Frequently Asked Questions (FAQs)

### Updated on March 6, 2019

This FAQs has been drafted by the Department of Licensing and Regulatory Affairs (LARA) and the Michigan Department of Health and Human Services (DHHS) to provide some clarification to help with implementation of the Michigan Opioid Laws. The answers to the frequently asked questions are not to be considered as legal advice.

# **Overview of the Public Acts**

In December of 2017, legislation was enacted to curb Michigan's persistent and increasing substance abuse and drug diversion problem. The 10-bill package represents a comprehensive approach to addressing the abuse and diversion issue, and encompasses the following laws:

| Provisions   |
|--|
| <ul> <li>Beginning June 1, 2018, a prescriber shall comply with the following before issuing a new prescription for a controlled substance containing an opioid to a minor:         <ul> <li>Discuss with the minor and the minor's parent or guardian the potential risks of addiction and overdose associated with the controlled substance.</li> <li>Discuss the increased risk of addiction to a controlled substance to an individual suffering from both mental and substance abuse disorders.</li> <li>Discuss the danger of taking a controlled substance containing an opioid with benzodiazepine, alcohol, or another central nervous system depressant.</li> <li>Discuss any other information in the patient counseling information section of the label for the prescription.</li> </ul> </li> <li>The signature of the minor's parent or guardian to consent to the minor's treatment is required on a "start talking consent form", which is to be filed in the minor's medical record.         <ul> <li>The form is to contain the signatures of the parties involved, information on the name and quantity of the controlled substance, acknowledgement that the drug has potential for abuse, and a statement certifying that the prescriber discussed with the minor and the minor's guardian the potential risks of the drug.</li> </ul> </li> <li>If the adult signing the consent form is not the parent or guardian, the prescriber shall not prescribe more than a single 72-hour supply of the controlled substance to the minor.</li> <li>Exceptions to the above requirements exist in the case of emergency, if it is detrimental to the minor's health, certain surgical circumstances, in</li> </ul> |
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- Beginning <u>June 1, 2018</u>, before an opioid is prescribed to a patient, a prescriber shall provide the following information:
  - o The dangers of opioid addiction.
  - How to properly dispose of an expired, unused, or unwanted controlled substance.
  - That the delivery of a controlled substance is a felonyunder 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 an opioid, including but not limited to neonatal abstinence syndrome.
  - After providing the information described above, the prescriber shall obtain the signature of the patient or the patient's representative on a start talking consent form as described by section (4) of PA 246 of 2017 The signed form shall be kept in the patient's medical record.
    - The requirement does not apply if the controlled substance is prescribed for inpatient use.
- Finally, the legislation provides sanctions for prescribers for failing to inform minors and their guardians of the risks of opioid abuse.
- A sample form can be found on the DHHS website, under the Prescribers Section: www.michigan.gov/stopoverdoses.

#### Public Act 247 of 2017

- Pursuant to <u>Public Act 101 of 2018</u>, except as otherwise provided by below, beginning <u>January 4, 2018</u>, a licensed prescriber shall not prescribe a controlled substance listed in Schedules 2-5 unless the prescriber has established a bona fide prescriber-patient relationship with the patient.
  - A licensed prescriber may prescribe a Schedule 2-5 controlled substance without first establishing a bona fide prescriberpatient relationship in the following circumstances:
    - The prescriber is providing on-call coverage or cross-coverage for another prescriber who is not available and has established a bona fide prescriber-patient relationship with the patient for whom the on-call or covering prescriber is prescribing the controlled substance. The prescriber, or an individual licensed under Article 15 of the Public Health Code, must review the patient's relevant medical or clinical records, medical history, and any change in medical condition, as well as provide documentation in the patient's medical record in accordance with medically accepted standards of care.
    - The prescriber is following or modifying the orders of a prescriber who has established a bona fide prescriberpatient relationship with a hospital in-patient, hospice patient, or nursing care facility resident, and provides documentation in the patient's medical record in accordance with medically accepted standards of care.
    - The prescriber is prescribing for a patient that has been





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admitted to a licensed nursing care facility or a hospice, meets the requirements of a bona fide prescriber-patient relationship, in compliance with R 325.20602 or R 325.13302, and provides documentation in the patient's medical record in accordance with medically accepted standards of care.

