Department of Licensing and Regulatory Affairs Bureau of Professional Licensing Administrative Rules for Pharmacy - General Rules Rule Set 2020-128 LR

NOTICE OF PUBLIC HEARING Tuesday, September 21, 2021 01:00 PM

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 revisions to the rules will: require preceptors to report internship hours; require an applicant who has failed the NAPLEX or the MPJE to review the material in a preparation course or with an instructor: clarify that an applicant who has completed the FPGEC certification has met the English proficiency requirement; allow an applicant for licensure by endorsement to obtain a license in this state if he or she either holds a license in another state or holds a license in Canada and meets additional requirements; add requirements for relicensure; establish the requirements for a remote pharmacy license; provide a waiver process from the 10 mile requirement for remote pharmacies; require any pharmacy that will provide sterile compounding in this state to submit an onsite physical inspection and report completed no more than 18 months before the application; clarify that a pharmacy that starts or resumes sterile compounding must apply to the Department and submit the required inspection report; require a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that is closing to maintain records; clarify the process for renewal versus relicensure; add the requirements for a facility manager for a manufacturer; adopt the federal exclusions to the definition of wholesale distribution; add the licensure and record keeping requirements for a wholesale distributor-broker: reduce the time from 3 years to 2 years before a prescription may be electronically duplicated; provide the requirements for electronic transmission of prescriptions; provide the process for a waiver from the mandate to electronically transmit a prescription; and clarify that if final product verification is delegated, then both the pharmacist and technician must record their initials.

By authority conferred on the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing in consultation with the Board of Pharmacy pursuant to MCL 333.16141, MCL 333.16145, MCL 333.16148, MCL 333.16174, MCL 333.16175, MCL 333.16178, MCL 333.16182, MCL 333.16186, MCL 333.16201, MCL 333.16204, MCL 333.16204e, MCL 333.16205, MCL 333.16215, MCL 333.16287, MCL 333.17707, MCL 333.17721, MCL 333.17722, MCL 333.17731, MCL 333.17737, MCL 333.17739, MCL 333.17742a, MCL 333.17742b, MCL 333.17746, MCL 333.17748, MCL 333.17748a, MCL 333.17748b, MCL 333.17748e, MCL 333.17751, MCL 333.17753, MCL 333.17754a, MCL 333.17757, MCL 333.17760, MCL 333.17767, MCL 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 web site at http://www.michigan.gov/ARD and in the Michigan Register in the 9/15/2021 issue. Copies of these proposed rules may also be obtained by mail or electronic transmission at the following address: BPL_BoardSupport@michigan.gov.

Comments on these proposed rules may be made at the hearing or by mail or electronic mail at the following address until 9/21/2021 at 05:00PM.

Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing – Boards and Committees, Attention: Policy Analyst

Email: BPL_BoardSupport@michigan.gov

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

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.