmacies drafts, so that they can go before the Board for a vote at the February 16, 2022 meeting.

Pharmacy – Pharmacist Continuing Education (A copy of the draft, pursuant to today's discussion, is attached)

R 338.3041 License renewals; continuing education requirements; applicability.

Subdivision (1)(d)(i): Ditschman stated that language was added to clarify pharmacy law.

The Rules Committee agreed with the language as written.

Subdivision (1)(d)(ii): Ditschman stated that language was added to clarify the formats that continuing education can be completed in.

The Rules Committee agreed with the language as written.

Subdivision (1)(d)(v): Ditschman stated that language was added to clarify that identical programs cannot be given credit in the same renewal period.

The Rules Committee agreed with the language as written.

R 338.3043 Continuing education courses and programs; standards for approval.

Subrule (b): Ditschman stated that language was added, requiring a sponsor to disclose if a program was not approved as of the date of the program, if approval had been requested.

Discussion was held.

Wysack stated that removing the "70 days prior to the next regularly scheduled board meeting" language and the new language about disclosure of approval covers any requests for retro-approvals as the "70 days prior to the date of the continuing education course or program" language covered that.

Discussion was held.

The Rules Committee agreed to remove the above language as suggested.

Subrule (d): Ditschman stated that this had been removed as the content was covered under subrule (c).

The Rules Committee agreed with the removal.

New subrule (d), formerly subrule (e): Ditschman stated that content was removed from this subrule in order to simplify.

The Rules Committee agreed with the language as written.

Subrule (f): Ditschman stated that this was previous subrule (k), reworded slightly for clarification.

The Rules Committee agreed with the language as written.

Subrule (h): Ditschman asked if the "70 days prior to the next regularly scheduled board meeting" language should be removed, to be consistent with subrule (b).

Mollien stated that changes to the title, number of requested continuing education hours, or the learning objectives, would constitute a new program, not a change.

Discussion was held.

Mollien suggested removing subrules (h) and (i) and change the language in subrule (g) to indicate when a new program needed to be applied for.

The Rules Committee agreed with Mollien's suggestion.

Miscellaneous: Mollien stated that the rules should encourage advancement but at the same time, not be too restrictive. Continuing education should be counted if earned during the 60-day grace period, just not toward the next renewal period.

Ditschman stated that rule must be consistent with the code, R 333.17731. That rule reads that continuing education needs to be completed in the 2 years preceding the date of the application for renewal.

Poynter stated that this was addressed in this set of rules, under R 338.3041 (1)(d).

Discussion was held about making sure that it was applied correctly.

Ditschman suggested splitting R 338.3041 (1)(d) into two parts, to clarify the 2-year cycle and that the continuing education period is 2 years preceding the date of application for renewal.

Mollien also suggested adding language to clarify that continuing education earned during the 60-day grace period could not be applied to the renewal cycle that is ending.

The Rules Committee agreed to the above suggestions.

Central Fill Pharmacies (A copy of the draft, pursuant to today's discussion, is attached).

R 338.3051 Definitions.

Ditschman stated that language was added for clarity.

Subdivision (1)(g): Taylor asked if this definition was clear.

Mollien explained that the two sentences were needed for clarification as they are two separate actions.

Discussion was held.

The Rules Committee agreed with the language as written.

R 338.3052 Central fill pharmacies rules; prevail over other pharmacy rules.

Ditschman stated that language was added for clarity.

The Rules Committee agreed with the language as written.

R 338.3053 Centralized prescription processing; requirements.

Ditschman stated that language was added for clarity and to updated rule numbers.

Subrule (5): Taylor stated that hospitals do not return to stock and asked whether retail pharmacies did.

Mollien stated that if the medication was dispensed outside of the pharmacy, but not to the patient, then it could be returned to stock, as no delivery took place.

Ditschman read the definition of a central fill pharmacy from the statute.

Discussion was held regarding what is not a prohibited task.

The Rules Committee agreed to add language to the rule to clarify what is not prohibited to include:

- Data entry.
- Verification of data entry.
- Drug utilization review.
- Claims processing.
- Product verification.

Subdivision (1)(c): Adams asked if this rule was stating that central fill pharmacies do not have to have all records from the originating pharmacy.

Mollien stated that referencing R 338.3054 clarified who "all" is, in the rule.

Ditschman asked if removing "all" who provide better clarification.

The Rules Committee agreed to remove "all."

