

MICHIGAN CONTROLLED SUBSTANCES
REGULATION IN RESPONSE TO
THE OPIOID EPIDEMIC

STATE BAR OF MICHIGAN HEALTH CARE LAW SECTION

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SUMMARY OF CHANGES

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- Electronic prescribing of controlled substances
- Workaround for “Start Talking” education and form

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I. Introduction

An American's chance of dying by drug overdose (1 in 96) is now higher than their chance of dying by motor vehicle accident (1 in 114).¹ Michigan has been hit particularly hard by the epidemic, with 2,662 Michiganders dying of drug overdose in 2017. Roughly two-thirds of those overdoses were linked to opioids, a class of drug that is effective at treating some types of pain, but also highly addictive.² The majority of those opioid overdoses involved fentanyl, a synthetic opioid 50-100 times more potent than heroin and widely used in healthcare.³

The opioid crisis has sometimes been characterized as an epidemic stemming from “non-medical” abuse of opioids; in other words, opioids used without a prescription or used other than prescribed. In response to this, policymakers initially focused on reducing access to non-medical opioids.⁴ The Drug Enforcement Administration (DEA), along with government, community, public health, and law enforcement partners, launched a national “Take Back” initiative in September 2010, resulting in events across the country to collect and destroy unwanted prescription drugs before they fell into the wrong hands.⁵ Subsequent action by Congress and President Obama furthered such initiatives.⁶ Despite these efforts, the opioid epidemic continued to grow. It is well understood today that the medical use of opioids significantly contributes to the rising rates of addiction.

There has been a well-documented dramatic increase in the medical prescribing of opioids in the past few decades – in 2015, patients were prescribed approximately three times the quantity of opioids as they had been prescribed in 1999.⁷ This rise in overprescribing has been fueled by the intersection of multiple factors, stemming from now-debunked research indicating opioids were low risk:

The more permissive attitude toward opioids for pain treatment began in the 1980s, after several reports suggested a low potential for iatrogenic addiction in patients treated with opioids. [Iatrogenic addiction is defined as addiction caused by medical treatment.]

[A] 1997 consensus statement concluded there was insufficient evidence to suggest that opioids result in iatrogenic addiction. Belief in the safety of opioids proliferated rapidly throughout the medical education system and inappropriate application of observational research bolstered this thinking.

Other factors included attempts to improve pain management, emphasis on patient satisfaction and inclusion of pain relief in patient satisfaction assessments, aggressive marketing of opioids by the pharmaceutical industry, and welfare and health care reform.⁸

One study of 254 unintentional opioid overdoses showed that 92% of the decedents had a legitimate opioid prescription for chronic pain.⁹ Another study showed that patients with no history of opioid use who received an opioid prescription post-surgery were 44% more likely to become long-term opioid users within one year than those not receiving opioids.¹⁰

States have recently begun aggressively legislating in an attempt to curb the growing problem. For example, forty-nine states have adopted prescription drug monitoring programs (PDMPs), which collect and share patient prescription information in a centralized state database—enabling health care providers to ensure their patients are not inappropriately receiving drugs from multiple sources.

Michigan’s most recent legislative response to the opioid epidemic began with a series of bills in 2014 that authorized the use of, and regulated, Naloxone (an opioid overdose “rescue” drug). This paper focuses primarily on the subsequent round of legislation, most of which was enacted in 2017 and became effective in 2018. This legislative package created the changes most relevant to health care providers and hospitals. Much of the legislation has practice implications, and operationalization raises practical interpretive questions. Some of the legislation is particular to opioid management while other laws are inclusive of all controlled substances. This paper particularly highlights the subsequent legislative revisions, administrative rules, and guidance that have clarified—and at times modified—the original legislation.

II. Patient education requirements and the “Start Talking” form

Michigan’s patient education requirement seeks to ensure patients know the risks of, and are given the opportunity to decline, opioids. [Act 246 of 2017](#) created two new statutes that require prescribers to provide patients (or, if applicable, a patient’s parent, guardian, or other authorized adult) with certain information on opioids before prescribing a new opioid and memorialize that conversation on the “[Opioid Start Talking](#)”¹¹ form created by the Michigan Department of Health and Human Services (DHHS) (referred to herein as the “Start Talking” form; see example at **Exhibit 1**). For purposes of this law, there is no distinction between acute pain (“temporary” pain that is expected to resolve) and chronic pain.

The requirements vary for adult versus minor patients: [MCL 333.7303c](#) sets forth the requirements for adult patients, and [MCL 333.7303b](#) sets forth the requirements for minor patients.¹² It is worth pointing out that the statutes for adult and minor patients were developed independently, which led to some variances for which a rationale is not readily apparent. The minor’s statute, for example, includes some exceptions—while the adult’s statute does not.

Another eccentricity worth noting is that the adult’s statute has language about a minor patient’s parent or guardian, which is moot since all provisions relevant to minors are contained within the minor’s statute.¹³

Under Michigan’s licensee/registrar reporting/sanction statute, penalties for noncompliance include: Probation, limitation, denial, fine, suspension, revocation, or permanent revocation. [MCL 333.16221\(v\)](#); [MCL 333.16226\(1\)](#).

A. Applicability

The education and “Start Talking” requirement apply when a prescriber issues an opioid prescription to a patient. If the patient was already on opioid prior to June 1, 2018, education need not be provided and the form need not be collected for current or future usage of that specific opioid for further use for that specific indication.

As noted above, there is some variation in language between the adult’s statute and minor’s statute:

Applicability for adult patients under MCL 333.7303c(1)	Applicability for minor patients under MCL 333.7303b(1)
The law is applicable when, on or after June 1, 2018, “a controlled substance that is an opioid is prescribed to a patient.”	The law is applicable when, on or after June 1, 2018, a prescriber is “issuing for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid, regardless of whether the prescriber modifies the dosage during the course of treatment.”

The minor’s statute is applicable only if the prescription is for a “single course of treatment.” Consider a patient that has back pain and is prescribed an opioid; the patient’s use of that opioid for back pain would constitute a “single course of treatment,” regardless of how long they stayed on that opioid for back pain. If the same patient develops abdominal pain from a cancer diagnosis later, and they were prescribed an opioid, it would constitute a new course of treatment, and would require new education and a new “Start Talking” form. While the adult’s statute does not reference “single course of treatment,” the same principle should apply under standard practice such that different pain would necessitate a new prescription, and trigger the need for new education and a new “Start Talking” form.

The law explicitly only applies when an opioid is prescribed in an outpatient setting or upon discharge from an inpatient/procedure unit. It does not apply to inpatient administration¹⁴ of opioids. Additionally, a dosage change is not considered a new prescription, and does not necessitate new education or a new form.

B. Content requirements

When the above conditions are met, the law sets forth the information that must be provided, which again varies between adults and minors:

Educational content requirements	
Adult patient MCL 333.7303c(1)	Minor patient MCL 333.7303b(a)
The danger of opioid addiction.	The risks of addiction and overdose associated with the controlled substance.
How to properly dispose of an expired, unused, or unwanted controlled substance.	The increased risk of addiction to a controlled substance to an individual who is suffering from both mental and substance abuse disorders.
That the delivery of a controlled substance is a felony under Michigan law.	The danger of taking a controlled substance containing an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.
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.	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) .

