MEMORANDUM

MUNSON HEALTHCARE

TO: Munson Healthcare Provider Community

FROM: Munson Healthcare Legal Department

DATE: Updated as of July 15, 2018

RE: Understanding and Implementing the New Controlled Substance Laws- **UPDATED ITEMS**

In December 2017, the Michigan legislature passed a series of bills that will impact the processes Munson Healthcare's providers have in place for prescribing certain types of drugs. These bills are referred to in this memorandum as the "**New Laws**". The New Laws build upon prior laws that were passed in early 2017. The New Laws have a number of nuances of which you need to be aware. For these and more important details, please continue reading!

Note: the analysis and interpretation of the New Laws are an ongoing process. It may be possible that, as guidance is provided by the State of Michigan and stakeholders within Michigan's healthcare community, some of the analysis may change. The Munson Healthcare Legal Department will provide updates as appropriate.

HIGHLIGHTS OF THE NEW LAWS

Action Item	Critical Date
Educating patients being treated for an opioid-related overdose	**3/27/2018**
Reporting any dispensing of a controlled substance that is not done on an inpatient basis or which is done by a health facility or agency in quantities not greater than needed to treat the patient for forty-eight (48) hours	**3/27/2018**
Start Date for the Requirement to Have a Bona Fide Prescriber-Patient Relationship Prior to Prescribing Covered Drugs	**No later than 3/31/2019**
Deadline for Existing Prescribers to Register to use MAPS	**5/31/2018**
Start Date for Mandatory Pulling of MAPS Reports	**6/1/2018**
Start Date for Enhanced Patient Education Regarding Opioids	**6/1/2018**
Start Date for Limitations on Opioid Prescriptions	**7/1/2018**

OVERVIEW

Why were the New Laws passed?

The News Laws were passed to try and stem the epidemic of heroin and prescription opioid abuse and overdoses, which have resulted in a sharp increase in overdose deaths in the past few years. However, the New Laws reach beyond just those drugs containing opioids.

What drugs are covered by the New Laws?

The New Laws apply to controlled substances listed in schedule 2 through schedule 5 as defined under Michigan law ("**Covered Drugs**"). However, some of the New Laws apply only to those Covered Drugs that contain an opioid[1] ("**Opioid Drugs**"). A list of commonly-prescribed Covered Drugs is attached.

How do the New Laws approach the issue?

The New Laws are designed to reduce abuse and overdose through four different mechanisms:

- Mandatory registration of licensed prescribers to access MAPS.
- Mandatory use of MAPS.
- Mandatory patient education.
- Penalties for prescribers who do not comply with the New Laws.

The New Laws amend Michigan's substance control laws set forth in Article 7 of the Public Health Code.

UNDERSTANDING MAPS

What is MAPS?

Most providers are familiar with the Michigan Automated Prescription System ("**MAPS**"). MAPS is a prescription monitoring system developed by the State of Michigan to track the prescribing of Covered Drugs, providing a tool to both help assess patient risk and identify potential diversion and abuse issues. In early 2017, MAPS was replaced with a new and improved software platform called PMP AWARxE. For purposes of this memorandum, MAPS means the new and improved software platform.

What is a MAPS Report?

MAPS is part data aggregator and part analytics tool. It automatically analyzes MAPS data and a patient's health history to provide a patient risk score, or NarxScore, in a NarxReport (for consistency, this memorandum refers to the report as a "**MAPS Report**"). In that report, prescribers can immediately see predictive risk scores, red flags, a prescription graph and PDMP data, which alert prescribers to patients at risk for drug addiction or overdose or a potential dangerous drug interaction.

Is the score in the MAPS Report determinative of whether I can write a prescription for a Covered Drug?

No. A MAPS Report is not intended to replace the independent medical judgment of a prescriber. Nevertheless, a prescriber should indicate in the patient's medical record any course of prescription that might be inconsistent with what is in the MAPS Report. For example, if a MAPS Report suggests the patient is at high risk for an overdose, but the prescriber proceeds to write the

[1] "Opioid drugs" are those containing an opium or an opiate (including morphine and codeine).

prescription anyway, the medical record should indicate the reason for discounting the MAPS Report.

PRESCRIBERS

The New Laws apply to pharmacists and licensed prescribers. Who is a prescriber?

A licensed prescriber is defined as: (a) a licensed doctor of medicine; (b) a licensed doctor of osteopathic medicine and surgery; (c) a licensed dentist; (d) a licensed doctor of podiatry and surgery; (e) a licensed physician's assistant; (f) a licensed optometrist (with certain exceptions); (g) an advanced practice registered nurse (on a delegated basis for Covered Drugs); and (h) another licensed healthcare professional acting under proper delegation, having a DEA license, and using, recording or otherwise indicating the name of the delegating doctor of medicine or doctor of osteopathic medicine and surgery.