R 338.3054 Records maintenance; requirements for central fill pharmacies.

Ditschman stated that language was added for clarity.

The Rules Committee agreed with the language as written.

R 338.3055 Schedule 2, 3, 4, or 5 controlled substances prescriptions; requirements for central fill pharmacies.

Subrule (2): Ditschman asked the Rules Committee if this language was inconsistent with the new electronic transmitting rules.

Mollien stated that it was not as it is a different type of transmission.

The Rules Committee agreed with the language as written.

Subrule (3): Ditschman asked the Rules Committee if "originating pharmacy" was applied correctly throughout the rule.

The Rules Committee stated it was.

Subdivision (4)(c): Ditschman stated this was a new subdivision added to provide clarity.

The Rules Committee agreed with the language as written.

Subdivision (3)(d): Taylor asked if a paper prescription was needed, then why was a paper copy being requested.

Mollien stated that the paper prescription is being converted to an electronic, at which point it can be printed.

Mollien suggested changing "paper" to "printed."

The Rules Committee agreed with the suggested change.

Subdivision (4)(a): Ditschman asked the Rules Committee if 5 years was correct for retention.

Mollien stated it was correct.

ADJOURNMENT

Ditschman stated that the Pharmacist Continuing Education and the Central Fill Pharmacies drafts would go before the full Board for a vote on February 16, 2022.

Ditschman adjourned the meeting at 8:32 a.m.

Prepared by:
Stephanie Wysack, Board Support Technician February 3, 2022
Bureau of Professional Licensing

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PHARMACIST CONTINUING EDUCATION

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the **director of the** department of licensing and regulatory affairs by sections 16145, 16148, 16184, 16201, 16204, 16205, 17731, ~~17737,~~ and 17767 of the public health code, 1978 PA 368, MCL 333.16145, 333.16148, 333.16184, 333.16201, 333.16204, 333.16205, 333.17731, ~~333.17737,~~ and 333.17767, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3041, R 338.3043, and R 338.3044, of the Michigan Administrative Code are amended, and R 338.3040 is added, as follows:

R 338.3040 Definitions.

Rule 1. (1) As used in these rules:

(a) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.

(b) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(c) "Department" means the department of licensing and regulatory affairs.

(2) Unless otherwise defined in these rules, the terms defined in the code have the same meaning when used in these rules.

R 338.3041 License renewals; continuing education requirements; applicability.

Rule 1. (1) These rules apply to applications for renewal of a pharmacist's license and a special retired volunteer pharmacist's license under sections 16201 and 16184 of the code, MCL 333.16201 and 333.16184. A licensee seeking renewal shall comply with all of the following:

(a) Submit a completed application on a form provided by the department, together with the requisite fee.

(b) Beginning with renewals on January 1, 2020, an applicant for license renewal shall have completed a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(c) An applicant for license renewal, who also applies for a controlled substance license, shall have completed a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

(d) **The continuing education requirements shall apply to** ~~An~~ **an** applicant for license renewal, who has been licensed for the 2-year period immediately preceding the end of the license cycle~~,~~**.**

(e) An applicant for license renewal shall furnish the board with satisfactory evidence that the applicant completed not less than 30 hours of continuing education approved by the board, under R 338.3043 and R 338.3044, during the ~~2 years~~ **24 months prior to the date they file their** ~~immediately preceding the~~ application for renewal, **which may include the 60 days grace period after the expiration date of the license if the license is renewed within 60 days after the expiration date and the late renewal fee is paid. The continuing education** ~~which~~ must comply with all of the following:

(i) An applicant for license renewal shall complete at least 1 hour of the 30 required hours of continuing education in pharmacy ethics and ~~jurisprudence~~**pharmacy law, which may be completed in one or more courses**. ~~This paragraph applies only to renewals after December 30, 2020.~~

(ii) An applicant for license renewal shall complete a minimum of 10 hours of the 30 required hours of continuing education by attending live**, synchronous,** courses or programs**, in-person or virtual,** that provide for **the opportunity of** direct interaction between faculty and participants, including but not limited to, lectures, symposia, live teleconferences, and workshops. **ACPE courses designated as live meets this requirement.**

(iii) An applicant for license renewal shall complete at least 1 hour of the 30 required hours of continuing education in pain and symptom management, as required under section 16204(2) of the code, MCL 333.16204~~(2)~~. Continuing education in pain and symptom management includes, but is not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interventions as they relate to professional practice.