The MDHHS template “Start Talking” form combines the above educational requirements so that a single form can be used for both adult and minor patients. Notably, the form is described as “a form...indicating that the patient has received [the opioid education]” in the adult’s statute, and is described as a “*consent* form” in the minor’s statute. The form itself is not labeled as a consent. This distinction has resulted in confusion operationally, as many practices have specific policies related to the “consent” process, such as nursing’s role. Practically speaking, the “Start Talking” form serves as documentation that the education has been delivered—which necessarily includes discussion of the risks and benefits—in both cases.

There are additional practical challenges when integrating the “Start Talking” form into practice since many providers use electronic health records (EHR) rather than paper forms. While the law does allow the form to be digitized, not all providers have the ability or capital to do so and still rely on using the paper “Start Talking” form and scanning the signed document into the EHR. The workflow would be similar to other documents that a patient may present to their provider that must be integrated into the EHR, such as an Advance Directive.

As a final point, the MDHHS template “Start Talking” form is at a more advanced reading level than is recommended for patient materials,¹⁵ and practices would be well-advised to consider rephrasing. Use of the template form is not mandatory under the current law; the law sets forth the elements that must be included at [MCL 333.7303b\(4\)](#) and the MDHHS/LARA FAQ document confirms that practices may create their own form (which may be electronic) ([LARA FAQ, page 6, #3](#)).

C. Minors: Exceptions

There are a few exceptions that apply only to minor patients; in contrast, there are no statutory exceptions for adult patients. As noted above, it is unclear why these exceptions were limited to minors, when almost all of them should in theory be equally applicable to an adult.

Exceptions, for minor patients only, to the education and “Start Talking” form requirement MCL 333.7303b(2)	
Exception	Example/Discussion
Treatment associated with a medical emergency A medical emergency is defined as “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.” MCL 333.7303b(5)(b)	In some cases, aggressive analgesic care may be required quickly (e.g., bone fracture, acute appendicitis).

Exceptions, for minor patients only, to the education and “Start Talking” form requirement MCL 333.7303b(2)	
Exception	Example/Discussion
If fulfilling the requirements of the law would be detrimental to the minor’s health	The parents of older adolescents may maintain involvement in their child’s care, but also elect to give their child some privacy at appointments—such as by waiting in the waiting room. If the minor’s care requires an opioid, and their parent has an active, untreated opioid use disorder, the minor may be vulnerable to under-treatment of pain if the parent is included in the education and “Start Talking” form process and diverts the opioid for their own use.
Treatment associated with surgery (inpatient or outpatient)	<p>Notably, there is no distinction between major or minor surgery in this exception: spinal fusion and mole removal are considered equal, and both would technically fall under this exception.</p> <p>Ambiguity arises when a procedure requires anesthesia, but is not technically “surgery,” such as treatment of a hip dislocation. Since the procedure is performed by a surgical service, for operational and pragmatic purposes, such procedure would generally be considered “surgery” and should fit within the exception.</p>
If treatment is rendered in hospice or upon discharge from hospice	End of life care may require extensive pain management to keep the patient comfortable. This includes both care in a hospice facility and in-home hospice care.
If treatment is rendered in an oncology department or upon discharge from an oncology department	Oncology care may require extensive pain management to keep the patient comfortable. Interestingly, the exception does not explicitly include hematology, which is generally grouped with oncology and deals with blood malignancies such as leukemia.
If the consent of the minor's parent or guardian is not legally required for the minor to obtain treatment	In Michigan , minors can receive certain types of healthcare (e.g., prenatal and pregnancy-related care, certain mental health services, certain substance use disorder services) without the consent or knowledge of a parent/guardian. ¹⁶ Emancipated minors also fall under this exception. ¹⁷

D. Minors: 72-hour supply limit if “other adult” consents

The law specifies that the education should be provided to, and the “Start Talking” form signed by, a minor’s parent, guardian, or “another adult authorized to consent to the minor’s medical treatment.” [MCL 333.7303b\(1\)](#). This is defined as “an adult to whom a minor’s parent or guardian has given written authorization to consent to the minor’s medical treatment,” such as a temporary delegation of parental rights. [MCL 333.7303b\(5\)\(a\)](#); see [MCL 700.5103](#) regarding a temporary delegation of parental rights. In such cases, the law limits any prescription to a single, 72-hour supply of the medication. [MCL 333.7303b\(3\)](#).

E. Defining “outpatient” setting

As noted above, the education and “Start Talking” form require that the opioid be prescribed in an “outpatient” setting. This may become complicated due to the nuances of how health care services are characterized for billing, licensing, and other purposes. For example, some dermatology practices designated as “outpatient centers” may perform minor surgical procedures. These minor surgical procedures may necessitate some pain control, such as prescribing patients a single tablet of hydrocodone/acetaminophen (e.g., Norco) to be taken prior to the procedure. The law makes no exception for this scenario, as the drug is prescribed rather than being administered. Therefore, the education and “Start Talking” form would be required by the law.

Furthermore, the designation of inpatient and outpatient is not always obvious, even to providers who practice at those locations. Consider a free-standing hospital for eye care that performs surgery but does not have beds to admit patients. If a patient is in need of overnight observation, they are transferred to the main hospital. Yet the eye center may be designated as a hospital and is technically an inpatient setting; therefore, the provision of opioids there is exempt from the education and “Start Talking” form requirements.

F. The challenge of treating late-developing pain

A significant operational challenge occurs when a patient does not need an opioid when they are in clinic or at discharge, but after returning home develop pain for which an opioid is indicated.

For example, consider an adult patient who has surgery at an ambulatory surgery center designated an outpatient facility. The education and “Start Talking” form process is implicated if an opioid is prescribed. In an effort to reduce opioid prescribing, many providers will not prescribe an opioid if the pain is well-controlled prior to discharge. It is, however, not at all uncommon for patients, in the following hours or days, to experience intense acute pain not relieved by over-the-counter medications. It is difficult, if not impossible, for a provider to predict who will need an opioid and who will not. In this scenario, it is medically appropriate for a short course of an opioid to be prescribed. Yet if the surgery was on an extremity or if the patient lives geographically distant and has no driver, it may be impossible for the patient to return for education and to sign the “Start Talking” prior to prescribing the opioid, as the law requires.

Similarly, consider an adult patient seen at an outpatient clinic appointment for suspected shingles. The provider may treat the pain with over-the-counter pain medication; often this is all that is required. However, it is also not uncommon for this to evolve into a more painful state as the virus destroys the ganglion of the impacted nerve. This may require escalation of care, namely, a short course of a weak opioid. If this occurs on a weekend and the practice is closed, the on-call provider would be unable to fulfill the requirements of the law.

Furthermore, in both cases, a return visit may be an unnecessary waste of resources from a public health perspective: the provider has recently assessed the patient, and the pain progression in and of itself does not warrant further assessment or examination.

There has been no official guidance on handling these “late developing pain” situations. A proactive approach may involve the provider speculating a particular patient may need an opioid, providing the education, and obtaining the patient’s signature on the form “just in case.” If the patient does end up needing the opioid, the legal requirements have already been fulfilled. Problematically, this would require that the provider guess what drug and quantity would be required, which may or may not turn out to be correct. Additionally, this approach would put distance between the education and the provision of the opioid prescription—although not directly addressed in the law, this may reduce the effectiveness of the education. A more elegant solution that maintains real time education could involve a process similar to that used for telephone consent, in which the education would be provided via telephone and documentation of that phone call would take the place of a wet signature on the form.

