State Budget Office
Office of Regulatory Reinvention
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REQUEST FOR RULEMAKING (RFR)

Under the Administrative Procedures Act (APA), 1969 PA 306, the agency that has the statutory authority to promulgate rules must electronically file a RFR with the Office of Regulatory Reinvention (ORR) before initiating any changes or additions to the rules. Submit copy to the ORR at **orr@michigan.gov**.

1. Agency Information

Agency name:	Department of Licensing and Regulatory Affairs
Division/Bureau/Office:	Legal Affairs/Enforcement Division/Bureau of Professional Licensing
Agency contact person name, e-mail, and phone:	Andria M. Ditschman DitschmanA@michigan.gov 517-241-9255

2. Rule Set Information

Title of proposed rule set:	Board of Pharmacy – General Rules
Rule number(s) or range of numbers:	R 338.471 – R 338.590
Included in agency's annual regulatory plan as rule to be processed in current year?	Yes.

3. Estimated timetable for completion, or statutory deadline, if applicable:

1 year

4. Describe the general purpose of these rules, including any problem(s) the changes are intended to address:

The current Pharmacy – General Rules are incomplete, disorganized, and difficult to use. The draft rules have been reorganized and substantially rewritten to provide for rules that encompass all the necessary requirements for licensing and regulating the practice for pharmacists, pharmacies, and manufacturers and wholesale distributors of drugs and devices. The draft rules include parts for general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, and the practice of pharmacy.

Part 1 of the proposed pharmacy rules pertains to definitions, resale of drugs and devices, and inspections of applicants and licensees.

Part 2 of the proposed pharmacy rules pertains to licensure of pharmacists. This part includes the rules pertaining to training for identifying victims of human trafficking, educational limited licenses, internship requirements, preceptor licenses, examinations, pharmacist licensure by examination and endorsement, and relicensure.

Part 3 of the proposed pharmacy rules pertains to pharmacy licenses. This part includes the application requirements for pharmacies, sterile compounding services and the adoption by reference of standards that apply to these services, inspections, discontinuance and resumption of sterile compounding services, housing of a pharmacy, professional and technical equipment and supplies, closure of a pharmacy, and relicensure.

Part 4 of the proposed pharmacy rules pertains to a manufacturer license. This part includes licensure requirements for manufacturers of drugs and devices, persons to whom drugs or devices

may be sold, adoption by reference of a federal regulation on good manufacturing practices for finished pharmaceuticals, closure of a manufacturer, and relicensure.

Part 5 of the proposed pharmacy rules pertains to a wholesale distributor license. This part includes the determination of a pharmacy as a wholesale distributor, the licensure requirements for wholesale distributors of drugs and devices, persons to whom drugs or devices may be sold, wholesale distributor practices, recordkeeping and policy requirements for wholesale distributors, facility requirements, examination of drugs and devices, closure of a wholesale distributor, and relicensure.

Part 6 of the proposed pharmacy rules pertains to the practice of pharmacy. This part includes pharmacy services by medical institutions, prescription drug labeling and dispensing, prescription drug receipts, noncontrolled prescriptions, a customized patient medication package~~s~~, prescription records, prescription refill records, automated devices, professional responsibility of a pharmacist, and a hospice emergency drug box.

5. Cite the specific rule promulgation authority (i.e. agency director, commission, board, etc., listing all applicable statutory references. If the rule(s) are mandated by any applicable constitutional or statutory provision, please explain.

MCL 333.16145(2); MCL 333.16145(3); MCL 333.16148; MCL 333.17721; Executive Reorganization Order No. 1991-9, MCL 338.3501; Executive Reorganization Order No. 1996-2, MCL 445.2001; Executive Reorganization Order No. 2003-1, MCL 445.2011, and Executive Reorganization Order No. 2011-4, MCL 445.2030.

6. Describe the extent to which the rule(s) conflict with, duplicate, or exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level. Include applicable public act and statutory references.

Each state establishes its own requirements with respect to the licensing requirements of a pharmacy. There is no federal rule or standard set by a national or state agency that the proposed rules duplicate or are against. The rules adopt the sterile compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention.

7. Is the subject matter of the rule(s) currently contained in any guideline, manual, handbook, instructional bulletin, form with instructions, or operational memo?

No. The subject matter of these rules is not currently contained in any guideline, handbook, manual, instructional bulletin, form with instructions, or operational memoranda.

8. Explain whether the rule(s) will be promulgated under Sections 44 or 48 of the APA or the full rulemaking process:

These rules will be promulgated using the full rulemaking process.

9. Do the rule(s) incorporate the recommendations of any Advisory Rules Committee formed pursuant to Executive Order 2011-5? If yes, explain.

The proposed rules do not incorporate any recommendation of any Advisory Rules Committee.

10. Is there an applicable decision record as defined in Section 3(6) and required by Section 39(2) of the APA? If so, please attach the decision record.

The Michigan Board of Pharmacy voted to open the rules at the regularly scheduled board meeting on October 11, 2017. Please see attached copy of the minutes from that meeting.

11. Reviewed by the following Departmental Regulatory Affairs Officer:

Liz Arasim Department of Licensing and Regulatory Affairs

↓ **To be completed by the ORR** ↓

Date RFR received:5-29-2018

☒ **Based on the information in this RFR, the ORR concludes that there are sufficient policy and legal bases for approving the RFR.**

ORR assigned rule set number:	**2018-039 LR**
Date of approval:	**6/6/18**

☐ **Based on the information in this RFR, the ORR is not approving the RFR at this time.**

Date of disapproval:	
Explanation:	