- The prescriber is prescribing for a patient for whom the tasks of reviewing the patient's medical history and current medical condition, including a relevant medical evaluation of the patient, and the creation and maintaining of records of the patient's condition, have been performed by an individual licensed under Article 15 of the Public Health Code, and the prescriber provides documentation in the patient's medical record in accordance with medically accepted standards of care.
- The prescriber is treating a patient in a medical emergency. Medical emergency is defined as a situation that, in the prescriber's good-faith professional judgement, creates an immediate threat of serious risk to the life or health of the patient for whom the controlled substance prescription is being prescribed.
- If the prescriber provides a controlled substance, the prescriber shall
  provide follow-up care to the patient to monitor the efficacy of the use
  of the controlled substance as a treatment of the patient's medical
  condition.
- If the prescriber is unable to provide follow-up care, they shall refer the patient to the patient's primary care provider for follow-up care, or if a primary care provider does not exist, another licensed prescriber who is geographically accessible to the patient.
- The legislation defines a bona fide prescriber-patient relationship as treatment or a counseling relationship between a prescriber and a patient in which both of the following are present:
  - The prescriber has reviewed the patient's medical or clinical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant medical evaluation of the patient conducted in person or via telehealth.





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|                        | <ul> <li>The prescriber has created and maintained records of the patient's condition in accordance with medically accepted standards.</li> <li>By December 27, 2018, LARA, in consultation with the Michigan Boards of Medicine, Osteopathic Medicine and Surgery, Dentistry, Podiatric Medicine, Optometry, Nursing, and the Michigan Task Force on Physician Assistants, may promulgate rules describing circumstances under which a bona fide prescriber-patient relationship is not required for purposes of prescribing a Schedule 2 to 5 controlled substance. The rules may also include an alternative requirement for prescribing a Schedule 2 to 5 controlled substance when a bona fide prescriber-patient relationship is not required by the rules promulgated above. The contents of these rules are provided above.</li> <li>Finally, the legislation provides terms for sanction for violating the bona fide relationship requirements.</li> </ul>  |
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|                        | fide relationship requirements.  |
| Public Act 248 of 2017 | <ul> <li>Beginning June 1, 2018, before prescribing or dispensing to a patienta controlled substance in a quantity that exceeds a 3-day supply, a licensed prescriber shall obtain and review a MAPS report concerning that patient. The requirement does not apply in any of the following circumstances:         <ul> <li>If the dispensing occurs in a hospital or a freestanding surgical outpatient facility and the controlled substance is administered to the patient in the hospital or facility.</li> <li>If the patient is an animal, the dispensing occurs in a veterinary hospital or clinic, and the controlled substance is administered to the animal in that hospital or clinic.</li> <li>If the controlled substance is prescribed by a licensed prescriber who is a veterinarian and the controlled substance will be dispensed by a pharmacist.</li> </ul> </li> <li>Beginning June 1, 2018, before prescribing or dispensing a controlled substance to a patient, a licensed prescriber shall registerwith MAPS.</li> </ul> |
| Public Act 249 of 2017 |  |
| Fublic Act 249 Of 2017 | <ul> <li>Contains many of the provisions of the other bills, as it is being used as a vehicle to correct conflicts in statute created by the package of bills being passed.         <ul> <li>The bill contains the bona fide prescriber-patient relationship language of SB 270.</li> <li>The bill contains the MAPS report review language for prescribers contained in SB 166, as well as SB 166's language regarding mandatory registration with MAPS for prescribers.</li> </ul> </li> <li>Provides penalties for violation of the following:         <ul> <li>Beginning March 31, 2019 (or if rules are promulgated before then for alternatives to the bona fide relationship, the date on which rules are promulgated), prescribers failing to adhere to the bona fide prescriber-patient relationship requirements.</li> <li>Beginning June 1, 2018, prescribers failing to obtain and review</li> </ul> </li> </ul>   |