G. Delegating the requirements of the law

Michigan law authorizes health profession licensees (excluding subfield licensees, defined as PAs and LPNs) to:

[D]elegate to a licensed or unlicensed individual who is otherwise qualified by education, training, or experience the performance of selected acts, tasks, or functions where the acts, tasks, or functions fall within the scope of practice of the licensee's profession and will be performed under the licensee's supervision. [MCL 333.16215\(1\)](#).

The [LARA/MDHHS FAQ](#) confirms that both the education requirement ([LARA FAQ, page 7, #5](#)) and obtaining the signature on the “Start Talking” form ([LARA FAQ, page 7, #6](#)) may be delegated.¹⁸ As such, a model where, for example, the attending physician provides the education and a medical assistant later obtains signature on the “Start Talking” form, would be permissible so long as done within the confines of the delegation statute.

A complexity here, however, is that because PAs and LPNs cannot delegate, different workflows must be established for these providers if they prescribe and would like to delegate the provision of education, or collecting signature on the “Start Talking” form. This results in obvious

operational challenges given the need to develop different processes and workflows dependent on provider class.



H. The challenge of COVID-19

As COVID-19 spread throughout Michigan in March 2020, it quickly became apparent that strict compliance with the “Start Talking” education and form requirements was not tenable. As in-person outpatient clinical operations ground to a halt nearly overnight across the country, the U.S. Drug Enforcement Administration quickly authorized providers to prescribe Schedule II–V controlled substances via telemedicine on March 16, 2020, relying upon an exception in the Controlled Substances Act triggered by the declaration of a public health emergency. Under the exception, for the duration of the public health emergency:

DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II–V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.¹⁹

Michigan law did not broadly require an in-person medical evaluation before a new controlled substance prescription (note that the “bona fide” relationship requirement discussed in Section III of this paper allows for evaluation in person or via telehealth). Nonetheless, Governor Whitmer’s Executive Order No. 2020-86, Encouraging the use of telehealth services during the COVID-19 emergency (May 14, 2020) made confirmed that Michigan law supported the DEA’s approach:

A physician is not required to conduct an in-person examination before prescribing medication or ordering the administration of medication, including controlled substances except for methadone.²⁰

Despite this general authorization to prescribe controlled substances via telemedicine, other state law requirements still apply. For example, a new opioid prescription still requires compliance with the “Start Talking” education and form, including collection of the patient’s signature on the “Start Talking” form. E-mailing or mailing a blank form to the patient and asking

them to sign and return it may be burdensome, particularly in a time when resources are limited and most administrative staff are working remotely themselves. This signature requirement is not only difficult to satisfy in a telemedicine setting, but also in the in-person setting; because providers are trying to minimize exposure risk, taking a piece of paper into an exam room or inpatient hospital room for signature and then removing it for handling and scanning may be unnecessarily risky.

In March 2020 Providers across the state began implementing workarounds in an attempt to comply with the purpose and intent of the law under emergency conditions. For most, this includes the provision of education via telemedicine (in the outpatient setting) or in person (primarily in the inpatient setting) and documentation of the patient's receipt of and understanding of the education in the patient's medical record. While it has not publicly commented on this approach, the authors' communications with LARA have indicated that LARA is generally in agreement with such a process, despite the lack of the patient's inked signature to the "Stark Talking Form," at least for the duration of this public health emergency.

III. “Bona fide” prescriber-patient relationship requirement; patient follow-up

“Doctor shopping” has a variety of definitions and is not always nefarious in purpose. At the more innocuous end of the spectrum, a patient may seek advice from more than one provider in hopes they receive an alternative diagnosis. At the other end of the spectrum, a patient may visit multiple providers in an effort to inappropriately obtain more controlled substances than are medically indicated.²¹

In the latter example, some of those providers might be so-called “pill mills” where providers prescribe without more than a cursory review and examination (if any) and no follow-up. These are generally simple “cash-for-prescription” arrangements, but they may also be “prescription-for-procedure” arrangements where patients submit to unnecessary interventional procedures in order to obtain the prescription. There have been numerous prosecutions for such operations in Michigan: in April 2019, a Detroit physician was sentenced to 11 years in prison for running an \$18 million prescription drug scheme that included receiving payments (\$150-\$400 per prescription) in exchange for writing prescriptions for no medical purpose that were subsequently sold on the street.²²

In light of this environment, Michigan enacted legislation addressing the relationship between a provider who prescribes controlled substances and a patient. [Act 247 of 2017](#) created a requirement that a prescriber may only prescribe a Schedule II-V controlled substance if they are in a “bona fide prescriber-patient relationship with the patient,” which requires record review, evaluation of the patient, and documentation. [MCL 333.7303a](#); [Rule 338.3161a](#).²³

Furthermore, if a prescriber prescribes a Schedule II-V controlled substance, they 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 unable to do so, they may refer the patient to another provider. [MCL 333.7303a\(2\)](#). The requirement applies only in the outpatient / discharge setting (the law is about *prescribing*), and does not apply to inpatient *administration* of a Schedule II-V controlled substance.

Under Michigan’s licensee/registrator reporting/sanction statute, penalties for noncompliance with this requirement include probation, limitation, denial, fine, suspension, revocation, or permanent revocation. [MCL 333.16221\(v\)](#); [MCL 333.16226\(1\)](#).

A. Defining a “bona fide” relationship

A “bona fide” relationship is a “treatment or counseling relationship between a prescriber and a patient,” in which both of the following elements 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 through telehealth,” and

2. The prescriber has created and maintained records of the patient's condition in accordance with medically accepted standards. [MCL 333.7303a\(8\)\(a\)](#).

B. Fulling the “follow up” requirement

The prescriber must provide follow-up care to the patient to monitor efficacy. If unable to do so, the prescriber may 1) refer the patient to the patient's primary care provider (PCP) for follow-up or, 2) if the patient does not have a PCP, refer the patient to another licensed prescriber who is geographically accessible to the patient for follow-up. [MCL 333.7303a\(2\)](#). Giving the patient a list of PCPs or a physician locator hotline number fulfills the obligation of referral.

C. Exceptions

Upon initial enactment, the bona-fide prescriber-patient relationship requirement posed one major problem for health care providers: there was no carve-out for prescription refills. In many practices, a patient’s original prescribing provider may not be available when a patient requests a refill—whether they are tied up with other clinical or academic duties or on sabbatical, vacation, or medical leave—there was no mechanism by which a colleague could provide coverage to ensure the patient received their refill without having to go through an unnecessary appointment to fulfil the requirement of “a relevant medical evaluation of the patient conducted in person or through telehealth.” Because of this and other concerns, the effective date of the bona-fide prescriber-patient relationship requirement was delayed until the Michigan Board of Pharmacy enacted administrative rules; those rules were enacted on January 4, 2019:

Exceptions to the “bona fide” relationship requirement / special cases Rule 338.3161a(3)	
Exception	Example/Discussion
When the prescriber is providing on-call / cross-coverage for another provider who has established a bona-fide relationship with the patient; the prescriber must review the patient’s records, history, and any changes, and document in the patient’s medical record. Rule 338.3161a(3)(a)	<p>Consider when a patient’s primary provider is unavailable (e.g., on vacation, or it’s the weekend). Under this exception, the provider who is covering for the primary provider may provide the patient with a controlled substance prescription (including a refill, or a completely new prescription).</p> <p>For example, consider a patient on morphine who has a new issue with declining renal function and is calling in for a refill but their primary provider is on vacation. The covering provider could change the patient to hydromorphone (which does not rely on renal clearance), documenting the rationale for the change in the patient’s medical record.</p>