MANDATORY MAPS REPORT REVIEWING REQUIREMENTS

What is the deadline to register for MAPS?

June 1, 2018. A prescriber cannot prescribe or dispense a Covered Drug on or after June 1, 2018 until the prescriber is registered with MAPS.

I do not prescribe Covered Drugs. Must I register for MAPS?

No.

When does it become mandatory for a prescriber to obtain and review a MAPS Report prior to prescribing or dispensing a Covered Drug?

June 1, 2018.

Are there exceptions to having to obtain and review a MAPS Report? [UPDATED]

Yes. A prescriber need not order a MAPS Report if:

a. The prescriber is prescribing a Covered Drug in an amount that is **less than or equal to** a three-day supply; or

b. The Covered Drug is dispensed to a patient in a hospital or free standing surgical outpatient facility.

c. With respect to a prescriber who orders a schedule 2-5 controlled substance for inpatient administration. "Inpatient administration" is defined in LARA's updated FAQs as administration in an inpatient stay "within, but not limited to, a hospital, freestanding surgical outpatient facility, skilled nursing facility, hospice, homes for aged, etc."

I am writing a 7-day prescription for a Covered Drug for an inpatient, but the Covered Drug will be taken after the patient is discharged. Must I access and review a MAPS Report?

Yes.

Does the requirement to obtain and review a MAPS Report apply if the Covered Drug to be prescribed is buprenorphine (or contains buprenorphine) or methadone?

The New Laws add two new requirements with respect to prescribing those types of Covered Drugs to a patient in a substance abuse disorder program. First, the prescriber must obtain and review a MAPS Report. Second, unless prohibited by federal law, such a prescription must be reported using MAPS. ***Please note that federal law has an extensive prohibition on reporting substance abuse treatment matters. In most cases, you will not report the prescription of those types of Covered Drugs.***

Can I have a medical assistant or other staff member run a MAPS Report for me?

Yes. In such a case, the person would register as a "Prescriber Delegate-Unlicensed". All queries run would be attributed to the delegating prescriber. Please note that it remains the delegating prescriber's responsibility to comply with the New Laws.

Do I need to export the MAPS Report into the patient's medical records? [UPDATED]

No. The law prohibits others (including the patient) from accessing a patient's MAPS Report. Placing the MAPS Report in the record could result in the MAPS Report being disclosed/released in the case of a medical records subpoena, authorization, etc. As such, Munson's EHR system does not allow for the saving of the MAPS Report to the patient's chart. For non-Munson employed prescribers who have their own EHR system, should you choose to save a MAPS Report, it must be segregated from the rest of the patient's medical record. Please note that the MAPS software maintains detailed user records of MAPS usage for each user account and the system itself maintains audit trails. As such, there is no reason to retain a MAPS Report to provide evidence that the prescriber obtained a MAPS Report. It should be noted that information in the MAPS Report may be discussed with the patient generally.

Is there a time limit within which I must obtain a MAPS Report prior to prescribing a Covered Drug? [UPDATED]

No. However, best practice would be to minimize the amount of time that passes between obtaining the MAPS Report and prescribing the Covered Drug. Obtaining a MAPS Report no later than twenty-four hours prior to prescribing is recommended.

I write multiple prescriptions with "do not fill until date" restrictions. Do I need to pull a MAPS Report at the date of each refill? [NEW]

No. The MAPS Report must be pulled only at the time the prescription is written.

If an APP is writing a prescription based on delegated authority from a physician, under whose name should the MAPS Report be pulled? [NEW]

The MAPS Report should be queried under the APP's name.

PRESCRIBING LIMITATIONS FOR ACUTE PAIN (OPIOID DRUG SPECIFIC)

I occasionally prescribe Opioid Drugs to patients for pain following a procedure. May I continue to do so?

Yes, but with the following qualifiers. Beginning on July 1, 2018, a prescriber may prescribe an Opioid Drug to treat acute pain in seven-day increments only, and no more often than once in each seven-day period. Further, an opioid may only be prescribed for pain that is: (a) typically associated with invasive procedures, trauma or disease; and (b) usually of a limited duration.

Note: a number of payors have more restrictive limits (five days) on the increments that may be covered by an Opioid Drug prescription for acute pain.

Do the New Laws limit the dosage of an Opioid Drug?

No. However, any prescription for a dose in excess of ninety (90) morphine milligram equivalents per day should be carefully justified in the patient's medical record.

