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, and manufacturers and wholesale distributors of drugs and devices. The rules include parts for general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, and the practice of pharmacy.

The purpose of the proposed rules is to: establish any additional licensure requirements for a remote pharmacy and provide a procedure to request a waiver from the 10 mile rule for a remote pharmacy, pursuant to PA 4 of 2020; modify the requirements in the rules to require mandatory electronic transmission of a prescription and add the criteria for a waiver from electronic transmission, pursuant to PA 134 of 2020; establish licensure requirements for a wholesale distributor-broker and modify the activities allowed by an out-of-state pharmacy that is not licensed as a pharmacy in this state, pursuant to PA 142 of 2020; update rules affected by any other modified Public Health Code (Code) provisions; review practical experience requirements and limited licensure; review pharmacy ownership and licensure requirements; review the need for telehealth regulations; sanitation regulations; licensure reciprocity; and update definitions.

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

MCL 333.16141 authorized 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.

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

MCL 333.16141; MCL 333.16145; MCL 333.16148; MCL 333.16201; MCL 333.16204; MCL 333.16204e; MCL 333.16205; MCL 333.16215; MCL 333.16287; MCL 333.17707; MCL 333.17721; MCL 333.17731; MCL 333.17737; MCL 333.17739; MCL 333.17742a; MCL 333.17742b; MCL 333.17746; MCL 333.17748a; MCL 333.17748b; MCL 333.17748e; MCL 333.17754a; MCL 333.17757; 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, 17748e, and 17754a of the Code, MCL 333.16287, MCL 333.17722, MCL 333.17731, MCL 333.17737, MCL 333.17742a, 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.

There are no other laws, rules or other legal requirements that conflict with the proposed rules. Each state establishes its own requirements with respect to the licensing requirements of pharmacists, pharmacies, manufacturers, and wholesale distributors. In addition to state laws and rules, federal laws regulate the practice of pharmacy with respect to controlled substances and chemicals used in the manufacture of controlled substances.

The proposed rules are being modified pursuant to additions to the Code.

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 will work with associations, related businesses, and lobbyists 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 December 22, 2020. There have been no technological factors, economic conditions or other factors that would necessitate amendment of the rules.

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