Exceptions to the “bona fide” relationship requirement / special cases Rule 338.3161a(3)	
Exception	Example/Discussion
When the prescriber is prescribing for a patient for whom the “bona fide” requirements have already been met by a different provider, and the prescriber documents in the patient’s medical record. Rule 338.3161a(3)(d)	The intent behind this broadly worded exception is not readily apparent. Whereas the previous exception would generally allow a prescriber providing coverage to prescribe for an absent colleague’s patient, this exception would seemingly allow a prescriber to rely on <u>any</u> other prescriber’s “bona fide” relationship in order to prescribe. Providers should be cautious in relying on this exception, since it would be difficult to assess the legitimacy of a non-affiliated prescriber’s “bona fide” relationship.
When the prescriber is following or modifying orders for inpatient, hospice, or nursing facility, and the prescriber documents in the patient’s medical record. Rule 338.3161a(3)(b)	Consider a patient admitted to a hospital on an opioid regimen who is being discharged to hospice in the evening. Upon arrival at hospice, a prescriber (such as a nurse) can review what was being provided at the hospital and provide a continuation of what the patient had been on until the patient established a new “bona fide” relationship with their treating provider at the hospice facility.
When the prescriber is prescribing for a patient admitted to a nursing care facility or hospice, the prescriber must fulfill the “bona fide” relationship requirements within 48 hours, and the prescriber documents in the patient’s medical record. Rule 338.3161a(3)(c)	See LARA FAQ, page 10, #5-#6 . This is less of an exception, and more of a “special case” in that it allows for a “bona fide” relationship to be established within 48 hours of the prescribing.
If “in the prescriber’s good-faith professional judgment, [the situation] creates an immediate threat of serious risk to the life or health of the patient for whom the controlled substance prescription is being prescribed.” Rule 338.3161a(3)(e)	Consider a pregnant patient on a high dose of opioids who needs a refill. While opioid withdrawal itself is not a life-threatening condition, it can cause preterm labor. Under this exception, a prescriber could provide the refill without meeting all of the “bona fide” requirements, such as reviewing records or conducting an exam.

IV. Mandatory use of Michigan's prescription drug monitoring program

Prescription drug monitoring programs (PDMPs) are statewide electronic databases that collect data on certain drugs dispensed within that state. The first PDMP was developed in Oklahoma City in the early 1990s and was used as a law enforcement tool. It has since evolved into a clinical tool used in 49 states and DC.

PDMPs . . . are critical decision support tools that state officials, health care professionals, and law enforcement officers use to address opioid and prescription drug abuse and diversion. PDMPs electronically collect, analyze and disclose specified information about prescribed controlled substances and other monitored substances dispensed to patients and their representatives.²⁴

In the healthcare context, PDMPs provide information on the types and quantities of drugs that patients may be receiving from other providers and pharmacists—which may reveal “doctor shopping” or other inappropriate behavior. Some states also require the reporting of “substances of concern,” such as over the counter preparations of cold and flu medication containing substances that can be extracted in the process of methamphetamine manufacturing.

Michigan's PDMP, the Michigan Automated Prescription System (MAPS) went live in 2003. Initially, pharmacists were required to enter data on individuals who received Schedule II-V controlled substances, but were not required to run reports before dispensing to ensure the individual picking up the drug was not already receiving drugs elsewhere. Physicians were not required to use MAPS at all, unless they also practiced in-office dispensing, which necessitated data entry much like the pharmacist requirement. Prescribing providers were instead “encouraged” to register and use MAPS, but there was no statutory mandate to do so.

Further development of the legal requirements related to MAPS has increased health care providers' responsibilities. Under the current law, prior to prescribing, the provider must: (1) register with MAPS and (2) check MAPS before prescribing or dispensing²⁵ a controlled substance in a quantity that exceeds a three-day supply. [MCL 333.7303a\(4\),\(5\)](#). Providers must also ask the patient if they are taking a controlled substance and record the response in the patient's medical record; this is a long-standing requirement. [MCL 333.7303a\(3\)](#). This applies any time a prescription is written (in an outpatient setting, or upon discharge), and does not apply to inpatient administration of a controlled substance. MAPS has used Appriss Health's PMP AWA Rx E software since April 2017.²⁶

Under Michigan's licensee/registrant reporting/sanction statute, penalties for noncompliance include: Denial, fine, reprimand, probation, limitation, suspension, revocation, or permanent revocation. [MCL 333.16221\(w\)](#). However, “[i]f the department has a reasonable basis to believe that a licensee has violated section 7303a(4) [requirement to check MAPS] or (5) [requirement to register with MAPS], the department is not required to investigate under section 16221 or 16231 and may issue a letter to the licensee notifying the licensee that he or she may be in

violation of section 7303a(4) or (5). A letter that is issued under this section is not considered discipline.” [MCL 333.16221b](#).

A. Web-based MAPS and EHR integration

In an effort to encourage use, the State has helped finance MAPS “integration,” such that MAPS data is displayed directly in a practice’s EHR. This saves providers the extra step of performing a web-based search outside the EHR. In an integrated system, the EHR also provides an audit trail showing that MAPS was checked by the provider for a particular patient. State funding is currently supporting integration, but eventually the provider or employer will be responsible to finance continued integration.²⁸

It is worth noting that the web-based version and the integrated version do not necessarily have the same data. Web-based MAPS receives data from 32 states/entities (as of September 2019); this data is available via agreement between Michigan and the participating states. In an integrated system, the individual practice must contract directly with the participating state and reach agreement on security protocols and other contractual elements. The law does not require a provider to search the web version; using integrated MAPS fulfills the obligation. However, providers with a concern about a patient’s history should use web-based MAPS to access the most complete information.

Michigan web-based MAPS participating states as of February 2020	
Alabama	Montana
Arizona	Nevada
Colorado	New Mexico
Connecticut	New York
Delaware	North Carolina
Florida	North Dakota
District of Columbia	Ohio
Illinois	Rhode Island
Indiana	South Carolina
Iowa	South Dakota
Kansas	Tennessee
Kentucky	Texas
Louisiana	VA
Maine	Virginia
Military Health System ²⁷	West Virginia
Minnesota	Wisconsin
Mississippi	

B. Delegation

It is permissible for a prescriber to delegate running a MAPS report to another individual, including office support staff. MAPS allows prescribers to name “delegates” within the MAPS system who are able to retrieve MAPS reports on behalf of their designated prescriber:

PMP AWARXE requires that every individual register as a separate user, using their email address as their username within the system. A user can register as a delegate, a role which is designed to allow the user to generate reports on the behalf of another current user. An example for a delegate role would be a nurse at a small doctor’s office. The nurse would act as a delegate to the physician to create Patient Rx reports for the patients that physician would be seeing that day.²⁹

The law does not specify whether the act of *reviewing* the MAPS report may be delegated under Michigan’s delegation statute. It is, however, LARA’s expectation that the prescriber will review the report. As stated in LARA’s FAQ, page 13, #9: “Please note it is important that the prescriber

reviews the MAPS report prior to prescribing or dispensing a schedule 2-5 controlled substance that exceeds a 3- day supply.”

