MICHIGAN

Prepared by:
Timothy Gutwald, Miller Johnson Attorneys, Grand Rapids, MI
Stephanie Ottenwess, Ottenwess Taweel & Schenk PLC, Detroit, MI
Kathryn Hickner, Kohrman Jackson & Krantz LLP, Cleveland, OH

I. PRESCRIPTION DRUG MONITORING SYSTEM REQUIREMENTS

(Michigan Compiled Laws (MCL) 333.7303a; 333.7333a; Michigan Administrative Code R 338.11101-33811821; R338.3162b-3162e)

Michigan's Prescription Drug Monitoring Program (PDMP) is known as the MI Automated Prescription System (MAPS). MAPS is a web-based system used to track prescriptions for controlled substances. It is a tool used by prescribers and dispensers to assess patient risk and to prevent drug abuse and diversion at the prescriber, pharmacy, and patient levels. Prescribers include dentists, physicians (MD, DO), physician assistants, podiatrists, optometrists, veterinarians, and advanced practice registered nurses under delegation. The information is available to prescribers, dispensers, and their delegates.

The information is also available to the Michigan Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing. MAPS software maintains detailed user records for each user account. The system maintains audit trails that the Bureau of Professional Licensing may review to verify compliance. Law enforcement entities do not have direct access to MAPS reports. If a prescriber, dispenser, or delegate suspects possible illegal activity they are prohibited from providing the report directly to law enforcement. However, prescribers, pharmacists, and their delegates can notify law enforcement of the suspected illegal activity. Law enforcement may open a bonafide drug related investigation and request a MAPS report through the Bureau of Professional Licensing.

Under Michigan law, all licensed prescribers must register with MAPS prior to prescribing or dispensing a controlled substance to a patient. Michigan law also requires prescribers to review MAPS prior to prescribing or dispensing a controlled substance that exceeds a three-day supply and when prescribing or dispensing a drug containing buprenorphine or methadone.

The law includes exceptions to the mandatory checks prior to prescribing or dispensing a Schedule II–V controlled substance that exceeds a three-day supply:

If the dispensing occurs in a hospital or freestanding surgical outpatient facility licensed under Article 17 and the controlled substance is administered to the patient in that hospital or facility.

If the prescriber orders a Schedule II–V controlled substance for inpatient administration.

Failure to register for MAPS may subject prescribers to sanctions against their license that include: denial, fine, reprimand, limitation, suspension, revocation, or permanent revocation. Prescribers that fail to request and review the MAPS report prior to prescribing or dispensing a controlled substance that exceeds a three-day supply may receive a letter notifying the prescriber of the violation of the requirement to obtain a MAPS report. Receiving the letter is not considered discipline. Alternatively, failure to request and review the MAPS report may subject prescribers to sanctions against their license up to and including revocation.

For additional information on MAPS, including responses to FAQs and technical guidance, please *see* the following:

https://www.michigan.gov/opioids/0,9238,7-377-88141_88294---,00.html
https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_55478_55483---,00.html

II. OPIOID PRESCRIBING REQUIREMENTS

A. Physicians

Michigan has dictated a strict policy for prescribers of prescriptions of Schedule II–V controlled substances (including Opioids). Prescribers have several criteria they must be in compliance with including proper registry and query in MAPS (*see* discussion above); establishing a bona fide prescriber-patient relationship; obtaining proper informed consent; properly prescribing for acute pain; and properly using their delegation authority.

Bona fide prescriber-patient relationship
(MCL 333.7303a; Mich. Admin. Code R 338.3161a)

Effective January 4, 2019, MCL § 333.7303a(2) requires that, except as provided in exceptions detailed in administrative rules, the prescriber must be in a bona fide prescriber-patient relationship with the patient to prescribe a controlled substance to that patient. A bona fide relationship has been defined as a treatment or counseling relationship between a prescriber and a patient in which both of the following are present:

1. The prescriber has reviewed the patient's medical or clinical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant medical evaluation of the patient conducted in person or via telehealth; and
2. The prescriber has created and maintained records of the patient's condition in accordance with medically accepted standards.

Follow-Up Care: To further comply with the bona fide relationship pursuant to MCL 333.7303(a)(2) the prescriber *must* provide follow-up care to the patient to monitor the efficacy of the controlled substance. In the event that the prescriber is unable to provide

follow-up care, the prescriber *must* refer the patient to their primary care provider or must refer to a geographically accessible provider.

Failure to comply with the bona fide relationship requirement is considered professional misconduct and may subject the prescriber to professional discipline.