(iv) An applicant for license renewal shall earn no more than 12 hours of continuing education during a 24-hour period.

(v) **Except for the 1-time training in human trafficking, the 1-time training in opioid and controlled substances awareness, and the implicit bias training, which may be used to comply with both the training requirement and the continuing education requirement in the same renewal period,** ~~An~~**an** applicant for license renewal ~~shall~~ **may** not earn **continuing education** credit **for a program or activity that is identical to a program or activity an applicant has already earned credit for during that renewal period**~~for taking the same continuing education course or program twice during 1 renewal period~~.

(2) Submission of an application for renewal constitutes the applicant's certification of compliance with the requirements of this rule. An applicant shall retain documentation of meeting the requirements of this rule for a period of 4 years from the date of applying for license renewal. The board may require an applicant to submit evidence to demonstrate compliance with this rule. Failure to comply with this rule is a violation of section 16221(h) of the code, MCL 333.16221~~(h)~~.

(3) A request for a waiver under section 16205 of the code, MCL 333.16205, must be received by the department before the expiration date of the license.

(4) Except as otherwise stated, this rule takes effect upon promulgation of the rules.

R 338.3043 Continuing education courses and programs; standards for approval.

Rule 3. The board shall approve continuing education courses or programs pursuant to the following standards in this rule:

(a) A continuing education course or program sponsor shall submit a completed application on forms provided by the department and provide a "Patient Protection" form for any course or program that involves treatment of live patients.

(b) A completed application form shall be submitted to the department at least 70 days prior to the date the continuing education course or program is conducted ~~and 70 days prior to the next regularly scheduled board meeting~~ for the proposed continuing education to be considered for approval by the board. ~~A continuing education course or program conducted prior to board consideration will not be approved.~~

(c) A continuing education course or program must meet the standards and criteria for an acceptable category of continuing education under this rule and R 338.3044 and must be relevant to health care **services, pharmacy operations, or** ~~and~~ advancement of the licensee's pharmacy education.

~~(d) A continuing education course or program must be a planned learning program designed to promote the continual development of knowledge, skills, and attitudes on the part of the pharmacist. The course or program must be an individual organized educational experience under responsible sponsorship and capable direction and must provide qualified instruction.~~

~~(e)~~**(d)** A continuing education course or program shall be developed and presented by a sponsor and must provide all of the following:

(i) ~~Administrative support that ensures maintenance and availability~~ **Availability** of adequate records of participation.

~~(ii) An adequate budget and resources.~~

~~(iii)~~**(ii)** ~~Appropriate, qualified, competent~~ **Qualified** teaching staff.

~~(iv)~~**(iii)** A statement of educational ~~goals or measurable behavioral~~ objectives~~, or both~~.

~~(v) Delivery methods that allow for active participation and involvement.~~

~~(vi) Appropriate, adequate facilities.~~

~~(vii) Evaluations of the participant and the provider.~~

~~(f) The continuing education course or program must include study in 1 or more of the following subjects:~~

~~(i) Social, psychological, economic, and legal aspects of health care delivery.~~

~~(ii) The properties and actions of drugs and dosage forms.~~

~~(iii) Etiology, characteristics, and therapeutics of the disease state.~~

~~(iv) Emergency skills related to the health and safety of the patient.~~

~~(v) Specialized professional services.~~

~~(vi) Other areas of study that the board finds are designed to maintain or enhance a pharmacist's ability to deliver competent pharmacy services.~~

~~(g)~~**(e)** Board approval is valid for a 3-year term of approval from the date of approval.

(f) The subsequent dates that the course or program will be offered do not require further board approval and may be changed without review by the board if the presentation dates are within the board's original 3-year term of approval.

~~(h)~~**(g)** The board shall reevaluate an approved continuing education course or program prior to any changes during the approval term~~, including but not limited to, changes~~ to ~~either of the following:~~

~~(i) Instructors and speakers.~~

~~(ii) Course or program content,~~ **the** title, ~~and~~ number of continuing education hours to be awarded to participants**, or learning objectives**.