C. Provider concerns about other providers’ prescribing practices

Since providers may now be more attuned to the prescribing practices of other providers, they may face more situations where they have a concern about another providers’ prescribing practices (whether internal to their practice or external). Low-level concerns are typically best handled by reaching out to the provider and expressing one’s reason for concern. More egregious situations may necessitate mandatory reporting to the relevant Board under various provisions of Michigan’s licensee/registrant reporting law ([MCL 333.16222](#); [MCL 333.16221](#)) such as violation of a general duty ([MCL 333.16221\(a\)](#)), violation of the Michigan Controlled Substances Law such that the prescriber is dispensing/prescribing/administering for other than a legitimate and professional recognized therapeutic or scientific purpose ([MCL 333.16221\(l\)](#)), or prescribing/administering for other than a lawful purpose ([MCL 333.16221\(c\)\(iv\)](#)).

Individuals authorized to receive MAPS data

[MCL 333.7333a\(2\), \(4\)](#)

- A designated representative of a board responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person that is authorized to prescribe, administer, or dispense controlled substances.
- An employee or agent of the Michigan Department of Health and Human Services.
- A state, federal, or municipal employee or agent whose duty is to enforce the laws of Michigan or the United States relating to drugs.
- A state-operated Medicaid program.
- A state, federal, or municipal employee who is the holder of a search warrant or subpoena properly issued for the records.
- A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.
- An individual with whom the Michigan Department of Health and Human Services has contracted with for the purpose of administering the MAPS program.
- A practitioner or other person that is authorized to prescribe controlled substances for the purpose of determining if prescriptions written by that practitioner or other person have been dispensed.
- The health care payment or benefit provider for the purposes of ensuring patient safety and investigating fraud and abuse.

D. Patient access to MAPS reports

As patients become increasingly aware of the existence of MAPS, they may ask their health care provider if they can have a copy of or view their MAPS report. The law surrounding MAPS is, however, an extremely restrictive law, and patients are not on the list of individuals authorized to access or receive a MAPS report. [MCL 333.7333a\(2\), \(4\)](#); [LARA FAQ, page 15, #18](#). The prescriber may, however, discuss what they find with the patient.

Given the strict confidentiality with which MAPS data must be kept, health care providers would be well-advised to limit their handling of a MAPS report to paraphrasing their findings within the patient's medical record. Electronically attaching a MAPS report, or copy/pasting a MAPS report into a medical record, should be avoided.

Note that [LARA FAQ, page 15, #20](#) seems to contradict this advice by stating that "MAPS users can maintain a MAPS report (HTML format)" in the medical record. The authors would nonetheless not recommend this approach since it would potentially provide other health care professionals, without a need to know, the ability to view the data. In addition, once MAPS data is replicated in the EHR, it is much more difficult to control future access (e.g., accidental disclosure when releasing medical records).

V. Prescribing limits for opioids used to treat acute pain

Opioid dependence can develop rapidly: the risk of persistent use increases sharply after just five days of opioid exposure.³⁰ In an effort to mitigate the risk associated with new persistent opioid use and transition to nonmedical opioid use, states have begun putting limits on the duration of opioid therapy for the treatment of acute pain—pain that is expected to be limited in duration. Over thirty states have implemented laws or guidelines setting limits on how providers can prescribe opioids³¹ and federal limits have been proposed.³² Some pharmacies³³ and insurance companies³⁴ also limit initial acute opioid prescriptions.

Michigan’s requirement states: “[I]f a 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.” [MCL 333.7333b\(1\)](#). Within this law, “acute pain” is defined as “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.” This definition is in contrast to standards set by common medical teaching and the position of the International Association for Study of Pain (IASP), which conceptualizes acute pain as pain that lasts for no more than three months, and classifies pain lasting beyond three months as chronic pain.

One of the key points related to this new requirement is that of patient communication and education. Many patients who have historically undergone procedures were prescribed an excessive quantity of opioids, such as an immediate 30-day supply. Receiving only a 7-day supply will come as a shock, and should be discussed early. Although many providers agree with a limit, there are also multiple operational issues. Some states, for example, have a 5-day limit, which can be a problem for Thursday surgeries going into a holiday weekend.

A. Applicability and best practice expansion to the inpatient setting

The law only addresses “prescribing,” indicating it is only applicable in an outpatient setting. The inpatient setting is not referenced at all within the law. Nonetheless, some providers have adopted the 7-day limit in the inpatient setting as well, as a best practice.

B. New acute pain versus exacerbation of a chronic condition

Michigan’s law allows for some provider latitude in determining whether pain is “acute” and the 7-day limit is triggered. For example, consider a patient with a history of metastatic cancer who has been on a long-acting opioid like MS Contin, but who now has acute pain from a new lesion and requires a short-acting opioid for acute pain, like Norco. The pain stems from an acute exacerbation, but the underlying problem (metastatic cancer) is a chronic one. If the pain is conceptualized as stemming from the new lesion, and considered a new acute pain episode, the provider would need to:

1. Limit the new opioid (Norco) to a 7-day supply

2. Provide education on opioids and have the patient sign a “Start Talking” form (even though the patient was already on an opioid)
3. Provide a follow up appointment for monitoring the effects of the Norco
4. Check MAPS

If the pain is conceptualized as stemming from the underlying chronic metastatic cancer diagnosis, none of the above requirements are triggered. Thus, it is sometimes left to the provider’s judgement whether to use the underlying chronic diagnosis to avoid the 7-day prescribing limit, and other requirements.

C. Refills

Notably, although there is a 7-day limit, refills (also of a 7-day duration) may be provided, so long as the other legal requirements are met: (1) there is a bona fide relationship, and (2) MAPS is checked. Many surgical procedures require ongoing opioid therapy for recovery. A typical total knee arthroplasty (knee replacement), for example, may require weeks of opioids to facilitate physical therapy. It is still up to the provider’s judgment to determine when the acute pain should subside and no further refills of opioid should be provided.

VI. Patients' ability to preemptively decline opioids: the nonopioid directive

In 2019, Michigan joined a number of states in giving patients greater control over their exposure to opioids via recognition of a “nonopioid directive” preemptively allowing patients to decline prescription opioids, as set forth in [MCL 333.9145](#) (see **Exhibit 2**). An patient’s guardian or patient advocate may also execute a nonopioid directive on that patient’s behalf.³⁵ Individuals who execute such a directive may be at risk of substance use disorder, recovering from substance use disorder, or simply wish to avoid the risks attendant with opioid use.³⁶

There is no requirement that a health care provider provide the form to a patient, nor ask patients if they have executed the form. Instead, if a patient proactively provides a nonopioid directive to their health care provider, the law requires it be made a part of the individual’s medical record and the health care provider must not (1) administer, or (2) offer a prescription for, an opioid.

MDHHS has made a sample nonopioid directive available on its website,³⁷ though its use is not mandatory. A nonopioid directive may also be incorporated into existing patient forms/documentation already in use.

