New Laws For Prescribing Controlled Substances in Michigan

Are You Ready?

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In an effort to further combat prescription drug and opioid addiction, the Michigan legislature recently enacted new legislation affecting the prescribing of controlled substances by physicians and other licensed prescribers. These new laws are intended to help improve education on the dangers of opioid abuse, increase monitoring of a patient's drug history, and establish follow-up care as part of an existing prescriber-patient relationship before a prescription for a controlled substance is issued.

It is important that physicians and other licensed prescribers are aware of the new laws and when they become effective, in addition to existing state and federal laws and rules regulating the prescribing and dispensing of controlled substances. A physician or other licensed prescriber who fails to comply may be subject to licensing disciplinary action and other consequences, particularly in light of increased enforcement action by state and federal agencies.

Fast Facts: New Prescribing Laws by Effective Date

Effective March 27, 2018	• When treating a patient for an opioid-related overdose, must provide the patient with information on substance use disorder services. • Obtain and review MAPS report when prescribing or dispensing buprenorphine or a drug containing buprenorphine or methadone to a patient in a substance use disorder program. • Must make MAPS report if dispensing buprenorphine or a drug containing buprenorphine or methadone and federal law does not prohibit reporting.
Effective March 31, 2018	• Cannot prescribe schedule 2 to 5 controlled substances unless a bona fide prescriber-patient relationship exists and follow-up care is established.
Effective June 1, 2018	• Must register with MAPS prior to prescribing controlled substances. • When prescribing or dispensing greater than a 3-day supply of a controlled substance, obtain and review MAPS report (unless exception applies). • Before prescribing an opioid to a patient, provide required information and obtain the patient's signature on a DHHS acknowledgement form (unless exception applies). • Before prescribing a controlled substance containing an opioid to a minor in a single course of treatment, engage in discussion with minor and parent/guardian/authorized adult and obtain a signed "start talking consent form" (unless exception applies).
Effective July 1, 2018	• Must limit prescriptions of opioids for treating "acute pain" to a maximum of a 7-day supply within a 7-day period.

Bona Fide Prescriber-Patient Relationship and Follow-Up Care

Beginning March 31, 2018, a licensed prescriber shall not prescribe a schedule 2 through 5 controlled substance to a patient unless the prescriber is in a bona fide prescriber-patient relationship with the patient. A bona fide prescriber-patient relationship is defined to mean 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 relevant 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.

The Department of Licensing and Regulatory Affairs ("LARA") may promulgate rules before the end of the year that would clarify the application of this new law, including exceptions to the bona fide prescriber-patient relationship requirement and/or an alternative requirement for prescribing a schedule 2 to 5 controlled substance when a bona fide prescriber-patient relationship is not required.

In addition to having a bona fide prescriber-patient relationship, the prescriber must also provide follow-up care to the patient to monitor the efficacy of the use of the controlled substance as a treatment of the patient's medical condition. If the prescriber is unable to provide such follow-up care, the prescriber must refer the patient to the patient's primary care provider or another geographically-accessible licensed prescriber for follow-up care.

MAPS Registration and Reports

Michigan's Automated Prescription System ("MAPS") is the prescription monitoring program used to track controlled substances, assess patient risk, and prevent drug abuse and diversion. Beginning June 1, 2018, licensed prescribers are required to register with the MAPS system before prescribing or dispensing a controlled substance to a patient. In addition, licensed prescribers must obtain and review a patient's MAPS report before prescribing greater than a 3-day supply of a schedule 2 through 5 controlled substance to the patient, except if the dispensing occurs in a licensed hospital or freestanding surgical outpatient facility and the controlled substance is administered to the patient in that hospital or facility. Certain exceptions also apply to veterinarians.

Beginning March 27, 2018, physicians and licensed prescribers who are treating a patient in a substance use disorder program must obtain and review a MAPS report before prescribing or dispensing buprenorphine or a drug containing buprenorphine or methadone to the patient. A prescriber must also report the information to MAPS when dispensing buprenorphine or a drug containing buprenorphine or methadone to a patient in a substance use disorder program, if federal law does not prohibit reporting.

Information for Patients Treated for Opioid-Related Overdose

Beginning March 27, 2018, a licensee or registrant who treats a patient for an opioid-related overdose must provide information to the patient on substance use disorder services. "Substance use disorder services" means one or both of the following:

(1) substance use disorder prevention services, including services intended to reduce the consequences of substance use disorders in communities by preventing or delaying the onset of substance abuse and that are intended to reduce the progression of substance use disorders in individuals; and

(2) substance use disorder treatment and rehabilitation services, including identifiable recovery-oriented services such as early intervention and crisis intervention counseling services for individuals who currently or formerly have a substance use disorder, referral services for individuals with substance use disorder, their families, and the general public, and planned treatment services, including chemotherapy, counseling or rehabilitation for individuals physiological or psychologically dependent upon or abusing alcohol or drugs.

