MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
DECEMBER 1, 2021

The Michigan Board of Pharmacy Rules Committee Work Group met on December 1, 2021. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman, Departmental Specialist, called the meeting to order at 8:03 a.m.

ATTENDANCE

Members Present: Pierre Boutros, R.Ph.
Charles Mollien, PharmD, JD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph.

Members Absent: None

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

RULES DISCUSSION

Pharmacy – 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 she has received many questions, asking for clarification of this subrule.

Mollien stated that if both topics were covered within the one hour, then that would count. If only one topic is covered within the one hour, then an additional hour would need to be taken in the missing topic. He suggested clarifying "jurisprudence" to "pharmacy law."

Sleiman suggested adding "which may be completed in 1 or more courses" after "pharmacy law."

The Rules Committee agreed with both of the above suggestions.

Subdivision (1)(d)(ii): Ditschman stated that she has received questions regarding this provision, and she asked the Rules Committee if they believed the rule was clear as written regarding live courses.

Mollien stated that the Accreditation Council for Pharmacy Education (ACPE) distinguishes whether a course was taken at home (H) or live (L). He suggested changing to "live (synchronous) courses or programs that provide opportunity for direct, in person or virtual, interaction…."

The Rules Committee agreed with the language change.

Taylor asked about adding language regarding ACPE.

Ditschman suggested adding "ACPE courses designated as live meet this requirement."

The Rules Committee agreed with the additional language.

Subdivision (1)(d)(v): Ditschman asked if this subdivision should be left as is which would prohibit a licensee from counting non-continuing education requirements such as the human trafficking course toward continuing education requirements, or if exception language should be added, allowing for human trafficking, opioid training, and implicit bias training to count towards continuing education as well.

Discussion was held.

The Rules Committee agreed to add the exception language.

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

Subrule (b): Ditschman asked if the Board's intent was to not disallow approval of any program that has been given before Board approval.

Mollien stated that it could be approved after, as long as the sponsor disclosed at the time it was given that approval had not yet been obtained.

Discussion was held.

The Rules Committee agreed to change the last sentence to read “A continuing education course or program conducted prior to application will not be approved.”

Subrule (d): Ditschman asked if this subrule was needed.

Discussion was held.

The Rules Committee agreed to remove subrule (d) as its content was covered under subrule (c).

Ditschman stated that Wysack had suggested that subrules (e) and (f) be removed.

Subrule (e): Wysack stated that subrule (e) requested items that were not necessary in determining if the program met the requirement of subrule (c).

Discussion was held.

The Rules Committee agreed to keep subdivisions (i), (iii), and (iv).

The Rules Committee agreed to delete subdivisions (ii), (v), (vi), and (vii).

Subrule (f): Wysack stated that the subjects listed were covered under the statement in subrule (c) “….relevant to health care and advancement of the licensee’s pharmacy education.”

Discussion was held.

The Rules Committee agreed to delete subrule (f) and to change the language in subrule (c) to read “….be relevant to health care *services, pharmacy operations, or the* advancement of the licensee’s pharmacy education.”

Ditschman asked Poynter if the Department had ever approved continuing education for one of the health professions, instead of the Board.

Poynter stated that the Department has been used in the approval of refresher courses, etc. for the purpose of retesting, but not continuing education.

Mollien stated that, for a future rule set, the Rules Committee should consider allowing for the Continuing Education Committee, in consultation with the Department, to approve continuing education in order to expedite the process of waiting to go before the Board for approval.

Mollien stated that the pharmacy technician rules should reference this set of rules for review of continuing education in order to be consistent.

Subrule (k): Wysack suggested changing the location of this subrule to below subrule (g) and to change the beginning of the sentence to "Subsequent…." Instead of "The specific…" as the start date is already disclosed on the application in order to comply with applying 70 days prior to conducting the course, as requested in subrule (b).

Discussion was held.

The Rules Committee agreed with the suggested change.

R 338.3044 Acceptable continuing education for licensees.

Subrule (a): Ditschman asked if the entities listed should have the ability to offer and approve as written in the rule.

The Rules Committee agreed to leave the language as is.

Subrule (c): Ditschman asked the Rules Committee to review this provision.

Mollien stated that the subrule allowed for credit to be given for participation, even if the certification program was not completed and a certificate issued.

The Rules Committee agreed to leave the language as is.

Taylor stated that it was unclear as to what each column was, as there were no headers.

Ditschman stated that she will add headers to clarify the columns.

Mollien stated that an activity should be added to allow for credit to be given for board meeting attendance. He suggested one hour of law, per occurrence, no matter how long the length of the meeting is.

Discussion was held on what the maximum should be.