A. Exceptions

There are several important exceptions, or situations when a patient’s valid nonopioid directive need not be followed:

1. Opioids provided to hospice patients
2. Opioids provided to substance use disorder patients
3. Opioids deemed medically necessary within the hospital, or in an emergency situation outside of a hospital:

[T]he individual is being treated at a hospital or in a setting outside of a hospital in the case of an emergency and, in the prescriber’s professional opinion, the administration of the opioid is medically necessary to treat the individual.³⁸

This last exception recognizes that opioids are almost always medically necessary for large surgical procedures. For example, a remifentanyl infusion (an opioid) prevents coughing in a patient waking up from a neck exploration or aneurysm clipping where the sudden increase in pressure in a fragile vascular tissue could result in life-threatening bleed. In cases where a patient has a nonopioid directive on file and is undergoing a procedure for which an opioid will likely be medically necessary, the provider should have a conversation with the patient about the patient’s wishes and the fact that an opioid may nonetheless be required. That conversation should be documented in the medical record. Importantly, if exception (3) is relied on, the prescriber must provide the patient with information on substance use disorder services.³⁹

B. Revocation of the nonopioid directive

A nonopioid directive may be revoked by the individual “at any time and in any manner by which he or she is able to communicate his or her intent to revoke the form.”⁴⁰ Operationally, this can be difficult to manage, since even a verbal revocation is valid and must be documented, as well as potentially communicated to other health care providers.

If a guardian or Patient Advocate signed the nonopioid directive, they must revoke it by providing notice in writing to the individual’s health care professional.⁴¹

C. Liability limitation

Health care providers acting within their scope of practice (and their employees), health facilities and agencies (and their employees), and emergency medical services personnel are largely protected from liability:

Except as otherwise provided by law, the following are not subject to civil or criminal liability or professional disciplinary action for failing to administer, prescribe, or dispense an opioid, or for the inadvertent administration of an opioid, to an individual who has executed a nonopioid directive form or who has had a nonopioid directive form executed on his or her behalf, if the failure to act or act was done reasonably and in good faith. [MCL 333.9145\(4\)](#).

VII. Provider training on the risks of opioids and controlled substances

One of the latest new rules requires anyone holding a Michigan Board of Pharmacy Controlled Substance license to prescribe or dispense controlled substances (or seeking such licensure), and any nurses who prescribes, dispenses, or administers, must complete a one-time training on “opioids and controlled substances awareness.” [Rule 338.3135\(1\)](#). This requirement seeks to ensure that anyone who prescribes, dispenses, or administers⁴² controlled substances has a minimum level of education specifically on the opioid crisis and the use and abuse of controlled substances.⁴³ The rule is effective for initial licenses issued after 9/1/19 and for renewals beginning with the first cycle after 1/4/19. Although no sanctions are stated, the rule provides that the state may audit, and acceptable proof of training is either (1) a completion certificate, or (2) a self-attestation. [Rule 338.3135\(4\)](#).

A. Applicability

Although subsection (1) states applicability is for those licensed (or seeking license) to prescribe or dispense, subsection (2) notes that a prescriber or dispenser cannot delegate or order prescribing, dispensing, or administering to a nurse unless the nurse has also complied with the rule. Thus, nurses must also comply—whether they are acting under delegated authority or are acting pursuant to an order. The underlying rationale for this requirement is likely a desire for anyone who is involved in the provision of an opioid or controlled substance to know the dangers involved.

B. Training contents, form, and venue

The contents of the training, which may be by live presentation, online presentation, teleconference/webinar, or printed/electronic media, must include the following:

- Use of opioids and other controlled substances
- Integration of treatments
- Alternative treatments for pain management
- Counseling patients on the effects and risks associated with using opioids and other controlled substances
- The stigma of addiction
- Utilizing the Michigan Automated Prescription System (MAPS)
- State and federal laws regarding prescribing and dispensing controlled substances
- Security features and proper disposal requirements for prescriptions. [Rules 338.3135\(1\)\(c\); 338.3135\(1\)\(a\)](#)

Training can be provided by the following:

- Training offered by a nationally recognized or state recognized health related organization
- Training offered by, or in conjunction with, a state or federal agency

- Training offered by a continuing education program or activity that is accepted by a licensing board established under article 15 of the act
- Training obtained in an educational program that has been approved by a board established under article 15 of the act for initial licensure or registration, or by a college or university. [Rule 338.3135\(1\)\(d\)](#)

VIII. Resources

Michigan.gov, Opioid Addiction Resources, <https://www.michigan.gov/opioids>

Michigan Department of Health and Human Services, Behavioral Health Recovery and Substance Use, https://www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_79584---_00.html

Michigan Department of Licensing and Regulatory Affairs, Board of Pharmacy, Administrative Rules, Controlled Substance Rules, https://dtmb.state.mi.us/ARS_Public/AdminCode/DownloadAdminCodeFile?FileName=R%20338.3101%20to%20R%20338.3199q.pdf.

Michigan Department of Licensing and Regulatory Affairs, FAQs, https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf (March 6, 2019 version)

Michigan Health & Hospital Association, Opioid and Prescription Drug Epidemic, <https://www.mha.org/Issues-Advocacy/Opioid-Epidemic>

Michigan Senate Fiscal Agency, Issue Paper, An Overview of Michigan's Efforts in Combating the Opioid Epidemic, April 2019, <http://www.senate.michigan.gov/sfa/Publications/Publications.html>

Table 1: Michigan legislation in response to the opioid epidemic

Summary	Description	Public Act	Statute	Admin. Rule	Effective Date
Overdose rescue drugs	Authorizes a prescriber to issue, and a dispensing prescriber or pharmacist to dispense, an opioid antagonist to an individual at risk for an opioid-related overdose; a family member, friend, other individual	Act 311 of 2014	Amended: MCL 333.1106 , 333.17745 , 333.17751 , 333.17754 , 333.17757 Added: MCL 333.7421 , 333.17744b	N/A	10/14/2014
Overdose rescue drugs	Certain first responders must be trained to administer opioid antagonists and be equipped with opioid antagonists	Act 312 of 2014	Amended: MCL 333.20919 , 333.20965	N/A	10/14/2014
Overdose rescue drugs	Provides civil liability protection to an individual administering an opioid antagonist in good faith under the State's Good Samaritan Law.	Act 313 of 2014	Added: MCL 333.7422 , 333.17744c	N/A	10/14/2014
Overdose rescue drugs	Authorized the Chief Medical Executive of the State to issue a statewide standing order for opioid antagonist	Act 383 of 2016	Added: MCL 333.17744e	N/A	3/28/2017

Summary	Description	Public Act	Statute	Admin. Rule	Effective Date
Overdose rescue drugs	Permits state and local law enforcement agencies to purchase opioid antagonists and distribute them to their officers.	Act 462 of 2014	Added: MCL 28.541 , 28.542 , 28.543 , 28.544	N/A	1/12/2015
Providers must educate patients on the dangers of opioids	Education requirements and the “Start Talking” form	Act 246 of 2017	Added: MCL 333.7303(b) ; 333.7303(c)	N/A	12/27/2017
Providers must have a bona fide relationship with patients before prescribing an opioid	Bona Fide Relationship and Follow-Up	Act 247 of 2017	Amended: MCL 333.7303a	Rule 338.3161a	12/27/2017
Providers who prescribe a S2-5 controlled substance must consult MAPS	Mandatory use of Michigan’s prescription drug monitoring program: Michigan Automated Prescription System (MAPS)	Act 248 of 2017	Amended: MCL 333.7303a	N/A	6/1/2018
N/A	Cleaned up conflicts amongst other bills; revised sanctions for certain violations	Act 249 of 2017	Amended: MCL 333.7303a , 333.16221 , 333.16226 , and 333.16231 Added: MCL 333.16221b	N/A	12/27/2017