~~(i) Subject to subdivision (j) of this rule, all changes to a previously approved course or program must be submitted on required department forms at least 70 days prior to the date the course or program is offered to participants and 70 days prior to the next regularly scheduled board meeting to be considered for approval by the board. Any changes to a submitted and previously approved course or program conducted prior to board reconsideration and approval will not be approved.~~

~~(j) Emergency changes to instructors and speakers that cannot be submitted to the board at least 70 days prior to the date of the course or program may be reviewed by the department in consultation with the board chair or a continuing education board committee member if proof that is acceptable to the department and that supports the nature of the emergency is submitted with the change.~~

~~(k) The specific dates that the course or program will be offered do not require further board approval and may be changed without review by the board if the presentation dates are within the board's original 3-year term of approval.~~

~~(l)~~**(h)** A sponsor conducting the course or program shall record all of the following on a continuing education certificate or other proof prepared by that sponsor:

(i) The name of the sponsor.

(ii) Continuing education approval number assigned by the department.

(iii) Course title or name of the program.

(iv) Name of the speaker or instructor.

(v) Date the approved course or program was conducted.

(vi) Number and type of continuing education hours awarded.

(vii) Approved sponsor's signature.

(viii) Dates of the current approval term.

(ix) Name of participant.

~~(m)~~**(i)** The board may revoke the approval status of any approved course or program at any time the course or program fails to comply with these rules.

R 338.3044 Acceptable continuing education for licensees.

Rule 4. The board shall consider all of the following as acceptable continuing education:

ACCEPTABLE CONTINUING EDUCATION ACTIVITIES		
	Type of Activity	~~#~~ **Number** of Hours Earned/Maximum Hours
(a)	Completion of an approved continuing education course or program related to the practice of pharmacy. A continuing education course or program is approved, regardless of the format in which it is offered, if it is approved or offered for continuing education credit by any of the following: A pharmacy program accredited by the Accreditation Council for Pharmacy	The number of hours earned will be the number of hours approved by the sponsor or the approving organization. If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.

	Education (ACPE) or the Canadian Council for Accreditation of Pharmacy Programs (CCAPP). A continuing education sponsoring organization, institution, or individual approved by the ACPE. Another state board of pharmacy. If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held, or activity completed.	No limitation on the number of hours earned.
(b)	Completion of postgraduate pharmacy practice or administration courses offered for credit in a pharmacy school accredited by the ACPE or the CCAPP. If audited, a licensee shall submit an official transcript that reflects completion of the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.	Twelve hours of continuing education will be earned for each academic quarter credit earned and 18 hours will be earned for each academic semester credit earned. No limitation on the number of hours earned.
(c)	Participation in a home study program offered through an ACPE-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles. If audited, a licensee shall submit an affidavit attesting to the number of hours the licensee spent participating in the home study program that includes a description of the activity.	One hour will be earned for each hour devoted to a home study program. A maximum of 20 hours **may be earned** per renewal period.
(d)	Participation as a preceptor for at least 1 pharmacy intern. A preceptorship shall be for a minimum of 120 hours in person and have a 1 intern - to - 1 preceptor ratio. This may involve multiple preceptor relationships at different times. If audited, a licensee shall submit written	Five hours of continuing education may be earned for a minimum of 120 hours in person of preceptorship in each renewal period. A maximum of 5 hours may be earned in each renewal period.

	documentation from the educational institution or preceptor's supervisor verifying the dates and hours of the preceptorship.	
(e)	Renewal of a pharmacy license held in another state that requires continuing education for license renewal that is substantially equivalent in subject matter and total amount of required hours to that required in these rules if the licensee resides and practices in another state. If audited, a licensee shall submit proof of current licensure in another state and a copy of a letter or certificate of completion showing all of the following: the licensee's name, number of hours earned, the sponsor's name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held**,** or the activity was completed.	Thirty hours will be earned. A maximum of 30 hours may be earned in each renewal period.
(f)	Initial publication of an article or a chapter related to the practice of pharmacy in either of the following: A pharmacy textbook. A peer reviewed journal. If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.	Ten hours will be earned per publication. A maximum of 10 hours may be earned in each renewal period.
(g)	Successful completion of a board certification national pharmacy examination through Board of Pharmacy Specialties (BPS). If audited, a licensee shall submit proof of a passing score on the examination.	Ten hours may be earned in the year in which the licensee achieves a passing score. A maximum of 20 hours may be earned in each renewal period. Credit will not be given for repeating the same examination twice in a renewal period.
(h)	Presentation of a continuing education program approved by the board under R 338.3043 or subdivision (a) of this rule that is not a part of the licensee's regular job description.	Two hours for every 50 minutes devoted to presenting the program. A maximum of 10 hours ~~will~~ **may** be earned in each renewal period.

