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 - Controlled Substances

5. Rule numbers or rule set range of numbers:
R 338.3101 – R 338.3199q

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 - Controlled Substances Rules is to regulate the schedules, licenses, security, records, dispensing and administering, prescriptions, distributions, and administrative and disciplinary procedures for controlled substances. The proposed rules will: clarify R 338.3135 and require physician's assistants to meet the opioid training requirements that apply to controlled substances licensees because they hold a controlled substance license; expand the individuals who must take the opioid training; require individuals to take the opioid training by July 1, 2022; exempt an individual licensed under section 7303 of the code, MCL 333.7303, who prescribes or dispenses controlled substances only for research on animals from taking the opioid training; clarify that R 338.3162b requires additional information to be submitted to the Prescription Drug Monitoring Program (MAPS) database; clarify rules regarding electronic transmission of prescriptions pursuant to section 17754a of the Public Health Code; update the controlled substances schedules; update rules related to the opioid crisis; clarify licensing provisions; evaluate the need for a separate license to treat a drug-dependent person; clarify when inventories and records are required; update prescription requirements; clarify dispensing and distribution requirements; and clarify refilling of prescriptions.

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

MCL 333.7203 requires the Board to promulgate a rule to schedule a substance if it finds the substance has a potential for abuse. MCL 333.7301 authorizes the Board to promulgate rules relating to the licensure and control of the manufacture, distribution, prescribing of controlled substances included in schedule 2, and dispensing of controlled substances in this state.

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

MCL 333.7106, MCL 333.7109, MCL 333.7203, MCL 333.7216, MCL 333.7301, MCL 333.7303, MCL 333.7303a, MCL 333.7321, MCL 333.7333, MCL 333.17754, MCL 333.7333a, and Executive Reorganization Order No. 1991-9, MCL 338.3501; Executive Reorganization Order No. 1996-2, MCL 445.2001; Executive Reorganization Order 2003-1, MCL 445.2011, and Executive Reorganization Order 2011-4, MCL 445.2030.

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

Yes. MCL 333.7333a requires the Department to establish an electronic system for monitoring controlled substances. MCL 333.7203 requires the Board to promulgate a rule to schedule a substance if it finds the substance has a potential for abuse. MCL 333.7303 requires the Board to designate by rule the controlled substances in schedules 3 to 5 to be reported.

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.

Under the Controlled Substances Act, 21 USC 801 et seq., and federal regulations, the federal government regulates the production, possession, and distribution of controlled substances. The Act and federal regulations place drugs, chemicals, and plants into one of five schedules based on certain factors, including but not limited to, the medical use of the substance and the potential abuse of the substance. In addition, the Act and federal regulations require individuals who manufacture, distribute, or dispense a controlled substance to be registered with the Drug Enforcement Administration in the U.S. Department of Justice. The Act and federal regulations do not require registrants to take training on opioids and controlled substances. Registrants, however, are required to keep a record of each controlled substance that was manufactured, received, sold, delivered, or disposed of, and maintain detailed inventories. There are also federal regulations on issuing prescriptions, refilling prescriptions, and labeling and packaging prescriptions.

Each state establishes its own requirements with respect to the manufacture, distribution, and dispensing of controlled substances. In Michigan, Article 7, Controlled Substances, of the Public Health Code provides for the scheduling of controlled substances as well as establishing requirements for the manufacture, distribution, and dispensing of controlled substances.

While there is no federal rule or standard, or national licensing agency or accreditation association that requires a controlled substance licensee to take a training regarding opioids and controlled substances, the federal act requires individuals who are registered under that act to keep certain records.

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 do not exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

Many states have adopted controlled substances or pain control training. Although none of the states in the Great Lakes region require individuals delegated, ordered, or allowed by a practice agreement to prescribe or dispense controlled substances to take a specific training in opioid and controlled substances awareness, New York requires every medical resident who is prescribing under a facility registration number from the United States Department of Justice to take a course in pain management, palliative care, and addiction.

All states in the Great Lakes region have a prescription drug monitoring program.

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.

In 2019, R 338.3135 was promulgated, which required an opioid awareness training by licensees; gabapentin was added to schedule 5; and R 338.3161a was promulgated, which established exceptions to the bona fide prescriber-patient relationship. Otherwise, the last evaluation of the rules was in 2016. 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