Summary	Description	Public Act	Statute	Admin. Rule	Effective Date
Overdose patients must receive SUD information	Provided patients being treated for opioid-related overdose with information regarding Substance Use Disorder services	Act 250 of 2017	Added: MCL 333.16282	N/A	3/27/2018
Opioid prescribing limit	Prescribing limits if prescribing an opioid for acute pain	Act 251 of 2017	Added: MCL 333.7333b	N/A	3/27/2018
Mandatory use of MAPS	Requires prescribers to obtain and review a MAPS report for a patient before prescribing of dispensing buprenorphine, a drug containing buprenorphine, or methadone to a patient in a substance disorder program.	Act 252 of 2017	Amended: MCL 333.7333a	N/A	3/27/2018
Michigan Medicaid's coverage of detox programs	Amends the Social Welfare Act to provide that an eligible individual can receive medically necessary treatment for opioid abuse. The bill codifies coverage by Michigan's Medicaid program for detox programs.	Act 253 of 2017	Amended: MCL 400.109	N/A	3/27/2018
Created a nonopioid directive, allowing patients to preemptively decline opioids	Nonopioid directive	Act 554 of 2018	MCL 333.9145	N/A	3/28/2019

Summary	Description	Public Act	Statute	Admin. Rule	Effective Date
Mandatory training requirements	Controlled substances/opioids awareness training for Michigan Board of Pharmacy Controlled Substance Licensees and their delegates	N/A	N/A	Rule 338.3135(1)	New licensees: 9/1/2019 Renewals: First renewal cycle after 1/4/2019

Exhibit 1

OPIOID START TALKING (MUST BE INCLUDED IN THE PATIENT'S MEDICAL RECORD) Michigan Department of Health and Human Services

Patient Name		Date of Birth	
Name of Controlled Substance containing an Opioid			
Dosage	Quantity Prescribed (For a minor, if signature is not the parent or guardian, the prescriber must limit the opioid to a single, 72 hour supply)		
Number of refills			
<p>A controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse. My provider shared the following:</p> <ul style="list-style-type: none"> a. The risks of substance use disorder and overdose associated with the controlled substance containing an opioid. b. Individuals with mental illness and substance use disorders may have an increased risk of addiction to a controlled substance. (Required only for minors.) c. Mixing opioids with benzodiazepines, alcohol, muscle relaxers, or any other drug that may depress the central nervous system can cause serious health risks, including death or disability. (Required only for minors.) d. For a female who is pregnant or is of reproductive age, the heightened risk of short and long-term effects of opioids, including but not limited to neonatal abstinence syndrome. e. Any other information necessary for patients to use the drug safely and effectively as found in the patient counseling information section of the labeling for the controlled substance. f. Safe disposal of opioids has shown to reduce injury and death in family members. Proper disposal of expired, unused or unwanted controlled substances may be done through community take-back programs, local pharmacies, or local law enforcement agencies. Information on where to return your prescription drugs can be found at http://www.michigan.gov/deqdrugdisposal. g. It is a felony to illegally deliver, distribute or share a controlled substance without a prescription properly issued by a licensed health care prescriber. 			
<p>I acknowledge the potential benefits and risks of an opioid medication as described by my provider along with the responsibility of properly managing my medication as stated above.</p>			
Signature of Prescriber (when prescribing to a minor)		Date	
Signature of Patient, if a minor, patient's parent/guardian		Date	
Signature of Patient's Representative or other authorized adult		Date	
Printed Name of Parent/Guardian; Patient's Representative or other authorized adult			

<p>The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.</p>	<p>AUTHORITY: PCA 246 of 2017, MCL 333.7303b and MCL 333.7303c COMPLETION: Required. PENALTY: Probation, limitation, denial, fine, suspension, revocation or permanent revocation.</p>
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Exhibit 2

NONOPIOID DIRECTIVE

Michigan Department of Health and Human Services
Required by MCL 333.9145 effective 3/28/2019

MUST BE INCLUDED IN THE PATIENT'S MEDICAL RECORD

Patient Name	Date of Birth
Other names used by patient	Preferred language of patient
Emergency Contact	Name of primary care provider
Drug allergies	
<p>The patient above must not be administered an opioid or offered a prescription for an opioid while this directive is in effect.</p> <ul style="list-style-type: none"> • An individual who has executed a nonopioid directive on their own behalf may revoke the directive at any time and in any way they are able to communicate their intent to revoke the form. • A guardian or patient's advocate can revoke at any time by issuing a revocation in writing and providing notice of the revocation to the individual's health professional or their delegate. • This directive does not apply to: <ul style="list-style-type: none"> •• A patient receiving opioids for substance use disorder treatment; •• A patient who is in hospice; •• A patient is being treated at a hospital, or in a setting outside of a hospital in the case of an emergency, and, in the prescriber's professional opinion, the administration of the opioid is medically necessary to treat the individual. 	
Signature of patient, or if the patient is a minor, parent	Date
Printed name of Patient	Date
Signature of guardian or patient's advocate, if applicable	Date
Printed name of parent/guardian/patient's advocate, if applicable	Date
<p>The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.</p>	

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¹ National Safety Council, *What Are the Odds of Dying From*, <<https://www.nsc.org/work-safety/tools-resources/injury-facts/chart>> (accessed Jan. 29, 2020).

² Michigan Senate Fiscal Agency, *Issue Paper, An Overview of Michigan's Efforts in Combating the Opioid Epidemic* (April 2019), available at <<http://www.senate.michigan.gov/sfa/Publications/Publications.html>> [at the time of publication, the article is accessible by selecting "Most recent issue" under the "Issue Papers" heading] (accessed Jan. 29, 2020).

³ DrugStrategies and Shatterproof, *The Fentanyl Epidemic: State Initiatives to Reduce Overdose Deaths* (2019) <<https://www.shatterproof.org/fentanyl-epidemic>> (accessed Jan. 29, 2020).

⁴ Kolodny et al. [The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction](#), 36:1 Annual Rev. of Public Health 559 (2015).

⁵ U.S. Dep't of Justice, *DEA Heads First-ever Nationwide Prescription Drug Take-back Day* (Aug. 19, 2010) <<https://www.justice.gov/opa/pr/dea-heads-first-ever-nationwide-prescription-drug-take-back-day>> (accessed Dec. 10, 2019).

⁶ Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011) <https://obamawhitehouse.archives.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf> (accessed Jan. 29, 2020).

⁷ Guy et al. [Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015](#), 66(26) MMWR Morb. Mortal. Wkly Rep. 697 (2017).

⁸ Beauchamp et al. [Moving Beyond Misuse and Diversion: The Urgent Need to Consider the Role of Iatrogenic Addiction in the Current Opioid Epidemic](#), 104(11) Am. J. of Pub. Health 2023 (2014).

⁹ Johnson et al. [Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008–2009](#), 28 J. Gen. Intern. Med. 522 (2013).

¹⁰ Alam et al. [Long-term analgesic use after low-risk surgery: a retrospective cohort study](#), 172(5) Arch. Intern. Med. 425 (2012).

