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:
Central Fill Pharmacies

5. Rule numbers or rule set range of numbers:
R 338.3051 - R 338.3056

6. Estimated time frame:
12 months

Name of person filling out RFR:
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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 Centralized Prescription Processing Pharmacies Rules is to regulate the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, to perform processing functions such as dispensing, performing drug utilization review, completing claims adjudication, obtaining refill authorization, initiating therapeutic intervention, and other functions related to the practice of pharmacy.

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

MCL 333.16145 authorizes the Board to promulgate rules necessary or appropriate to fulfill its functions as prescribed in the Article 15 of the Public Health Code.

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

Rule promulgation authority includes: MCL 333.17753; 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.

No.

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 proposed rules duplicate the requirements in the Code of Federal Regulations, Part 1306, entitled Prescriptions, Title 21 CFR 1306.15, regarding the prescription information between retail pharmacies and central fill pharmacies for prescriptions of schedule II controlled substances, and Title 21 CFR 1306.27, regarding the prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of schedule III, IV, or V controlled substances.

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

Yes, the subject matter of these rules is contained in the Code of Federal Regulations, Part 1306, entitled Prescriptions, Title 21 CFR 1306.15, and Title 21 CFR 1306.27.

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

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 promulgated in 2008. 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