PRESCRIBER-PATIENT RELATIONSHIP [IMPLEMENTATION DELAYED]

The New Laws prohibit a prescriber from prescribing a Covered Drug to a patient unless the prescriber is in a bona fide prescriber-patient relationship. What is a bona-fide prescriber-patient relationship?

Such a relationship is defined as a treatment or counseling relationship in which the prescriber: (a) has conducted a review of the patient's medical records; (b) has performed a total assessment of the patient's medical history and condition, including an appropriate medical evaluation conducted in person or via telehealth (which is defined to be electronic information and telecommunication technologies to support or promote long-distance clinical health care, patient and professional health-related education, public health, or health administration); **and** (c) has created and maintained records of the patient's condition in accordance with medically accepted standards.

Note: it is anticipated that administrative rules will be adopted later on that create exceptions to the need for a prescriber-patient relationship.

I am a physician that delegates prescriptive authority to advanced practice providers. Am I required to conduct an assessment of the patient for purposes of establishing a bona fide prescriber-patient relationship?

No. So long as the APP meets the definition of "prescriber", the APP can establish the bona fide prescriber-patient relationship. This will require, among other things, that the APP obtain a DEA license.

When does the requirement for a bona fide prescriber-patient relationship become effective? [UPDATED]

No later than March 31, 2019.

I prescribed a Covered Drug to a patient for which there is a bona fide prescriber-patient relationship. Do I need to provide any follow-up care?

Generally, you must provide follow-up care to assess the efficacy of the Covered Drug in managing the patient's condition. If you do not, you must refer the patient to the patient's primary care

provider or, if the patient has no such provider, to another licensed prescriber who is geographically accessible to the patient.

Can I have one of my practice partners prescribe Covered Drugs to a patient of mine while I am out of the office?

As drafted, the New Laws would not permit this unless the covering physician has a prescriber-patient relationship.

PATIENT EDUCATION AND CONSENT (OPIOID-DRUG SPECIFIC)

What type of information must be provided to all patients prior to the patient being prescribed an Opioid Drug?

Beginning on June 1, 2018, except when an Opioid Drug is prescribed for inpatient use, a prescriber or another health professional must provide information on all of the following to the patient or the patient's representative:

- The danger of opioid addiction
- Proper disposal of expired, unused, or unwanted Opioid Drugs
- The fact 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, but not limited to, neonatal abstinence syndrome

Further, the New Laws require the licensed prescriber or other health professional to obtain the signature of the patient or the patient's representative on a suitable form indicating that the patient or the patient's representative has received the information described above. The licensed prescriber or other health professional must then place the signed acknowledgment in the patient's medical or clinical record.

How do I determine if a person is a "patient's representative"?

To be a "patient's representative", a person must be a guardian of a patient, if appointed, or a parent, guardian, or person acting *in loco parentis*, if the patient is a minor, unless the minor lawfully obtained health care without the consent or notification of a parent, guardian, or other person acting in loco parentis. A person who is acting "in loco parentis" is one who is not the parent or guardian of a minor, but who has either legal custody or physical custody of a minor and is providing support and care for the minor.

I heard the New Laws impose additional requirements on prescribers who prescribe Opioid Drugs to a minor. What are those requirements?

Beginning on June 1, 2018, before a prescriber can prescribe an Opioid Drug as part of a single course of treatment for an individual under the age of 18 who is not legally emancipated, the prescriber must:

1. Discuss with both the minor and the minor's parent, guardian or other adult authorized to consent to the minor's medical treatment (each a "**Authorized Patient Representative**"):
   - The risk of addiction and overdose with respect to the Opioid Drug

- ❖ The increased risk of addiction to that Opioid Drug if the person is suffering from both mental and substance abuse disorders
- ❖ The danger of taking the Opioid Drug with a benzodiazepine, alcohol or another central nervous system depressant
- ❖ The information contained on the patient counseling information label of the Opioid Drug for a patient to use it safely and effectively

2. Obtain the Authorized Patient's Representative's signature on a "start talking consent form"; and
3. Include the signed start talking consent form in the minor's medical records.

How do I determine if a person is an "adult authorized to consent to the minor's medical treatment"?

Such person must have presented a signed, written authorization from the minor's parent or guardian for such person to consent to the minor's treatment.

If the consent is provided by an "adult authorized to consent to the minor's medical treatment", can I prescribe the same amount of the Opioid Drug as if the consent had been provided by the minor's parent or guardian?

No. In that case, you may only prescribe one (1) three-day supply of the Opioid Drug.

The minor notification and consent process seems impractical in certain situations. Are there exceptions?