Exceptions: a licensed prescriber may prescribe a Schedule II–V controlled substance without first establishing a bona fide prescriber-patient relationship in the following five circumstances:

1. On-Call Prescribing. The prescriber is providing on-call coverage or cross-coverage for another prescriber who is not available and who has established a bona fide prescriber-patient relationship with the patient for whom the on-call or covering prescriber is prescribing the controlled substance. The prescriber, or an individual licensed under article 15 of the Michigan Public Health Code, must review the patient's medical or clinical records, medical history, and any change in medical condition, and provide documentation in the patient's medical record in accordance with the medically accepted standards of care.
2. Modifying Orders for Hospital Inpatients, Hospice Patients and Nursing Facility Residents. The prescriber is following or modifying the orders of a prescriber who has established a bona fide prescriber-patient relationship with a hospital inpatient, hospice patient, or nursing facility resident and provides documentation in the patient's medical record in accordance with the medically accepted standards of care.
3. Admitting Orders for Hospice Patients and Nursing Facility Residents. When prescribing for an individual who has been admitted to a licensed nursing care facility or a hospice, the prescriber need not have a bona fide prescriber-patient relationship with the patient prior to prescribing controlled substances on admission. A bona fide relationship can be established *after* prescribing to a hospice patient or nursing care resident as long as the prescriber stays in compliance with proper regulations and time frames.
4. Required Assessment and Review Done by Another Licensed Individual. Another properly licensed health care provider can establish the bona fide relationship as long as the prescriber provides proper documentation in that relative patient's medical record.
5. Medical Emergency. The prescriber is treating a patient in a medical emergency, defined as a situation that, in the prescriber's good faith professional judgment, creates an immediate threat of serious risk to the life or health of the patient for whom the controlled substance is being prescribed.

Informed Consent

(MCL 333.7303c)

Before issuing an opioid prescription to a patient *for other than inpatient use*, the prescriber or another health professional must provide all of the following information to the patient or the patient's representative:

1. The danger of opioid addiction;
2. How to dispose of unused/unwanted controlled substance properly;
3. That delivery of a controlled substance is a felony under Michigan law;
4. If the patient is pregnant or a female of reproductive age, the short- and long-term effects of exposing a fetus to a controlled substance, including fetal abstinence syndrome.

After providing the above information, the prescriber or health professional must obtain the patient's/representative's signature on a form prescribed by the department of health and human services, certifying that the patient/representative received the above information. This form must be included in the patient's medical or clinical record.

Acute Pain

(MCL 333.7333b)

For treatment of acute pain, a prescriber cannot prescribe more than a seven-day supply within a seven-day period. Acute pain is typically limited to the pain that is associated with post-invasive or surgical procedures, trauma, or disease and lasts for a limited amount of time.

B. Physician's Assistants

(MCL 333.17076)

Physician's assistants are authorized to prescribe Schedule II–V controlled substances under the following criteria:

1. Obtain their own Michigan controlled substance license;
2. Register with MAPS;
3. Enter into a practice agreement with a physician;
4. Include their own name and Drug Enforcement Administration (DEA) registration number with the prescription.

Physician's Assistants must comply with the same prescribing requirements as physicians. For detailed information on the prescribing requirements, *see* Section A. Physicians. Also, *see* the LARA Frequently Asked Questions regarding physician assistants.

C. Advanced Practice Registered Nurses (APRNs)

***(MCL 333.17211a; MCL 333.17212;** Mich. Admin. Code R 338.2411(1))*

In 2016 Michigan created a new category of specialty certified nurses, the Advanced Practice Registered Nurse (APRN). This category now includes: (1) certified nurse practitioners; (2) certified nurse midwives; and (3) clinical nurse specialists-certified.

APRNs are not designated prescribers of Schedule II–V controlled substances and can only prescribe them as a *delegated* act of a physician under a written authorization agreement. With each prescription, an APRN must properly record both their name and the physician's name and provide both DEA registration numbers connected with the prescription. As far as ordering, receiving, and dispensing complimentary starter doses of controlled substances, an APRN can do so under delegated authority as well. Because an APRN is not a designated prescriber, they are not permitted to obtain a Michigan controlled substance license.

A physician can only delegate prescribing authority under a written authorization that must contain the following and must be updated annually with the following:

1. Name, license number, and signature of the delegating/supervising physician;
2. Name, license number, and signature of the specialty certified RN;
3. The limitations or exceptions to the delegation; and
4. The effective date of the delegation.

Limitations: A physician is prohibited from authorizing an APRN to issue a prescription for a Schedule II controlled substance with a quantity greater than a 30-day supply, but for no more than a seven-day supply of opioids within a seven-day period when being used to treat acute pain.

