

Department of Licensing and Regulatory Affairs  
Bureau of Professional Licensing  
Administrative Rules for Pharmacy - Controlled Substances  
Rule Set 2022-6 LR

NOTICE OF PUBLIC HEARING

Monday, October 16, 2023

09:00 AM

UL-3

611 W. Ottawa Street, Lansing, Michigan or  
<https://ars.apps.lara.state.mi.us/Transaction/RFRTransaction?TransactionID=1365>

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

The proposed rules will be modified as follows:

For schedules, the proposed changes adopt the federal schedule subject to drugs scheduled by the state after January 6, 2022, and the rules promulgated by the Michigan Board of Pharmacy; remove Brorphine and Gabapentin as exceptions to the federal schedule; remove Pentazocine from Schedule 5 to Schedule 4; provide an exception to the federal scheduling for isomers, Salvia Divorum, Salvinorum A, Synthetic Cannabinoids, and Synthetic Cathinones.

For controlled substances licensure, the proposed changes require a designated prescriber to have a controlled substance license for a health facility if substances are stored there without an on-site pharmacy or an automated device stocked by a pharmacy and provide an exception to licensure for an emergency kit that contains controlled substances.

For records, the proposed rules permit an electronic duplicate of the original paper prescription, which will become the original prescription, 2 years from the last dispensing date; require a pharmacy that holds an additional license for an automated dispensing system, that dispenses controlled substances, to store inventories and schedule order forms at the licensed location of the automated device; and clarify that if a controlled substance is dispensed from an automated device, documentation maintained on-site in the pharmacy must include the automated device's manufacture's name, model number, and the name and address of the facility where the automated device is located.

For controlled substance prescriptions, the proposed changes clarify that a paper prescription is not required to have preprinted numbers representing the quantity next to a box or line; require that the professional designation for the prescribing practitioner be stored electronically; allow a prescriber to seek waiver of electronic prescription transmission requirements if the prescriber can attest that he or she intends, within 12 months, to not regularly practice their licensed profession for financial gain or as a means of livelihood; and clarify that the prescriber must deliver to the dispensing pharmacist a written prescription postmarked within 7 days after the date the prescription was dispensed, or electronically transmit the prescription under R 338.3162a.

For controlled substance distributions, the proposed changes require a licensee to provide written notification to the department 15 days before controlled substances are transferred.

By authority conferred on the director of the department of licensing and regulatory affairs and the board of pharmacy by sections 7106, 7109, 7203, 7216, 7301, 7303, 7303a, 7321, 7333, 7333a, and 17754 of the public health code, 1978 PA 368, MCL 333.7106, 333.7109, 333.7203, 333.7216, 333.7301, 333.7303, 333.7303a, 333.7321, 333.7333, 333.7333a, and 333.17754, 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 10/15/2023 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 10/16/2023 at 05:00PM.

Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, Boards and Committees Section, Attention: Departmental Specialist

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 711- to make arrangements.