a MAPS report, when required, prior to prescribing or dispensing

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| Public Act 250 of 2017        | to a patient a controlled substance in a quantity that exceeds a 3-day supply.  Beginning June 1, 2018, prescribers failing to register with MAPS prior to prescribing or dispensing a controlled substance to a patient.  Beginning June 1, 2018, prescribers failing to provide minors, and their parents or guardians, with proper education regarding the risks of opioid abuse.  Beginning June 1, 2018, if the department has a reasonable basis to believe that a prescriber has failed to obtain and review a MAPS report before prescribing or dispensing to a patient a controlled substance in a quantity that exceeds a 3-day supply, or if the department has a reasonable basis to believe that before prescribing or dispensing a controlled substance to a patient a licensed prescriber has failed to register with MAPS, the department is not required to conduct an investigation and may issue a letter to the licensee notifying the licensee that he or she may be in violation of statute. A letter issued under this section is not considered a disciplinary action. |
|-------------------------------|--|
| <u>Public Act 250 of 2017</u> | Requires a health professional licensee or registrant that treats a patient  |
|                               | for an opioid-related overdose to provide that patient with information  |
|                               | regarding Substance Use Disorder Services.   |
|                               | For resources and additional information go to the DHHS website:   |
|                               | www.michigan.gov/stopoverdoses.  |
| B. I.B. A. LOTA COST          | Effective March 27, 2018.  |
| Public Act 251 of 2017        | <ul> <li>Beginning July 1, 2018, if a prescriber is treating a patient for acute pain, that the prescriber shall not prescribe the patient more than a 7-day supply of an opioid within a 7-day period.</li> <li>Beginning March 27, 2018, a pharmacist, consistent with federal lawand regulations on the partial filling of a controlled substance included in Schedule 2, may partially fill in increments, a prescription for a controlled substance included in Schedule 2.</li> </ul>  |
| Public Act 252 of 2017        | <ul> <li>Adds the dispensing of a controlled substance at a veterinary hospital or clinic that administers the controlled substance to an animal that is an inpatient, to the following list of exemptions for MAPS reporting requirements:         <ul> <li>A hospital.</li> <li>A health facility or agency if the controlled substance is dispensed by a dispensing prescriber in a quantity adequate to treat the patient for not more than 48 hours.</li> </ul> </li> <li>Provides that before dispensing or prescribing buprenorphine or a drug containing buprenorphine or methadone to a patient in a substance disorder program, the prescriber shall obtain and review a MAPS report on the patient.</li> <li>A prescriber shall report data to MAPS if federal law does not prohibit the reporting of data concerning the patient, to LARA.</li> </ul>  |





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|                        | <ul> <li>R 338.3162E is rescinded from the pharmacy rules, and deals with exemptions to MAPS reporting requirements.</li> <li>Effective March 27, 2018</li> </ul>   |
|------------------------|---|
| Public Act 253 of 2017 | <ul> <li>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.</li> <li>Effective March 27, 2018.</li> </ul>   |
| Public Act 254 of 2017 | Requires PDOAC, by <u>July 1, 2018</u> , to develop or adopt for the Department of Education, recommendations for the instruction of pupils on the dangers of prescription opioid drug abuse.   |
| Public Act 255 of 2017 | <ul> <li>By <u>July 1, 2019</u>, the Department of Education shall make available to school districts the model program of instruction on the dangers of prescription opioid drug abuse, developed or adopted by the Prescription Drug and Opioid Abuse Commission (PDOAC).</li> <li>Beginning in the <u>2019-2020 School Year</u>, the Department of Education shall ensure that the state model of academic standards for health education includes instruction on prescription opioid drug abuse, including at least the PDOAC recommendations.</li> </ul> |

### **FAQs Section**

### Public Act 246 of 2017 – Start Talking Form:

- 1. Will a form be developed to provide guidance on compliance for the new opioid education requirements related to implementing the Start Talking Form, and opioid disclosure form, required by Public Act 246 of 2017?
  - a. The Department of Health and Human Services (DHHS) and Licensing and Regulatory Affairs (LARA) worked with various health care providers and stakeholders in developing a single page form that can be used to meet the requirements of this new law. This new form can be found under the "Prescribers" tab at the DHHS website: <a href="https://www.michigan.gov/stopoverdoses">www.michigan.gov/stopoverdoses</a>.
- 2. Is a provider required to use the state's form?
  - a. No, but the provider will have to use a similar form that is saved to the patient's medical record and complies with the requirements of Public Act 246 of 2017.
- 3. Can a provider use the state's form as a template and create a form that can be used electronically?
  - a. Yes, however both DHHS and LARA recommend that a provider reach out to their legal counsel and/or health care association to make sure the form meets the requirements of the law.





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### 4. Will the state's form be in other languages?

a. Yes, in addition to English, the form will be available in Spanish and Arabic.

# 5. Can a prescriber delegate the task of providing a patient with the opioid education requirements of Public Act 246 of 2017 to another health professional?

- a. Pursuant to MCL 333.16215 a prescriber 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.
- b. Please note that not all prescribers as defined under the Public Health Code have the ability to delegate under the delegation provision of MCL 333.16215.
- c. Licensees holding a health profession subfield license should note, MCL 333.7303c provides statutory authority for another licensed health professional to provide a patient with the opioid education requirements of MCL 333.7303c. However, please be aware that this same statutory authority does not exist in MCL 333.7303b, for prescribing situations involving minors.