A physician is also prohibited from delegating the prescription of a drug or device individually, in combination, or in succession for a known pregnant woman with the intent to cause a miscarriage or fetal death.

Please *see* the LARA_Frequently Asked Questions regarding APRNs.

D. Prescribing Opioids to Minors

(MCL 333.7303b)

In Michigan, a minor is an individual under the age of 18. There is a differing protocol for prescribing opioids to minors under MCL 333.7303b(1). This includes a special informed consent using the "Start Talking Consent Form" specifically tailored for minor patients.

Informed Consent

Before issuing the first prescription for a controlled substance containing an opioid for a single course of treatment to a minor, the prescriber must discuss all of the following

topics with the minor, the minor's parent or guardian, or other adult authorized in writing to consent to treatment for the minor:

1. The risk of addiction and overdose associated with the controlled substance;
2. The increased risk of addition to a controlled substance for an individual suffering from both mental and substance abuse disorders;
3. The danger of taking a controlled substance containing an opioid with a benzodiazepine, alcohol, or other central nervous system depressant; and
4. Any other information in the patient counseling section of the label for the prescribed controlled substance that is required under federal regulations.

The prescriber must also obtain the signature of the minor's parent/guardian/authorized consenting adult on a separate, specific Start Talking Consent Form certifying that the prescriber discussed the above information with the minor and the parent/guardian/authorized adult. The form shall be included in the minor's medical record.

If the adult signing the Start Talking Consent Form is another adult authorized to consent by a parent or guardian, the prescriber shall not prescribe more than a single, 72-hour supply of a controlled substance containing an opioid.

https://www.mha.org/Newsroom/ID/1427/MDHHS-Opioid-Start-Talking-Form-Now-Available-to-Hospitals-Healthcare-Providers

Exceptions: The informed consent discussion and signature on a Start Talking Consent Form are not required in the following situations:

1. The minor's treatment is associated with or incident to a medical emergency;
2. The minor's treatment is associated with or incident to surgery;
3. If compliance with these requirements would, in the prescriber's professional judgment, be detrimental to the minor;
4. If the minor's treatment is rendered in a hospice or oncology department of a licensed hospital;
5. The prescriber is issuing the prescription for the minor at the time of discharge from a hospice or oncology department of a licensed hospital; or
6. The consent of the minor's parent or guardian is not required for the treatment.

HOWEVER,

Prescriber must still provide the following formation to both the minor and parent, guardian, or authorized consenting adult:

1. Danger of opioid addiction;
2. How to properly dispose of unused or unwanted controlled substances;
3. Delivery of a controlled substance is a felony in Michigan;

4. Short-term and long-term effects of exposing a fetus to a controlled substance if the patient is pregnant or a female of a reproductive age.

E. Requirements for a Valid Prescription

The numerous criteria that a prescriber must satisfy when issuing a prescription for a controlled substance have been detailed above. For a detailed checklist, *see*: https://www.msms.org/Portals/0/Documents/MSMS/Resources/For_Practices/Pain_Management/Prescribing%20Checklist%20for%20Controlled%20Substances%202.12.19.pdf?ver=2019-02-13-111727-040

MCL 333.7333 provides additional requirements for a valid prescription. In each instance, the prescriber must have a good-faith basis for prescribing the controlled substance.

1. **MCL 333.7333(2)** A prescriber can issue a prescription for more than one Schedule II controlled substance on a single prescription form.
2. **MCL 333.7333(3)** allows for a valid prescription in an *emergency situation* for a Schedule II controlled substance, to be dispensed upon oral prescription, if that prescriber promptly fills out a prescription form and forwards it to the applicable pharmacy within seven days of the oral prescription. A Schedule II controlled substance prescription cannot be filled more than 90 days after the prescription was issued.
3. **MCL 333.7333(4)** A Schedule III or IV controlled substance cannot be filled or refilled later than six months after the date of the prescription and cannot be refilled more than five times, absent a proper renewal by the prescriber.
4. **MCL 333.7333(6)** A prescription must contain the quantity of the controlled substance prescribed in both written and numerical terms. The numerical terms can also be in the form of pre-printed numbers of the quantity that the prescriber may check.
5. **MCL 333.7333(7)** A prescriber *cannot post-date* a prescription for a controlled substances but can indicate the earliest the prescription can be filled.