	If audited, a licensee shall submit a copy of the curriculum and a letter from the program sponsor verifying the length and date of the presentation.	
(i)	Attendance at a pharmacy-related program that is approved by the board pursuant to R 338.3043. If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or course for continuing education credit, and the date on which the program was held**,** or the activity was completed.	The number of hours earned will be the number of hours approved by the sponsor or the approving organization. If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned. No limitation on the number of hours earned.
(j)	**Attendance at a full Board of Pharmacy meeting, Disciplinary Subcommittee meeting, or Rules Committee Work Group meeting.**	**1 hour may be earned for attending a full meeting. This category of CE qualifies as 1 hour in pharmacy law.** **A maximum of 5 hours may be earned in each renewal period.**

DEPARTMENT OF ~~COMMUNITY HEALTH~~**LICENSING AND REGULATORY AFFAIRS**

DIRECTOR'S OFFICE

~~CENTRALIZED PRESCRIPTION PROCESSING~~ **CENTRAL FILL** PHARMACIES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a~~(6)~~**(9)** of the administrative procedures act of 1969,1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the ~~department of community health~~ **department of licensing and regulatory affairs** by sections 16145**,** ~~and 17701~~**17753, and 17767** of **the public health code,** 1978 PA 368, MCL 333.16145**,** ~~and 333.17701~~ **333.17753,** ~~et seq.~~ and **333.17767, and** Executive Reorganization Order ~~Numbers~~ **Nos.** ~~1996-1~~ **1991-9**, 1996-2, ~~and~~ 2003-1, **and 2011-4,** ~~being~~ MCL ~~330.3101~~ **338.3501**, 445.2001, ~~and~~ 445.2011 **and 445.2030**)

R 338.3051, R 338.3052, R 338.3053, R 338.3054, R 338.3055, and R 338.3056 of the Michigan administrative code are amended, as follows:

PART 1. GENERAL PROVISIONS

R 338.3051 Definitions.

Rule 1. (1) As used in **these rules** ~~parts 1 and 2 of the centralized prescription processing rules, R 338.3051 to R 338.3054~~:

(a) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.

(b) ~~(a)~~ "~~Centralized prescription~~ **Central fill pharmacy**~~processing center~~" means a pharmacy ~~operated under the direction of a pharmacist~~ that ~~processes information related to the practice of pharmacy and~~ engages in centralized prescription processing **at the request of an originating pharmacy**.

(b) "Centralized prescription processing" is the term defined in section 17753(3) of the code **but does not include the following functions, which are not covered by these rules:**

(i) Entering information into a data system.

(ii) Pharmacist verification of data entered into a data system.

(iii) Completion of drug utilization review.

(iv) Claims processing.

(v) Remote product verification.

(c) "Code" means **the public health code,** 1978 PA 368, MCL 333.1101 ~~et seq.~~ **to 333.25211.**

(d) "Department" means the department of licensing and regulatory affairs (LARA).

~~(d)~~ **(e)** "Deliver" as used in this part means **the actual, constructive, or attempted transfer of** ~~to~~ a prescription drug, including a controlled substance, directly to a patient or a patient's agent by the lawful order of a practitioner. A ~~centralized prescription~~ **central fill** ~~processing center~~ **pharmacy** that provides a prescription product to another pharmacy for subsequent issuance to a patient or a patient's agent has not met the definition of deliver as defined in this subrule.

~~(e)~~ **(f)** "Delivering pharmacist" means a pharmacist who is responsible for delivering a prescription directly to a patient or a patient's agent.

~~(f)~~ **(g)** "Delivering pharmacy" means the pharmacy that delivers the filled or refilled prescription to the patient or the patient's ~~authorized representative~~**agent**. The delivering pharmacy shall be either the originating pharmacy or the centralized prescription processing center **central fill pharmacy**.

~~(g)~~ **(i)** "Originating pharmacy" means a pharmacy that initially receives a patient's or a prescribing practitioner's request to fill or refill a prescription.

(2) **Unless otherwise defined in these rules, the** ~~The~~ terms defined in the code have the same ~~meanings~~ **meaning** when used in these rules.

R 338.3052 ~~Centralized prescription~~ **Central fill pharmacies** rules; prevail over other pharmacy rules.

