June 12, 2024

LARA Revises Controlled Substance Administrative Rules (SNF/AL)

The Michigan Department of Licensing & Regulatory Affairs (LARA) recently revised the Administrative Rules for prescribing of controlled substances; the changes are effective immediately.

Please note: Gabapentin was removed from the controlled substance list. A prescriber without a controlled substance license can now prescribe Gabapentin, and Gabapentin no longer needs to be included in reporting to the Michigan Automated Prescription System. Despite this, prescribers should continue to monitor the use and potential misuse of this drug.

Here is a summary of the significant rule changes:

- For definitions, the changes add clarity and a tribal government identification number to the definition of patient identifier.
- For schedules, the changes adopt the federal schedule for drugs scheduled by the state after January 6, 2022, and the rules promulgated by the Michigan Board of Pharmacy; remove Brorphine, Gabapentin and Pentazocine as exceptions to the federal schedule; provide an exception to the federal scheduling for isomers, Salvia Divorum, Salvinorum A, Synthetic Cannabinoids and Synthetic Cathinones.
- For controlled substance licensure, the changes: (1) require a designated prescriber to have a controlled substance license for a health facility if substances are stored without an onsite pharmacy or an automated device stocked by a pharmacy; (2) provide an exception to licensure for an emergency kit that contains controlled substances; (3) clarify the investigator information required for research and chemical analysis laboratory applicants; (4) require training in opioids and controlled substances awareness for initial licensure and license renewal, and (5) remove training requirements that are duplicative with federal requirements for a DEA registration for licensees required to obtain a DEA registration.
- For records, the rule changes permit an electronic duplicate of the original paper prescription, which will become the original prescription, 2 years from the last dispensing date and clarify that, if a controlled substance is dispensed from an automated device, documentation maintained onsite in the pharmacy must include the automated device's manufacturer's name, model number, and the name and address of the facility where the automated device is located.
- For controlled substance prescriptions, the changes: (1) clarify that a paper prescription is not required to have preprinted numbers representing the quantity next to a box or line; (2) require that the professional designation for the prescribing practitioner be written on the prescription or stored electronically in the pharmacy's automated data processing system; (3) allow a prescriber to seek waiver of electronic prescription transmission requirements if the prescriber can attest that they intend, within 12 months, to not regularly practice their licensed profession for financial gain or as a means of livelihood; (4) 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; and (5) rescind R 338.3163 concerning prescribing, dispensing and administering a controlled substance to an individual with substance use disorder.

- For controlled substance distributions, the changes require a licensee to provide written notice to the department 15 days before transferring controlled substances.
- For individuals applying for their initial controlled substance license, as well as those renewing their controlled substance license, rule changes made to R 338.3135 now require continued training in opioids and controlled substance awareness before applying for the initial license and each subsequent renewal of a controlled substance license.