Michigan Office of Administrative Hearings and Rules

Administrative Rules Division (ARD)

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REQUEST FOR RULEMAKING (RFR)

1. Department:
Licensing and Regulatory Affairs

2. Bureau:
Bureau of Professional Licensing

3. Promulgation type:
Full Process

4. Title of proposed rule set:
Pharmacy-General Rules

5. Rule numbers or rule set range of numbers:
R 338.471 – R 338.590

6. Estimated time frame:
12 months

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7. Describe the general purpose of these rules, including any problems the changes are intended to address.

The purpose of the Pharmacy – General Rules is to encompass all the necessary requirements for licensing and regulating the practice for pharmacists, pharmacies, manufacturers, wholesale distributors, and wholesale distributor-brokers. The rules include parts for general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, wholesale distributor-broker licenses, and the practice of pharmacy.

The purpose of the proposed rules is to: implement section 17744f of the Public Health Code (Code), MCL 333.17744f, regarding dispensing emergency supplies of insulin, pursuant to PA 36 of 2021; clarify the internship requirements; clarify the regulations regarding compounding accreditation, inspections, and applicable standards; update rules affected by any other modified Code provisions or federal regulations; review refill requirements; review the professional and technical equipment and supply requirements; review licensure requirements including the necessity of the Multistate Pharmacy Jurisprudence Examination; review the need for telehealth regulations; and update definitions.

8. Please cite the specific promulgation authority for the rules (i.e. department director, commission, board, etc.).

MCL 333.16141 authorizes the Department to promulgate rules to promote the effective and consistent administration of Article 15 of the Public Health Code. MCL 333.16145 authorizes a Board to promulgate rules necessary or appropriate to fulfill its functions as prescribed in Article 15. MCL 333.17742a authorizes the Department, in consultation with the Board, to establish requirements for licensure for remote pharmacies. MCL 333.17748a authorizes the Department, in consultation with the Board, to promulgate rules regarding conditions and facilities for the compounding of nonsterile and sterile pharmaceuticals. MCL 333.17748e authorizes the Department, in consultation with the Board, to establish requirements for licensure as a wholesale distributor-broker. MCL 333.17754a authorizes the Department to establish by rule the requirements for obtaining a waiver from electronically transmitting a prescription, as well authorizing the Department, in consultation with the Board, to promulgate rules to implement MCL 333.17754a. MCL 333.17767 authorizes the Board to promulgate rules necessary or appropriate to the licensing of pharmacists, drugs, dispensers, manufacturers, wholesale distributors, and wholesale distributor-brokers. MCL 333.17744f authorizes the Board to promulgate rules necessary to effectuate PA 36 of 2021, regarding dispensing emergency supplies of insulin.

A. Please list all applicable statutory references (MCLs, Executive Orders, etc.).

MCL 333.16141; MCL 333.16145; MCL 333.16148; MCL 333.16174; MCL 333.16175; MCL 333.16178; MCL 333.16182; MCL 333.16186; MCL 333.16204; MCL 333.16205; MCL 333.16215; MCL 333.16287; MCL 333.17707; MCL 333.17721; MCL 333.17722; MCL 333.17731; MCL 333.17737; MCL 333.17739; MCL 333.17742a; MCL 333.17742b; MCL 333.17744f; MCL 333.17746; MCL 333.17748; MCL 333.17748a; MCL 333.17748b; MCL 333.17748e; MCL 333.17751; MCL 333.17753; MCL 333.17754a; MCL 333.17757; MCL 333.17760; MCL 333.17767; MCL 333.17775; 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.

B. Are the rules mandated by any applicable constitutional or statutory provision? If so, please explain.

The proposed rules are required by sections 16287, 17722, 17731, 17737, 17742a, 17744f, 17748e, and 17754a of the Public Health Code, MCL 333.16287, MCL 333.17722, MCL 333.17731, MCL 333.17737, MCL 333.17742a, MCL 333.17744f, MCL 333.17748e, and MCL 333.17754a. The rules are not federally mandated.

9. Please describe the extent to which the rules conflict with or duplicate similar rules, compliance requirements, or other standards adopted at the state, regional, or federal level.

