

OPIOID *Alert*



UPDATED APRIL 2018

On December 27, 2017, the Lieutenant Governor signed into law several new requirements aimed at combating the opioid epidemic. On the following pages is an objective analysis of the new laws that could have direct implications for physicians and medical practices.



PRESCRIBING OPIOIDS TO A MINOR – REQUIREMENT FOR INFORMED CONSENT

(House Bill 4408, Public Act 246 of 2017)

Effective June 1, 2018, before issuing an initial prescription for an opioid in a single course of treatment to a minor, a prescriber must discuss all of the following with the minor and the minor's parent or guardian:

- The risks of addiction and overdose
- The increased risks of addiction for patients with underlying mental health or existing substance use disorders
- The danger of taking an opioid along with a benzodiazepine, alcohol or other central nervous system depressant
- Any other information in the patient counseling information section of the label for the controlled substance that is required under federal law (21 CFR 201.57(c) (18))
- The prescriber must document the informed consent on a "Start Talking Consent Form," which must contain:
 - » *The name and quantity of the controlled substance being prescribed for the minor and the amount of the initial dose*
 - » *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*
 - » *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 outlined in the bill*
 - » *The number of refills, if any, that are authorized by the prescription*
 - » *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*

Exceptions to the informed consent include:

- If the minor's treatment is associated with or incident to a medical emergency
- If the minor's treatment is associated with or incident to a surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis
- If, in the prescriber's professional judgment, fulfilling the requirements of the bill would be detrimental to the minor's health or safety
- If the minor's treatment is rendered in a hospice or oncology department of a hospital that is licensed by the state
- If the prescriber is issuing the prescription for the minor at the time of discharge from hospice
- If the consent of the minor's parent or guardian is not legally required for the minor to obtain treatment

ENFORCEMENT

Failure to comply with this section could result in the following disciplinary actions against a physician's license: probation, limitation, denial, fine, suspension, revocation or permanent revocation.

PATIENT INFORMATION ON OPIOID RISKS – REQUIREMENT FOR INFORMED CONSENT

(House Bill 4408, Public Act 246 of 2017)

Effective June 1, 2018, before an opioid is prescribed to a patient by a physician (and/or any other prescribers licensed with the state), the physician will be required to obtain the patient's informed consent on a form prescribed by the Michigan Department of Health and Human Services that they have received from the physician, the following information:

- The danger of opioid addiction
- How to properly dispose of an expired, unused or unwanted controlled substance
- That the delivery of a controlled substance is a felony under Michigan law
- If the patient is pregnant or is a female of reproductive age, the short- and long-term effects of exposing a fetus to a controlled substance, including neonatal abstinence syndrome

Exception:

If the opioid is prescribed for inpatient use.

ENFORCEMENT

Failure to comply with this section could result in disciplinary action by the Michigan Board of Medicine.

MANDATORY MICHIGAN AUTOMATED PRESCRIPTION SYSTEM (MAPS) CHECKS

(Senate Bills 166 & 167, Public Act (PA) 248 of 2017, and PA 249 of 2017)

Effective June 1, 2018, all licensed prescribers in Michigan will be required to query the Michigan Automated Prescription System (MAPS) when prescribing controlled substances to any patient.

Exceptions include the following:

- Prescriptions written for quantities less than or equal to a 3-day supply
- If dispensing occurs in hospital or surgical freestanding outpatient facility and is administered in the facility
- If the patient is an animal and the controlled substance is administered in a veterinary hospital or clinic
- If the controlled substance is prescribed by a veterinarian and dispensed by a pharmacist

Beginning **June 1, 2018**, all licensed prescribers in Michigan must be registered with MAPS before prescribing or dispensing a controlled substance to a patient.

ENFORCEMENT

Prescribing or dispensing a controlled substance on or after **June 1, 2018**, without first registering with MAPS could result in the following disciplinary actions against a physician's license: denial, fine, reprimand, probation, limitation, suspension, revocation, or permanent revocation.

Failure to query MAPS when prescribing controlled substances to any patient, starting June 1, 2018, could result in the following disciplinary actions against a physician's license: denial, fine, reprimand, probation, limitation, suspension, revocation, or permanent revocation.