Rule 2. To the extent that ~~any rule in parts 1 and 2 of the centralized prescription processing~~ **these** rules ~~conflicts~~ **conflict** with other board ~~of pharmacy~~ rules, the provisions in ~~parts 1 and 2 of the centralized prescription processing~~ **these** rules shall prevail.

R 338.3053 Centralized prescription processing; requirements.

Rule 3. (1) In addition to complying with the requirements of section 17753 of the code, **MCL 333.17753,** a pharmacy **shall meet all of the following requirements before it either performs** ~~may perform~~ centralized prescription processing ~~services~~ or ~~outsource~~ **outsources** ~~these services~~ **centralized prescription processing** to another pharmacy**:**~~.~~ ~~Pharmacies that perform or outsource prescription processing services shall meet all of the following requirements:~~

(a) ~~Be licensed by the Michigan board of pharmacy~~**The pharmacies shall hold a pharmacy license in this state**.

(b) **The pharmacies shall share** ~~Share~~ sufficient patient and drug information to minimize the possibility of an adverse drug event.

(c) **The pharmacies shall** ~~Maintain~~ **maintain** ~~prescription information or an equivalent record, as prescribed in section 17752(1) of the code, and the~~ records required in R 338.3054 ~~of this part~~, for 5 years **from the date of dispensing**. A ~~centralized prescription processing center~~ **central fill pharmacy** and an originating pharmacy shall ensure that the information is readily retrievable within 48 hours after the ~~board's agent~~ **department** makes a request for the information. If the records are maintained in a digital format, a printed copy shall be made available **to the department or other authorized individual**~~immediately to the board's agent~~ upon request.

(d) The originating pharmacy shall maintain the original prescription for a period of 5 years from the date the prescription was filled. After 2 years, the originating pharmacy may make an electronic duplicate of the original paper prescription, which will become the original prescription. A pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or other authorized individual upon request.

(2) A pharmacy engaging in centralized prescription processing shall be responsible for each function of the prescription's processing performed by that pharmacy.

(3) A delivering pharmacist shall be responsible for complying with ~~R 338.490(4)~~ **R 338.589(4)** regarding patient counseling.

(4) The prescription label for a prescription that was filled by a ~~centralized prescription processing center~~ **central fill pharmacy** shall identify each pharmacy that was involved in ~~preparing~~**dispensing** and delivering a prescription. A ~~centralized prescription processing center~~ **central fill pharmacy** may be identified on a prescription label by use of a unique identifier that is recognized by the delivering pharmacist. As used in this subrule, "unique identifier" means a unique combination of letters, numbers, or symbols that allows the delivering pharmacy to identify the specific ~~centralized prescription processing center~~ **central fill pharmacy** involved in the processing of the prescription. A ~~centralized prescription processing center~~ **central fill pharmacy** shall create and maintain a unique identifier and shall communicate the unique identifier to all pharmacies that use its services.

(5) A prescription that was not delivered to a patient may be transferred back to the pharmacy that filled the prescription, provided that the transfer records are maintained. A ~~centralized prescription processing center~~ **central fill pharmacy** and an originating pharmacy shall establish procedures for the disposition of prescription medication that was not delivered to patients. This medication may be returned to stock and may be ~~re-delivered~~ **re-dispensed** without constituting a violation of R ~~338.472(1)~~ **338.503(1)**.

(6) A pharmacy that performs or contracts for centralized prescription **processing** ~~services~~ shall comply with the procedures described in its policies and procedures manual, as provided in section 17753(2) of the code**, MCL 333.17753**.

R 338.3054 Records maintenance; requirements for ~~centralized prescription processing~~ **central fill** pharmacies.

Rule 4. (1) An originating pharmacy shall maintain records that indicate all of the following:

(a) The date the request for centralized prescription processing ~~services~~ was transmitted to a ~~centralized prescription processing center~~ **central fill pharmacy**.

(b) The method of transmittal.

(c) The identification of the pharmacist responsible for the transmission.

(d) The name and address of the ~~centralized prescription processing center~~ **central fill pharmacy** ~~to which~~ **where** the request for centralized prescription processing ~~services~~ was transmitted.

(e) The date the delivering pharmacy received the filled prescription from the ~~centralized prescription processing center~~ **central fill pharmacy**.

(f) The name of the pharmacy employee who accepted the ~~delivery~~ **transfer** of a filled prescription from a ~~centralized prescription processing center~~ **central fill pharmacy**.