¹¹ The "Start Talking" form is also available by visiting the [MDHHS Office of Recovery Oriented Systems of Care website](#), and clicking the "Prescribers" tab.

¹² See the legislative history, available at <http://legislature.mi.gov/doc.aspx?2017-HB-4408>.

¹³ For example, in the adult’s statute, “patient’s representative” is defined as “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.” [MCL 333.7303c\(4\)\(c\)](#).

¹⁴ Administer is defined as “the direct application of a controlled substance, whether by injection, inhalation, ingestion, or other means, to the body of a patient[.]” [MCL 333.7103\(1\)](#).

¹⁵ Safeer RS, Keenan J. [Health Literacy: The Gap Between Physicians and Patients](#), 1:72(3) Am Fam Physician 463 (2005).

¹⁶ The Network for Public Health Law, Michigan Laws Related to Right of a Minor to Obtain Health Care without Consent or Knowledge of Parents (2016) <<https://www.networkforphl.org/asset/d40g3d/Minors-Health-Privacy-Michigan.pdf>> (accessed Jan. 29, 2020).

¹⁷ Emancipation of Minors Act, [MCL 722.1 –722.6](#).

¹⁸ LARA/MDHHS, *Michigan Opioid Laws Frequently Asked Questions* (Mar. 6 2019), <https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf> (accessed Jan. 29, 2020).

¹⁹ Drug Enforcement Administration, *COVID-19 Information Page* <<https://www.deadiversion.usdoj.gov/coronavirus.html#TELE>> (accessed May 26, 2020).

²⁰ Michigan Executive Order 2020-86, Encouraging the use of telehealth services during the COVID-19 emergency (May 15, 2020), <https://www.michigan.gov/whitmer/0,9309,7-387-90499_90705-529458--,00.html> (accessed May 26, 2020).

²¹ Sansone RA, Sansone LA. [Doctor shopping: a phenomenon of many themes](#). 9(11-12) Innov. Clin. Neurosci. 42 (2012).

²² Associated Press, Michigan doctor gets over 11 years in prison for \$18 million opioid scheme (Apr. 18, 2019), <<https://www.wlns.com/news/michigan/michigan-doctor-gets-over-11-years-in-prison-for-18-million-opioid-scheme/>> (accessed Jan. 29, 2020).

²³ See the legislative history, available at <http://legislature.mi.gov/doc.aspx?2017-SB-0270>; https://dmbinternet.state.mi.us/DMB/ORRDocs/RIS/1801_2018-020LR_ris.pdf.

²⁴ National Alliance for Model State Drug Laws, *Prescription Drug Monitoring Programs*, <<https://namsdl.org/topics/pdmp/>> (accessed Jan. 29, 2020).

²⁵ Dispense means “to deliver or issue a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, or compounding necessary to prepare the substance for the delivery or issuance.” [MCL 333.7105\(3\)](#).

²⁶ Appriss Health, *State of Michigan to Fully Integrate Michigan Automated Prescription System (MAPS) Into Hospitals, Physician Groups and Pharmacies Across the State with Appriss Health’s PMP Gateway Solution* (Press Release) (June 19, 2017) <<https://apprisshealth.com/press-release/state-michigan-fully-integrate-michigan-automated-prescription-system-maps-hospitals-physician-groups-pharmacies-across-state-appriss-healths-pmp-gateway-solution/>> (accessed Jan. 29, 2020); Michigan Department of Licensing and Regulatory Affairs, MAPS Users <https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_55478_85993---,00.html> (accessed Jan. 29, 2020).

²⁷ Military Health System is a separate entity from the Office of Veteran’s Affairs.

²⁸ Michigan Health and Hospital Association, *MDHHS: State departments leverage \$1 million in federal funds to advance patient care improvements, continue health systems integrations* (Sept. 17, 2019) <<https://www.mha.org/Newsroom/ID/2119/MDHHS-State-departments-leverage-1-million-in-federal-funds-to-advance-patient-care-improvements-continue-health-systems-integrations>> (accessed Jan. 29, 2020).

²⁹ Michigan Department of Licensing and Regulatory Affairs and PMP Aware, *Michigan Automated Prescription System (MAPS) User Support Manual*, <https://www.michigan.gov/documents/lara/2b-Michigan_PMP_AWARxE_Requestor_User_Support_Manual_556541_7.pdf> (accessed Jan. 29, 2020).

³⁰ Shah et al, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. 66(10) MMWR Morb. Mortal. Wkly Rep. 265 (2017).

³¹ National Conference of State Legislatures, *Prescribing Policies: States Confront Opioid Overdose Epidemic* (June 30, 2019) <<http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx>> (accessed Jan. 29, 2020).

³² See, for example, the John S. McCain Opioid Addiction Prevention Act (S. 724/H.R. 1614), which would limit a patient’s first opioid prescription for acute pain to seven days.

³³ See, for example, the Walmart Opioid Stewardship Initiative, under which Walmart and Sam’s Club pharmacies limit a patient’s first opioid prescription for acute pain to seven days, available at <https://corporate.walmart.com/stewardship>.

³⁴Kacik A, *Blue Cross and Blue Shield discourages using opioids as primary pain treatment*, Modern Healthcare (Mar. 29, 2018), <https://www.modernhealthcare.com/article/20180329/TRANSFORMATION03/180329896/blue-cross-and-blue-shield-discourages-using-opioids-as-primary-pain-treatment> (accessed Jan. 29, 2020).

³⁵ [MCL 333.9145\(2\)](#).

³⁶ Samuels DJ, Enrico M, [Do Not Opiate! Anesthesiologists Must Be Prepared to Care for Patients Who Sign a "Nonopioid Directive"](#) 127(1) *Anesthesia & Analgesia*. 318-319 (July 2018).

³⁷ MDHHS, *Nonopioid Directive* (March 2018), https://www.michigan.gov/documents/opioids/MDHHS-5793_650584_7.dotx (accessed Jan. 29, 2020).

³⁸ [MCL 333.9145\(3\)](#).

³⁹ Substance use disorder services is defined as substance use disorder prevention services and substance use disorder treatment and rehabilitation services as defined in MCL 330.1100d, which includes “services that are 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. Substance use disorder prevention is an ordered set of steps that promotes individual, family, and community health, prevents mental and behavioral disorders, supports resilience and recovery, and reinforces treatment principles to prevent relapse.” [MCL 330.1100d\(12\)](#). Substance use disorder treatment and rehabilitation services include “identifiable recovery-oriented services” such as early intervention/crisis intervention counseling or planned treatment. [MCL 330.1100d\(13\)](#).

⁴⁰ [MCL 333.9145\(2\)](#).

⁴¹ [MCL 333.9145\(2\)](#).

⁴² Subsection (1) states applicability is for those who prescribe or dispense, but subsection (2) notes that a prescriber / dispenser cannot delegate or order the act of prescribing, dispensing, or administering by a nurse unless the nurse has also complied with the rule.

⁴³ State of Michigan, State Budget Office, Office of Regulatory Reinvention, *Regulatory Impact Statement and Cost-Benefit Analysis (RISCBA)*, Proposed rules for Board of Pharmacy Controlled Substance Rules, 2018-020 LR (Jan. 4, 2018), https://dmbinternet.state.mi.us/DMB/ORRDocs/RIS/1801_2018-020LR_ris.pdf (accessed Jan. 29, 2020).