If a physician has violated the requirement to check or register with MAPS, the Department of Licensing and Regulatory Affairs may issue a letter to the licensee notifying the licensee that he or she may be in violation. A letter would not be considered discipline.

LIMITATION ON OPIOID PRESCRIBING: 7-DAYS FOR ACUTE PAIN

(Senate Bill 274, Public Act 251 of 2017)

Beginning July 1, 2018, if a licensed prescriber is treating a patient for acute pain, the prescriber shall not prescribe the patient more than a 7-day supply of an opioid within a 7-day period.

“Acute pain” is defined as pain that is the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus and is typically associated with invasive procedures, trauma, and disease and usually lasts for a limited amount of time.

ENFORCEMENT

Non-compliance could result in disciplinary action by the Michigan Board of Medicine.

BONA FIDE PRESCRIBER-PATIENT RELATIONSHIP

(Senate Bill 270, Public Act 247 of 2017)

Beginning March 31, 2018, a licensed prescriber shall not prescribe a controlled substance listed in schedules 2 to 5 unless the prescriber is in a “bona fide prescriber-patient relationship.” **(Note: Pursuant to Public Act 101 of 2018 signed by the Governor on April 2, 2018, the effective date of this provision has been extended to March 31, 2019, or upon the promulgation of administrative rules if before March 31, 2019.)**

If a licensed prescriber prescribes a controlled substance, he or she must provide follow-up care to the patient to monitor the efficacy of the use of the controlled substance. If a licensed prescriber is not able to provide follow-up care, the prescriber shall refer the patient to the patient’s primary care provider for follow-up care or, if the patient does not have a primary care provider, the physician must refer the patient to another geographically accessible primary care provider.

“Bona fide prescriber-patient relationship” is defined as treatment or counseling relationship between a prescriber and a patient in which both of the following are present:

- 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 conditions, including a relevant medical evaluation of the patient conducted in person or via telehealth
- The prescriber has created and maintained records of the patient’s condition in accordance with medically accepted standards

ENFORCEMENT

Failure to comply with this section could result in the following disciplinary actions against a physician’s license: probation, limitation, denial, fine, suspension, revocation, or permanent revocation.

PHYSICIAN REFERRAL FOR SUBSTANCE USE DISORDER

(Senate Bill 273, Public Act 250 of 2017)

Effective March 27, 2018, a physician who treats a patient for an opioid-related overdose is required to provide information to the patient on “substance use disorder services.”

“Substance use disorder treatment and rehabilitative services” is defined under the Michigan Mental Health Code as including:

- Early intervention and crisis intervention counseling services for individuals who are current or former individuals with substance use disorder
- Referral services for individuals with substance use disorder, their families, and the general public
- Planned treatment services, including chemotherapy, counseling, or rehabilitation for individuals physiologically or psychologically dependent upon or abusing alcohol or drugs

DIRECT ADMINISTRATION OF A CONTROLLED SUBSTANCE & MEDICATION ASSISTED TREATMENT

(Senate Bill 47, Public Act 252 of 2017)

Effective March 27, 2018, when dispensing a controlled substance a dispensing prescriber is required to report the dispensing of the controlled substance to MAPS. Public Act 252 of 2017 also rescinded Rule 338.3162e of the Administrative Code, which exempted from mandatory MAPS reporting a controlled substance administered directly to a patient. **(Note: On April 3, 2018, The Michigan Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, clarified with MSMS that it is the agency's position that the legislatures repeal of the exemption does not require reporting to MAPS when a controlled substance is administered directly to a patient.)**

Moreover, physician offices that prescribe buprenorphine or methadone as part of an approved substance use disorder program, must query MAPS prior to prescribing. Physicians who dispense buprenorphine or methadone on premises, as part of an approved substance use disorder program, are required to query and report data associated with the encounter to MAPS so long as federal law does not prohibit the reporting of data concerning the patient.

Exceptions to the MAPS reporting requirement when dispensing a controlled substance include the following circumstances:

- A hospital that is licensed under article 17 that administers the controlled substance to an individual who is an inpatient.
- A health facility or agency licensed under article 17 if the controlled substance is dispensed by a dispensing prescriber in a quantity adequate to treat the patient for not more than 48 hours.
- A veterinary hospital or clinic that administers the controlled substance to an animal that is an inpatient.