The Drug Supply Chain Security Act (DSCSA) and corresponding federal regulations include requirements to develop and enhance drug supply chain security. They establish a federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and include product tracing requirements for entities in the drug supply chain, including manufacturers, repackagers, wholesale drug distributors, and pharmacies. They also require the Food and Drug Administration (FDA) to establish federal standards for licensing of wholesale drug distributors and third-party logistics providers. States may not regulate tracing that is inconsistent with, more stringent than, or in addition to the federal requirements. States are also preempted from establishing licensure requirements that are inconsistent with or below the minimum standards established by federal law for wholesale distributors and third-party logistics providers. The DSCSA and federal regulations require a wholesale drug distributor and third party logistics provider to maintain licensure in the state from which the drug is distributed and in most cases the state into which the drug is distributed if those states have a licensure process. State licensure information including significant discipline must be reported to the FDA on an annual

basis. The DSCSA and federal regulations exclude a list of activities from the definition of wholesale distribution that are being adopted in the rules.

The rules adopt the pharmaceutical compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, and the regulations regarding good manufacturing practices for finished pharmaceuticals set forth in 21 CFR sections 211.1 to 211.208 (1978). Some aspects of the practice of pharmacy, such as the labeling of prescription drugs, are regulated by the Federal Food, Drug, and Cosmetic Act of 2016, 21 USC sections 351 to 399f and have been adopted by the proposed rules.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act and corresponding Code of Federal Regulations, 42 CFR 423, require electronic prescribing under Medicare Part D for Schedule II to V controlled substances beginning in 2021 and provide for exceptions to this requirement. Section 17754a of the Public Health Code (Code), MCL 333.17754a, requires the Department to establish by rule the requirements for obtaining a waiver from electronically transmitting all prescriptions, including controlled substances. The proposed rules will provide for a waiver from electronic prescribing in certain circumstances. Most, but not all of the circumstances are consistent with the SUPPORT Act.

Under the Controlled Substances Act, (CSA), 21 USC 801 et seq., the federal government regulates the practice of pharmacy with respect to controlled substances and chemicals used in the manufacture of controlled substances and requires pharmacies to register or self-certify with the Drug Enforcement Administration (DEA). Registration with the DEA is required to prevent diversion and abuse of controlled substances and chemicals used in the manufacture of controlled substances, and to ensure an adequate and uninterrupted supply of controlled substances for the United States. A pharmacy must maintain a state license in order to get a DEA license.

The proposed rules require that pharmacies comply with all federal requirements regarding controlled substances when discontinuing operations and with security standards for the protection of protected health information set forth in the Health Insurance Portability and Accountability Act.

Taking into consideration the federal laws and regulations referenced above, each state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers of prescription drugs and devices (manufacturer), wholesale distributors of prescription drugs and devices (wholesale distributor), and wholesale distributor-brokers of prescription drugs and devices (wholesale distributor-broker).There are no other laws, rules or other legal requirements that conflict with the proposed rules.

10. Is the subject matter of the rules currently contained in any guideline, handbook, manual, instructional bulletin, form with instructions, or operational memoranda?

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

11. Are the rules listed on the department's annual regulatory plan as rules to be processed for the current year?

Yes.

12. Will the proposed rules be promulgated under Section 44 of the Administrative Procedures Act, 1969 PA 306, MCL 24.244, or under the full rulemaking process?

Full Process

13. Please describe the extent to which the rules exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

Although there are similar provisions to some of the proposed rules at the federal level and other states, the proposed rules are not expected to exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

The proposed rules are consistent with the standards required by the Code and are expected to be largely consistent with the requirements of other states in the Great Lakes region.

14. Do the rules incorporate the recommendations received from the public regarding any complaints or comments regarding the rules? If yes, please explain.

The Department and Board will work with associations, related businesses, lobbyists and other members of the public in preparing the proposed rules.

15. If amending an existing rule set, please provide the date of the last evaluation of the rules and the degree, if any, to which technology, economic conditions, or other factors have changed the regulatory activity covered by the rules since the last evaluation.

The rules were last promulgated on February 22, 2022. There have been no technological factors or economic conditions that have changed the regulatory activity covered by the rules since the last evaluation.

16. Are there any changes or developments since implementation that demonstrate there is no continued need for the rules, or any portion of the rules?

No, there are no changes or developments since implementation of the rules that demonstrate there is no continued need for the rules, or any portion of the rules.

17. Is there an applicable decision record (as defined in MCL 24.203(6) and required by MCL 24.239(2))? If so, please attach the decision record.

Yes