Information and Consent Form Requirements for Prescribing Opioids

For Patients, Generally

The new legislation imposes several new requirements to help educate patients and prevent opioid addiction. Beginning June 1, 2018, before an opioid is prescribed to a patient, a licensed prescriber or other health professional must provide information on all of the following to the patient or the patient's representative:

(1) the danger of opioid addiction;

(2) how to properly dispose of an expired, unused, or unwanted controlled substance;

(3) that the delivery of a controlled substance is a felony under Michigan law; and

(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, but not limited to, neonatal abstinence syndrome.

After providing the required information, the licensed prescriber or other health professional must obtain the signature of the patient on a Department of Health and Human Services acknowledgement form, indicating that the patient or the patient's representative has received the required information. The signed acknowledgement form must be included in the patient's medical or clinical record. Importantly, these requirements do not apply if the opioid is prescribed for inpatient use.

Special Requirements for Minor Patients

To further protect minors from opioid addiction, beginning June 1, 2018, before a prescriber may issue for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid, the prescriber must do both of the following:

(1) Discuss the following with the minor and the minor's parent, guardian, or an authorized adult:

- the risks of addiction and overdose associated with the controlled substance;
- the increased risk of addiction to a controlled substance to an individual who is suffering from both mental and substance abuse disorders;
- the danger of taking a controlled substance containing an opioid with a benzodiazepine, alcohol, or another central nervous system depressant; and
- any other information in the patient counseling information section of the label for the controlled substance that is required under 21 CFR 201.57(c)(18).

(2) Obtain the signature of the minor's parent or guardian to consent to the minor's medical treatment on a "start talking consent form." If the consent form is signed by another adult authorized to consent to the minor's medical treatment, the prescriber must not prescribe more than a single, 72-hour supply of the controlled substance to the minor.

These requirements do not apply in any of the following circumstances:

(1) if the minor's treatment is associated with or incident to a "medical emergency," which means a situation that, in the prescriber's good-faith medical judgment, creates an immediate threat of serious risk to the life or physical health of the minor;

(2) if the minor's treatment is associated with or incident to a surgery (whether performed on an inpatient or outpatient basis);

(3) if fulfilling the requirements would be detrimental to the minor's health or safety;

(4) if the minor's treatment is rendered in a hospice or oncology department of a licensed hospital or if the prescription is issued at the time of discharge from such facilities; or

(5) if the consent of the minor's parent or guardian is not legally required for the minor to obtain treatment.

Start talking consent form must be on a form that is separate from any other document that a prescriber uses to obtain the informed consent for the treatment of a minor and must contain all of the following information:

(1) the name and quantity of the controlled substance being prescribed for the minor and the amount of the initial dose;

(2) a statement indicating that a controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse;

(3) a statement certifying that the prescriber discussed with the minor, and with the minor's parent or guardian or with another adult authorized to consent to the minor's medical treatment, the topics described above;

(4) the number of refills, if any, that are authorized by the prescription; and

(5) a space for the signature of the minor's parent or guardian, or the signature of another adult authorized to consent to the minor's medical treatment, and a space to indicate the date that the minor's parent or guardian, or another adult authorized to consent to the minor's medical treatment signed the form.

MDHHS Form Templates

It is anticipated that the Michigan Department of Health and Human Services will have acknowledgment and start talking consent form templates electronically available on its website by June 1, 2018.

Limitations on Opioid Prescriptions for Patients with Acute Pain

Beginning July 1, 2018, if a prescriber is treating a patient for "acute pain," the prescriber must not prescribe the patient more than a 7-day supply of an opioid within a 7-day period. Under this requirement, "acute pain" is defined to mean pain that is the normal, predicted physiological response to a noxious chemical or a thermal or mechanical stimulus and is typically associated with invasive procedures, trauma, and disease and usually lasts for a limited amount of time.

Ensuring Compliance with New and Existing Laws and Regulations

It is anticipated that LARA will release guidance on the new laws to assist physicians and other licensed prescribers with compliance and clarify certain ambiguities in the language of the new laws (e.g., clarifying the meaning of a "single course of treatment" for prescribing opioids to minors). Nevertheless, physicians and other licensed prescribers may wish to evaluate their current prescribing and/or dispensing practices and consult with an attorney to ensure compliance with all applicable laws and regulations related to opioids and other controlled substances. In addition, any collaborative or other practice agreement with mid-level providers should be reviewed and updated to incorporate the new requirements and any related protocols established by the physician or licensed prescriber.

Questions?

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