# 6. Can a prescriber delegate to another licensed health professional the signing of the form on behalf of the licensed prescriber at the point of discharge of the patient?

- a. Yes. Pursuant to MCL 333.16215 this is allowed.
- b. Please note that not all prescribers as defined under the Public Health Code have the ability to delegate under the delegation provision of MCL 333.16215.

# 7. How often must practitioners provide opioid education to patients as required in Public Act 246 of 2017?

- a. This requirement applies to both minors and adult patients who are being prescribed an opioid beginning June 1, 2018. If a minor or adult patient is currently receiving any opioid prior to June 1, 2018 this form would not need to be completed for that specific prescription, as the requirements do not apply retroactively.
- b. Please note, practitioners should provide minor patients with the required opioid education and start talking form prior to issuing the first prescription, in a course of treatment, for a controlled substance that is an opioid. Continuation of the established previous therapy does not require a new form. The law does not define "course of treatment" so it will be up to the provider to determine and use his/her professional medical/clinical judgement and document appropriately. Also, change in dosage of the same opioid for the minor patient, a new start talking form would not be needed.





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- c. If a <u>minor</u> or <u>adult</u> patient has been on an opioid prior to June 1, 2018 and the prescriber decides to change the minor or adult patient's opioid to a <u>new</u> opioid, then the prescriber would need to provide the opioid education and complete the start talking form accordingly prior to prescribing or dispensing the drug to the patient. The completed form would need to be saved to the patient's medical file.
- d. It is important to note that the spirit and intent of the law is for prescribers to provide education around the risks of taking an opioid so their patients, regardless of age (minor or adult) know about the dangers and risks involved in taking these drugs while treating their condition.

# 8. Does the Start Talking Form have to be completed for <u>inpatient administration</u> of an opioid drug?

- a. No, for inpatient as well as outpatient surgical procedures, 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.
- b. With regard to minor patients, please refer to the PA 246 of 2017, <u>Section 7303b(2)</u>, for a list of exemptions to the form.
- c. Please note the Michigan Public Health Code under Section 7103(1) defines administering of a drug as follows:
  - Sec. 7103(1) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or other means, to the body of a patient or research subject by a practitioner, or practitioner's presence by his or her authorized agent, or the patient or research subject at the direction and in the presence of the practitioner.
- d. Please note the Michigan Public Health Code under Section 7105(3) defines dispensing of a drug as follows:
  - Sec. 7105(3) "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.

#### 9. Does the Start Talking Form apply to Veterinarian Medicine?

a. No, the Start Talking Form only applies to patients that are human.





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# <u>Public Act 247 of 2017 – Bona Fide Prescriber-Patient Relationship:</u>

- 1. How is a bona fide prescriber-patient relationship defined for the purpose of prescribing controlled substances? \*\*\*Please Take Notice, the provisions of PA 101 of 2018, moved the effective date of PA 247 of 2017 to <u>January 4, 2019</u>, which is when <u>rules</u> were promulgated for alternatives to the bona fide prescriber-patient relationship.
  - a. LARA has worked with licensing boards, health care providers, and stakeholders to address this new law through administrative rules contained in R 338.3161a.
- 2 Are prescribers required to see a patient in-person following the prescribing of a controlled substance?
  - a. Public Act 247 of 2017 does not provide explicit guidelines for what constitutes follow-up care. It is up to each practitioner to put forth a good-faith effort to determine what constitutes follow-up care, taking into consideration the unique variables that exist to meet a patient's specific circumstances in providing the appropriate medical treatment.
- 3. Can another physician, covering for a patient's physician, refill a patient's controlled substance prescription?
  - a. Yes, R 338.3161a(3)(a) provides that a licensed prescriber may prescribe a controlled substance listed in Schedules 2 to 5 without first establishing a bona fide prescriber-patient relationship in a situation in which the prescriber is providing on-call coverage or cross-coverage for another prescriber who is not available and has established a bona fide prescriber-patient relationship with the patient for whom the on-call or covering prescriber is prescribing a controlled substance. In this scenario, the prescriber, or individual licensed under Article 15 of the Public Health Code, is required to review the patient's relevant medical or clinical records, medical history, and any change in medical condition, as well as provide documentation in the patient's medical record in accordance with medically accepted standards of care.
- 4. Can a phone call fulfill the telemedicine requirements of Public Act 247?
  - a. Pursuant to the definition of Telemedicine (defined by MCL 500.3476) states that "Telemedicine" means the use of an electronic media to link patients with health care professionals in different locations. To be considered telemedicine under this section, "the health care professional must be able to examine the patient via a real-time, interactive audio or video, or both, telecommunications system and the patient must be able to interact with the off-site health care professional at the





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time the services are provided."

