

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing

NOTICE OF PUBLIC HEARING

June 2, 2023

9:00 a.m.

**Location: G. Mennen Williams - Auditorium
525 W. Ottawa Street, Lansing, Michigan**

The hearing is held to receive public comments on the following administrative rules:

Pharmacy - General Rules (MOAHR #2022-8 LR)

Authority: MCL 333.16141, 333.16145, 333.16148, 333.16174, 333.16175, 333.16178, 333.16182, 333.16186, 333.16204, 333.16205, 333.16215, 333.16287, 333.17707, 333.17721, 333.17722, 333.17731, 333.17737, 333.17739, 333.17742a, 333.17742b, 333.17744f, 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17748e, 333.17751, 333.17753, 333.17754a, 333.17757, 333.17760, 333.17767, and 333.17775, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030.

Overview: The proposed rules will be modified as follows: except for disciplinary inspections, inspections at the direction of the department will not involve purchasing data, other than shipment data and the current and historical selling price of the drug, or some research data; applicants will only be able to submit intern hours that are acquired through an educational program, under the personal charge of a preceptor, through a preapproved unconventional internship, or through an educational program outside of the United States; graduates of programs outside of the United States will be able to submit up to 1400 hours earned in an educational program experience if the hours are not completed through an approved educational program or under the person charge of a preceptor licensed in this state; preceptors in an educational program will not have to submit annual affidavits of hours; applicants for licensure by endorsement will no longer have to take the MPJE and instead will submit knowledge of the laws and rules affidavit; a PIC or facility manager who is unable to fulfill their duties for 120 consecutive days will appoint a new PIC or facility manager; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and, within 6 months, an inspection to assess USP compliance or accreditation; a pharmacy that dispenses drugs will have a sink with running water, a refrigerator for drugs, and a telephone; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation; a pharmacy intern who provides final product verification will record both the initials of the intern and supervising pharmacist; a pharmacy may locate an automated device as an extension of a pharmacy in additional locations with limitations; a pharmacy may locate a non-dispensing storage and pick-up device on the premises of the pharmacy; and a pharmacist may dispense an emergency supply of insulin.

The rules will take effect immediately upon filing with the Secretary of State, unless specified otherwise in the rules. Comments on the proposed rules may be presented in person at the public

hearing. Written comments will also be accepted from date of publication until **5:00 p.m. on June 2, 2023**, at the following address or e-mail address:

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing– Boards and Committees Section
P.O. Box 30670
Lansing, MI 48909-8170
Attention: Departmental Specialist Email: BPL-BoardSupport@michigan.gov

A copy of the proposed rules may be obtained by contacting Board Support at (517) 241-7500 or the email address noted above. Electronic copies also may be obtained at the following link:

Pharmacy - General Rules

<https://ars.apps.lara.state.mi.us/Transaction/RFRTransaction?TransactionID=1367>

The public hearing will be conducted in compliance with the 1990 Americans with Disabilities Act. If the hearing is held at a physical location, the building will be accessible with handicap parking available. Anyone needing assistance to take part in the hearing due to disability may call **517-241-7500** to make arrangements.

People with disabilities requiring additional accommodations (such as materials in alternative format) to participate in the meeting, or those that have questions should contact the department at BPL-BoardSupport@michigan.gov.

Please call (517) 241-7500 or email BPL-BoardSupport@michigan.gov with any questions related to the hearing.