Update on the New Requirements for Controlled Substance and Opioid Prescribing and Dispensing in Michigan

March 27, 2018

In February, we published a summary of 2017 Michigan legislation designed to address the opioid crisis that has gripped the country. On March 22, 2018, the Michigan Legislature passed HB 5678, which delays implementation of the bona fide prescriber-patient relationship requirement that was to go into effect March 31, 2018. The new effective date for this requirement is the earlier of March 31, 2019, or the date by which LARA publishes rules regarding the requirement. The following is a revised summary of the new controlled substance and opioid prescribing and dispensing requirements, reflecting the new effective date of the bona fide relationship requirement.

Effective February 11, 2018:

Option to Dispense Additional Quantities is Not Applicable to Controlled Substance Prescriptions

- A pharmacist who has consulted with the patient may, in accordance with his/her professional judgement, at one time dispense additional quantities of a prescribed drug, up to the total amount prescribed (including refills). This option is not permitted for controlled substances ("CS"), except schedule 5 CS that do not contain an opioid.

Effective March 27, 2018:

Providing Information on SUDS for OD Victims

- Any individual who holds a license or registration under the Public Health Code who treats a patient for an opioid-related overdose shall provide that patient with information on substance use disorder services.

Limitations on Initial, Refill, and Partial Fills of Controlled Substance Prescriptions

- Confirms restriction that a schedule 2 CS prescription may not be filled more than 90 days after the prescription was issued.
- Existing statutory language permitting partial filling of schedule 2 CS prescriptions for terminally ill patients is eliminated in favor of language permitting partial filling of schedule 2 CS prescriptions "consistent with federal law and regulations on the partial filling of prescriptions."
- Confirms no filling or refilling a schedule 3-4 CS prescription more than six months after the date of the prescription. Schedule 3-4 CS prescriptions may not be refilled more than five times unless renewed by the prescriber in accordance with the rules. Specific instructions are required for all schedule 3 and 4 CS prescription refills.

Reporting CS Dispensing in MAPS

- Continues the requirement that pharmacists/pharmacies, dispensing prescribers and veterinarians who dispense or administer CS to patient must report the dispensing/administration to MAPS. This requirement now specifically includes a prescriber who dispenses a drug containing buprenorphine or methadone to a patient in a substance use disorder program, unless federal law would prohibit such reporting.
- Reporting Exceptions: the following CS dispensing events are exempted from the MAPS reporting requirement by statute (the existing rule specifying the exceptions is rescinded):

1. Dispensing in a hospital licensed under Article 17 of the Code that administers the CS to a hospital inpatient;
2. Dispensing in a facility or agency that is licensed under Article 17 of the Code if the CS is dispensed by a dispensing prescriber in a quantity adequate to treat the patient for not more than 48 hours; or
3. Dispensing in a veterinary clinic or hospital when the CS is administered to an animal who is an inpatient.

Effective June 1, 2018

Providing Information about Opioids to Patients

- 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 CS properly;
3. that delivery of a CS 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 CS, 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 prepared by the Michigan Department of Licensing and Regulatory Affairs ("LARA"), certifying that the patient/representative received the above information.

Prescribing Opioids for a Minor – Special Informed Consent Requirements

- Before issuing the first prescription for a CS 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 CS;
2. The increased risk of addition to a CS for an individual suffering from both mental and substance abuse disorders;
3. The danger of taking a CS 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 CS that is required under federal regulations.

- The prescriber must obtain the signature of the minor's parent/guardian/authorized consenting adult on a separate, specific "**Start Talking Consent Form**" (currently being developed by LARA) 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.
- 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 judgement, 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.

- 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 CS containing an opioid.

MAPS Registration Requirement

- A licensed prescriber must **register** with the Michigan Automated Prescription Service ("MAPS") prior to prescribing or dispensing a controlled substance (any schedule).

MAPS Query Requirements

- A licensed prescriber must **obtain and review a MAPS report** before prescribing or dispensing more than a three-day supply of CS (any schedule).
  - **Exceptions** to this MAPS query requirement are made for:

1. Dispensing that occurs in a hospital or freestanding surgical outpatient facility and the CS is administered to the patient at the hospital or freestanding surgical outpatient facility;
2. The patient is an animal and the dispensing and the administration of the CS takes place in an animal hospital or clinic; or
3. The CS is prescribed for an animal and will be dispensed by a licensed pharmacist.

- *Failure to follow these MAPS requirements may subject the prescriber to professional discipline, including probation, reprimand or fine, or the suspension, limitation, or revocation, including permanent revocation, of a license. For prescribers who fail to follow the MAPS registration and query requirements, the Department of Licensing and Regulatory Affairs has the option to issue a notice letter describing the violation to the licensee. Such a notice letter would be issued in lieu of, and would not be considered professional discipline.*

Effective July 1, 2018

7-Day Limitation on Opioid Prescriptions for Acute Pain

- A prescriber who is treating a patient for **acute pain** shall not prescribe the patient more than a seven-day supply of an opioid within a seven-day period.
  - **Acute pain** is defined as the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus that is typically associated with invasive procedures, trauma and disease, and that usually lasts for a limited time.

Effective March 31, 2019 (or earlier date of implementing rules):

Bona Fide Patient Relationship and Follow-Up Care Required When Prescribing Controlled Substances

- A prescriber may not prescribe a schedule 2-5 CS unless the prescriber is in a **bona fide prescriber-patient relationship** with the patient for whom the CS is being prescribed.
  - A **bona fide relationship** is defined as a treatment or counseling relationship 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 condition, including a relevant medical evaluation of the patient in person or by telehealth; and
2. The prescriber has created and maintained records of the patient's condition in accordance with the medically accepted standard.

- The CS prescriber must provide **follow-up care** to the patient to monitor the efficacy of the prescribed CS in treating the patient's condition. If unable to provide follow-up care, the CS prescriber must refer the patient to his/her primary care provider. If no primary care provider exists, the prescriber must refer the patient to another licensed prescriber who is geographically accessible to the patient for follow-up care.

If you have questions or would like more information about the information in this alert, please contact Kathleen Reed at kreed@dykema.com or 231-348-8134, or your Dykema relationship attorney.

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