III. STATE MEDICAID REQUIREMENTS

A. General Requirements

Michigan Medicaid does not impose additional limitations on opioid prescriptions beyond those discussed above. Prior authorizations for all prescriptions, including opioids, are processed by the Michigan Department of Health and Human Services Pharmacy Benefit Manger. The Michigan Pharmaceutical Product List identifies drugs for which prior authorization is required.

Medicaid Health Plans may also impose prior authorization requirements related to opioids prescribed to Medicaid beneficiaries enrolled in their plans. Each plan maintains its own formulary and frequently imposes limits on the number of tablets of morphine, oxycodone, and other opioids that may be prescribed in a thirty day period.

Methadone is only covered when used as an analgesic for severe, intractable pain such as that produced by some types of terminal illnesses.

B. Exceptions

Opiate-dependent Medicaid beneficiaries may be provided chemotherapy using methadone as part of a treatment service provided:

Services are provided under the supervision of a licensed physician; and
The physician is licensed to prescribe controlled substances, as well as licensed to work at a methadone program;

The methadone component of the substance abuse treatment program must be:

Licensed by the state;
Certified by the Division of Pharmacologic Therapies/Center for Substance Abuse Treatment (DPT/CSAT);
Licensed by the DEA; and
Accredited by a DPT/CSAT and a state approved accrediting organization such as Joint Commission.

IV. STATE WORKERS' COMPENSATION REQUIREMENT

(Michigan Administrative Code R. 418.101008; R 418.101008a; and R 418.101008b)

Michigan workers' compensation reimburses for opioids used in the treatment of chronic pain resulting from work-related conditions. For this purpose, "chronic pain" is pain unrelated to cancer or is incident to surgery and that persists beyond the period of expected healing after an acute injury episode. It is pain that persists beyond 90 days following the onset of the pain.

In order to receive reimbursement for opioid treatment beyond 90 days, the physician seeking reimbursement shall submit a written report not later than 90 days after the initial opioid prescription fill for chronic pain and every 90 days thereafter. The written report shall include all of the following:

A review and analysis of the relevant prior medical history, including any consultations that have been obtained, and a review of data received from an automated prescription drug monitoring program in the treating jurisdiction, such as MAPS, for identification of past history of narcotic use and any concurrent prescriptions;
A summary of conservative care rendered to the worker that focused on increased function and return to work;
A statement on why prior or alternative conservative measures were ineffective or contraindicated;
A statement that the attending physician has considered the results obtained from appropriate industry accepted screening tools to detect factors that may

significantly increase the risk of abuse or adverse outcomes including a history of alcohol or other substance abuse;
An opioid treatment agreement that has been signed by the worker and the attending physician. This agreement shall be reviewed, updated, and renewed every six months. The opioid treatment agreement shall outline the risks and benefits of opioid use, the conditions under which opioids will be prescribed, and the responsibilities of the prescribing physician and the worker;
A treatment plan that includes all of the following:

- Overall treatment goals and functional progress;
- Periodic urine drug screens;
- A conscientious effort to reduce pain through the use of nonopioid medications, alternative non-pharmaceutical strategies, or both; and
- Consideration of weaning the injured worker from opioid use.

V. ADDITIONAL INITIATIVES/RESOURCES

For additional information regarding the state of Michigan's response to the opioid crisis, please *see* the following resources/links:

State of Michigan

- Opioid Addiction Resources
  - https://www.michigan.gov/opioids/
- Opioid Addiction Resources—Information for Prescribers
  - https://www.michigan.gov/opioids/0,9238,7-377-88141_88294---,00.html
- Michigan Opioid Laws—Frequently Asked Questions
  - https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf

State of Michigan Licensing and Regulatory Affairs

- Prescription Drug and Opioid Use Commission
  - https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72783_73913_80371---,00.html
- Michigan Automated Prescription System (MAPS)
  - https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_55478---,00.html

State of Michigan Department of Health and Human Services

- Prescription Drugs and Opioids in Michigan
  - https://www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_79584---,00.html

State of Michigan Workers' Compensation Agency

- Opioid Resource Information
  - https://www.michigan.gov/leo/0,5863,7-336-78421_95508_26922-357584--,00.html

- Frequently asked questions regarding Opioid Treatment Reimbursement Rules
    - https://www.michigan.gov/documents/wca/FAQ_opiod_treatment_489555_7.pdf

Michigan State Medical Society

- Reversing the Opioid Epidemic
    - https://www.msms.org/Resources/Quality-Patient-Safety/Reversing-the-Opioid-Epidemic

Michigan Health and Hospital Association

- Opioid and Prescription Drug Epidemic
    - https://www.mha.org/Issues-Advocacy/Opioid-Epidemic