Yes. The process is not required for treatment rendered in connection with the following instances:

1. A situation that the prescriber, exercising good-faith medical judgment, believes creates an immediate threat of serious risk to the physical health or life of the minor;
2. Inpatient or outpatient surgery;
3. Hospice care;
4. Treatment for which the consent of the parent or guardian is not required by law; or
5. The prescriber, in her/his professional judgment, believes that adhering to the process would be detrimental to the minor's health or safety.

I received an executed "start talking consent form" from the minor. Do I still need to obtain the signed general opioid information acknowledgment form? [UPDATED]

No.

Is Munson developing a form of the acknowledgement and the "start talking consent form"? [UPDATED]

The state has created a combined consent form to be used for both adults and minors. Munson's form tracks the state-created form.

Note: once a required consent or acknowledgment is completed and signed, it must be placed in the patient's medical record.

How often must I reeducate patients regarding the dangers of Opioid Drugs? [UPDATED]

Prior to the initial prescription, a consent must be obtained. Refills do not require new consents. Continuation of the established previous therapy does not require a new form. However, any change in the type or dosage will require a new consent.

Who must provide the education? [NEW]

Pursuant to MCL 333.16215, a prescriber who has delegation ability could potentially delegate the responsibility of providing opioid risk education for a patient to another licensed or unlicensed health professional, provided that health professional has sufficient training and background.

Are there exceptions to the consent form requirement? [NEW]

Yes. LARA has indicated that the form is not required for inpatient administration of an Opioid Drug. Per LARA, "the form does not have to be completed given that the opioid is being administered while the patient is at the facility. For example, administration of the opioid for inpatient stay within, but not limited to, a hospital, freestanding surgical outpatient facility, skilled nursing facility, hospice, homes for aged, etc."

NEW REQUIREMENTS WHEN DISPENSING CONTROLLED SUBSTANCES

In the past, I was not required to report the dispensing of a Covered Drug directly to a patient. I hear that has changed. How so?

Dispensing of a Covered Drugs must be reported on MAPS unless either:

1. The Covered Drug is dispensed directly to a patient in a hospital; or
2. The Covered Drug is dispensed in a health facility or agency[2] in a quantity adequate to treat the patient for no greater than forty-eight (48) hours.

PENALTIES

As a licensed prescriber, what if I fail to abide by the New Laws?

A prescriber could face disciplinary action from the State of Michigan for failing to: (a) have a bona fide prescriber-patient relationship; (b) register for MAPS; (c) obtain a MAPS report when required; and/or (d) educate and/or obtain a minor's consent as required by the New Laws.

Penalties can include reprimands, fines and licensure action (suspension, limitation or revocation).

This Memorandum provides an overview of the New Laws. It is for informational purposes only and is not intended as legal advice. For Munson employees, all questions should be directed to the Munson Healthcare Legal Department.

[2] "Health facility or agency" includes an ambulance operation, aircraft transport operation, non-transport prehospital life support operation, medical first response service, county medical care facility, freestanding surgical outpatient facility, health maintenance organization, home for the aged, hospital, nursing home, hospice, or hospice residence.

Controlled Substance Medications

Opioid-Containing Analgesics	**Hydrocodone-containing products (Norco, Vicodin, Lortab)** **Oxycodone-containing products (Percocet, OxyContin)** **Hydromorphone (Dilaudid)** **Fentanyl (Duragesic, Actiq, Sublimaze, Fentora)** **Morphine (MS Contin)** **Codeine (Tylenol #3, Cough medicines with Codeine)**
Benzodiazepines	Alprazolam (Xanax) Clonazepam (Klonopin) Chlordiazepoxide (Librium) Lorazepam (Ativan) Diazepam (Valium)
Stimulants	Amphetamines (Adderall) Dexmethylphenidate (Focalin, Focalin XR) Lisdexamphetamine (Vyvanse) Methylphenidate (Ritalin) Modafinil (Provigil) Armodafinil (Nuvigil)
Partial Opioid Agonists	Buprenorphine Containing Products (Subutex, Suboxone)
Migraine Medications	Containing butalbital (Fioricet, Fiorinal)
Muscle Relaxants	Carisoprodol (Soma)
Testosterone Products	Androderm, AndroGel, Depo-Testosterone, Testim
Bowel	Belladonna and Opium (B&O Suppositories) Diphenoxylate-Atropine (Lomotil)
Appetite Stimulants	Dronabinol (Marinol) Phentermine (Adipex-P)
Sleeping Agents	Eszopiclone (Lunesta) Zolpidem (Ambien) Zaleplon (Sonata)
Miscellaneous	Methadone (Dolophine, Methadose) Tramadol (Ultram, Ultram ER)