The Rules Committee agreed to 1 hour of law continuing education, per attendance at a Board meeting, which can include the Disciplinary Subcommittee and Rules Committee meetings, with a maximum of 5 hours of continuing education credit per renewal cycle.

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

R 338.3051 Definitions.

Subdivision (1)(b): Ditschman stated that she deleted "….operated under the direction of a pharmacist…." as this requirement was consistent with all pharmacies.

The Rules Committee agreed with the deletion.

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

Ditschman asked if this could be removed as the rules did not to specifically state that these rules prevailed over others.

Mollien stated that because central fill pharmacies operate differently than other pharmacies, they should be left in order to not cause any conflicts.

The Rules Committee agreed to leave the rule.

R 338.3053 Centralized prescription processing; requirements.

Ditschman stated that she added a reference to the statute and made some other minor changes.

Subdivision (1)(c): Ditschman asked the Rules Committee for direction on this provision.

Mollien stated that the originating pharmacy keeps the prescription and that the central fill pharmacy keeps an electronic version.

Ditschman asked if a new subdivision (d) would be needed in order to address all of the records.

Mollien stated that changing subdivision (c) to "The *pharmacies shall maintain all records* and records…." would address both the original and electronic prescription.

The Rules Committee agreed with the above change.

Ditschman asked the Rules Committee if the language regarding destroying records could be removed, due to the above change.

The Rules Committee agreed that the destroying records language could be removed.

Subrule (4): Ditschman stated that she changed “centralized prescription processing center” to “central fill pharmacy” throughout the rule set, where applicable.

The Rules Committee agreed with those changes.

Subrule (5): Ditschman asked if the term “re-delivered” was appropriate.

Discussion was held.

Poynter stated that the issue was with the prescription never leaving the possession of the central fill pharmacy as referenced in MCL 338.503(1). He suggested that the term “dispense” be used instead.

Mollien stated that the definition of “dispense” in the statute was changed after these rules were written. Dispense no longer includes delivery to the patient.

Taylor suggested the use of “re-dispense.”

The Rules Committee agreed to change “re-delivered” to “re-dispense.”

ADJOURNMENT

Ditschman stated that another Rules Committee meeting would be needed to complete the review of Central Fill Pharmacies rule set.

Ditschman stated that she would be asking the Full Board to open the Pharmacy Technician rules at the Board meeting on December 8, 2021. She stated that they could also be worked on at the next Rules Committee meeting, time permitting, and that the completed sets could go before the full Board for a vote on February 16, 2022.

Ditschman adjourned the meeting at 10:00 a.m.

Prepared by:
Stephanie Wysack, Board Support December 7, 2021
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 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, of the Michigan Administrative Code is amended as follows:

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) An applicant for license renewal, who has been licensed for the 2-year period immediately preceding the end of the license cycle, 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 immediately preceding the application for renewal, 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. 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 courses or programs that provide

for direct interaction between faculty and participants, including but not limited to, lectures, symposia, live teleconferences, and workshops.

(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) An applicant for license renewal shall not earn credit 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 338.3042 Rescinded.

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 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) 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 of adequate records of participation.

(ii) An adequate budget and resources.

(iii) Appropriate, qualified, competent teaching staff.

(iv) 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) Board approval is valid for a 3-year term of approval from the date of approval.

(h) 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, title, and number of continuing education hours to be awarded to participants.

(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) 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) 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		
(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 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.	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.
(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 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 documentation from the educational institution or preceptor's supervisor verifying the dates and hours of the preceptorship.	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.
(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.	Ten hours will be earned per publication. A maximum of 10 hours may be earned in each renewal period.

	If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.	
(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. 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.	Two hours for every 50 minutes devoted to presenting the program. A maximum of 10 hours will be earned in each renewal period.
(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.

R 338.3045 Rescinded.

DEPARTMENT OF COMMUNITY HEALTH

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) 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~~ **director of licensing and regulatory affairs** by sections 16145 and ~~17701~~**17753** of **the public health code,** 1978 PA 368, MCL 333.16145 and ~~333.17701~~ **333.17753** ~~et seq.~~ 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)

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 board of pharmacy.

(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.~~

(c) "Code" means 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 to issue 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 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 pharmacy shall** ~~Maintain~~ **maintain the original** 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 delivery**. **After 2 years, a pharmacy may make an electronic duplicate of the original prescription which will become the original prescription. If an electronic duplicate is made, the original prescription may be destroyed.** 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 immediately ~~to the board's agent~~ 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 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 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 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 paper copy of the electronic duplicate of the prescription to an authorized agent of the board 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 delivered and the method of delivery.

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~~.