

Department of Licensing and Regulatory Affairs  
Bureau of Professional Licensing  
Administrative Rules for Pharmacy-General Rules  
Rule Set 2022-8 LR

NOTICE OF PUBLIC HEARING

Friday, June 2, 2023

09:00 AM

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

The Department of Licensing and Regulatory Affairs will hold a public hearing to receive public comments on proposed changes to the Pharmacy-General Rules rule set.

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.

By authority conferred on the Department of Licensing and Regulatory affairs in consultation with the Michigan Board of Pharmacy, 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.

The proposed rules will take effect immediately after filing with the Secretary of State. The proposed rules are published on the State of Michigan's website at [www.michigan.gov/ARD](http://www.michigan.gov/ARD) and in the 6/1/2023 issue of the Michigan Register. Copies of these proposed rules may also be obtained by mail or electronic mail at the following email address: [BPL-BoardSupport@michigan.gov](mailto:BPL-BoardSupport@michigan.gov).

Comments on these proposed rules may be made at the hearing, by mail, or by electronic mail at the following addresses until 6/2/2023 at 05:00PM.

Attention: Departmental Specialist

Department of Licensing and Regulatory Affairs Bureau of Professional Licensing– Boards and  
Committees Section P.O. Box 30670 Lansing, MI 48909-8170

[BPL-BoardSupport@michigan.gov](mailto:BPL-BoardSupport@michigan.gov)

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.