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STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

Memorandum

VIA E-MAIL

DATE: August 24, 2020

TO: Senator Peter Lucido, Chairperson, JCAR
Representative Matt Maddock, Alternate Chairperson, JCAR
Evan Keimach, Senate Majority Policy Office
Jimmy Biehl, House Republican Policy Office
Tim Reeves, Counsel, JCAR
Elizabeth Edberg, Counsel, JCAR

FROM: Marlon I. Brown, Director of Policy and Legislative Affairs *MB*

SUBJECT: Joint Committee on Administrative Rules (JCAR) Briefing Memo for Rule Set 2018–39 LR (Pharmacy – General Rules)

Rules Primer

The Pharmacy – General Rules regulate pharmacists, pharmacist interns, preceptors, pharmacies, wholesale distributors of prescription drugs and devices, and manufacturers of prescription drugs and devices. The rules also regulate the practice of pharmacy, including how drugs are labeled, handled, and dispensed, as well as the preparation of receipts and the maintenance of records.

Summary of the Final Proposed Rule

The current Pharmacy – General Rules will be substantially rewritten and reorganized to provide rules that encompass all necessary requirements for licensing and regulating the practice for pharmacists, interns, preceptors, pharmacies, manufacturers, and wholesale distributors. The proposed revisions modify the parts pertaining to general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, and the practice of pharmacy.

Stakeholder Engagement

Development of the proposed rules occurred in consultation with, and approval of, the Michigan Board of Pharmacy. The web address for the Board is

https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_27529_27548---,00.html. The website for the Pharmacy Rules Committee Work Group is, https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_27529_27548_91202-493894--,00.html.

Public Engagement and Public Hearing/Comment/Information

The public comment period began on September 18, 2019 and ended on October 4, 2019. The notice of public comment period, in addition to being posted in various newspapers as required, was posted on the LARA website, and distributed via email listserv to all interested parties. The public hearing was held at 9:00 a.m. at the G. Mennen Williams Building Auditorium on October 4, 2019. There were three comments made at the public hearing and eighteen comments submitted in writing. Comments were received from the following individuals during the public comment period.

- Rose M. Baran, PharmD, MA, Assistant Professor, College of Pharmacy, Ferris State University
- Alyssa R. Baskerville, PharmD Candidate
- Adam Carlson, Senior Director, Government & Political Affairs, Michigan Health & Hospital Association (MHA)
- Thomas R. Clark, RPh, MHS, BCGP, Senior Director, Board of Pharmacy Specialties (bps)
- Maher Daman, PharmD, Ferris State University
- Deeb D. Eid, PharmD, Assistant Profession, Ferris State University
- Justin Kuhns, PharmD, Lab Director, Portage Pharmacy
- Joel Kurzman, Director, State Government Affairs, National Association of Chain Drug Stores (NACDS)
- Bradley McCloskey, PharmD, President/CEO
- Neal Mehta, Pharm D
- Ned Milenkovich, PharmD, JD, Much Shelist, P.C,
- Joseph C. Osborne, PharmD, Candidate, Ferris State University
- Scott Popyk, Health Dimensions/ member MPA and International Academy of Compound Pharmacists
- Eric Roath, PharmD, MBA, Clinical Care Coordinator, SpartanNash
- Brian Sapita, Government Affairs Manager, Michigan Pharmacists Association (MPA)
- Tom Sullivan, Michigan Surgical Hospital and Insight for Neurosurgery and Neurological Sciences
- Larry Wagenknecht, Pharmacist, FMPA, FAPhA, Chief Executive Officer, MPA

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- Neal Watson, Member Liaison, National Association of Boards of Pharmacy (NABP)

Rules Committee Work Group Meetings were held on November 15, 2019, December 3, 2019, January 28, 2020, and March 6, 2020, to review the public comments made during the open public comment period. The Board of Pharmacy Rules Committee, BPL staff, and several members of the public attended each meeting.

Modifications Made Due to Public Comment

Due to the large number of modifications made to the proposed rules as a result of public comment, it is recommended that the JCAR Agency Report be consulted to review the specific modifications.

Significant Issues Not Incorporated in the Final Proposed Rules

The following concepts were suggested and discussed, but did not have consensus among the Board members, and therefore, were not included within this rule set:

- Limit accessibility for inspections of pharmacies.
- Broaden application of USP 800 to pharmacies that do not compound and to physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities.
- List entities that can provide inspections in the rules instead of on the website.
- Increase the minimum size of a pharmacy, counterspace, and add temperature requirements on a refrigerator and freezer.

cc/att: Orlene Hawks, Director, LARA
Kim Gaedeke, Chief Deputy Director, LARA
Adam Sandoval, Deputy Director, LARA
Debra Gagliardi, BPL Bureau Director, LARA
Elizabeth Arasim, Regulatory Affairs Officer, LARA