(g) The identification of the pharmacist who was responsible for delivering the prescription to the patient or the patient's agent.

(2) A ~~centralized prescription processing center~~ **central fill pharmacy** that receives the transmitted prescription shall maintain records that indicate all of the following, as applicable to its function:

(a) The date the request for centralized prescription processing ~~services~~ was received from the originating pharmacy.

(b) The name and address of the originating pharmacy from which the request for centralized prescription processing ~~services~~ was received.

(c) The date the prescription was processed, verified, or filled.

(d) The identification of any pharmacist who was responsible for processing the prescription and shipping a filled prescription to an originating pharmacy or delivering a filled prescription to a patient or a patient's agent.

(e) The date the filled prescription was shipped to the originating pharmacy or was shipped or delivered to the patient or the patient's agent.

(f) If shipped, the name and address of the patient to whom the filled prescription was shipped.

(g) The method of delivery, such as private, common, or contract carrier, if shipped.

(3) If a prescription was not delivered to a patient and was transferred back to the pharmacy that filled the prescription, that pharmacy shall maintain the transfer records.

PART 2. CONTROLLED SUBSTANCES PRESCRIPTIONS

R 338.3055 Schedule 2, 3, 4, or 5 controlled substances prescriptions; requirements for ~~centralized prescription processing~~ **central fill** pharmacies.

Rule 5. (1) In addition to complying with the requirements of Part 1 of these rules, a pharmacy that performs or contracts for centralized prescription processing ~~services~~ shall comply with this rule when processing a prescription for a schedule 2, 3, 4, or 5 controlled substance.

(2) Prescriptions for controlled substances may be transmitted electronically, including by facsimile, from an originating pharmacy to a ~~centralized prescription processing center~~ **central fill pharmacy**.

(3) An originating pharmacy that transmits prescription information for a controlled substance to a ~~centralized prescription processing center~~ **central fill pharmacy** shall comply with all of the following:

(a) **The originating pharmacy shall ensure** ~~Ensure~~ that the words "CENTRAL FILL" are on the face of the original prescription and record all of the following information:

(i) ~~the~~ **The** name, address, and the ~~federal drug enforcement administration (dea)~~ **Federal Drug Enforcement Administration (DEA)** registration number of the ~~centralized prescription processing center~~ **central fill pharmacy** ~~to which~~ **where** the prescription ~~had been~~ **was** transmitted~~;~~ **.**

(ii) ~~the~~ **The** name of the pharmacist at the originating pharmacy who transmitted the prescription~~;~~ **.**

(iii) ~~and, the~~ **The** date of transmittal.

(b) **The originating pharmacy shall ensure** ~~Ensure~~ that all information that is required to be on a prescription pursuant to the provisions of 21 **CFR**~~C.F.R. §~~**section**

1306.05 and R 338.3161 is transmitted to the ~~centralized prescription processing center~~ **central fill pharmacy** either on the face of the original prescription or in the electronic transmission of **the** prescription ~~information~~.

(c) **The originating pharmacy shall** ~~Indicate~~ **include all of the following** in the prescription ~~information that is transmitted,~~.

(i) ~~the~~ **The** number of refills already dispensed**.**

(ii) ~~and the~~ **The** number of refills remaining.

(d) **The originating pharmacy shall maintain**~~Maintain~~ the original prescription for a period of 5 years from the date the prescription was filled. **After 2 years, the originating pharmacy may make an electronic duplicate of the original paper prescription, which will become the original prescription. A pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or other authorized individual upon request.**

(4) In addition to complying with the requirements in R ~~338.3053~~**338.3054**(2)(a), (b), (c), (d), (e), (f) and (g), a ~~centralized prescription processing center~~**central fill pharmacy** that receives the transmitted prescription shall comply with both of the following:

(a) **The central fill pharmacy shall maintain**~~Maintain~~ records for 5 years **from the date of transmittal**.

(b) Keep a copy of the prescription if it was sent via facsimile or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and ~~dea~~ **DEA** registration number of the originating pharmacy that transmitted the prescription.

(c) Keep a record of the date the filled prescription was dispensed and the method of dispensed.

R 338.3056 Reporting to the electronic system for monitoring controlled substances.

Rule 6. As used in this part, the pharmacy that uses its stock to fill a prescription for a controlled substance shall be the pharmacy responsible to report to the department or the department's contractor the information required in R 338.3162b for each **controlled substance** prescription ~~of a controlled substance~~.