# 5. What specific alternatives to the bona fide prescriber-patient relationship exist for hospice care?

a. Pursuant to R 338.3161a(3)(c), prescribers that prescribe for a patient that has been admitted to a hospice, must complete the bona fide prescriber-patient relationship requirements in compliance with R 325.13302. The rule provides a 48-hour window, beginning 48 hours immediately before, or following, the patient's admission, for the bona fide prescriber-patient requirements to be met.

# 6. What specific alternatives to the bona fide prescriber-patient relationship exist for nursing homes and nursing care facilities?

- a. Pursuant to R 338.3161a(3)(c), prescribers that prescribe for a patient that has been admitted to a licensed nursing care facility, must complete the bona fide prescriber-patient relationship requirements in compliance with R 325.20602. The rule provides a 48-hour window, after a patient's admission, for the bona fide prescriber-patient relationship requirements to be met, unless either of the following has occurred:
  - A patient was admitted to the licensed facility on a Friday, in which case a 72-hour window is provided.
  - The patient was examined by a licensed physician within 5 days before admission, the requirements of the bona fide prescriber-patient relationship are fulfilled during this examination, and a copy of this examination is available in the home at the time of the patient's admission.

#### Public Act 248 of 2017 & Public Act 249 of 2017 - MAPS Mandated Registration and Use:

# 1. Are licensed prescribers required to register to the Michigan Automated Prescription System (MAPS) prior to prescribing or dispensing a controlled substance?

 Yes, the law is effective on June 1, 2018 and prior to prescribing or dispensing a controlled substance to a patient, a licensed prescriber must be registered with MAPS.

# 2. Are licensed prescribers required to request MAPS reports prior to prescribing or dispensing a controlled substance?

- a. Yes, with the law taking effect on June 1, 2018, a licensed prescriber must request and review a MAPS report prior to prescribing or dispensing a schedule 2-5 controlled substance that exceeds a 3-day supply. Exemptions to this requirement include:
  - If the dispensing occurs in a hospital or freestanding surgical outpatient facility licensed under Article 17 and the controlled substance is





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administered to the patient in that hospital or facility.

- ii. If the patient is an animal as that term is defined in <u>Section 18802</u>, the dispensing occurs in a veterinary hospital or clinic, and the controlled substance is administered to the animal in that hospital or clinic.
- iii. If the controlled substance is prescribed by a licensed prescriber who is a veterinarian and the controlled substance will be dispensed by a pharmacist.
- b. This law does not apply to a prescriber who orders a schedule 2-5 controlled substance for inpatient administration.
- c. Please note that licensed veterinarians who dispense schedule 2-5 controlled substances in quantities that exceed a 3-day supply, in their clinic or hospital office, are required to review MAPS prior to prescribing or dispensing of the schedule 2-5 controlled substance.
- d. Please note the Michigan Public Health Code under Section 7103(1) defines administering of a drug as follows:
  - Sec. 7103(1) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or other means, to the body of a patient or research subject by a practitioner, or practitioner's presence by his or her authorized agent, or the patient or research subject at the direction and in the presence of the practitioner.
- e. Please note the Michigan Public Health Code under Section 7105(3) defines dispensing of a drug as follows:
  - Sec. 7105(3) "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.
- 3. If a provider issues multiple prescriptions of the same drug on the same date but with instructions that the prescriptions be filled at a later date, such as a "do not fill until date" is the provider mandated to check MAPS on the date the prescriptions are issued or on the dates they are filled?
  - a. The MAPS mandate is tied to the date the prescription is issued, not the date it is filled or subsequent refill dates. Before issuing a **new** prescription for a schedule 2-5 controlled substance, the prescriber must obtain and view a MAPS report.
  - b. It is important to note, however, that a provider is still expected to use his or her best clinical judgment in deciding whether issuing multiple prescriptions to a patient is appropriate.
  - c. Additionally, please be aware that the DEA has regulations around the refilling of schedule 2 controlled substance prescriptions: <a href="https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306">https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306</a> 12.htm





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- 4. Who should I contact should if I have difficulty registering to MAPS?
  - a. Please visit <a href="https://www.michigan.gov/mimapsinfo">www.michigan.gov/mimapsinfo</a>, for additional MAPS information, training videos, and contact information.
- 5. How is the mandate to check MAPS going to be enforced? Statute only refers to the checking of MAPS before prescribing or dispensing a schedule 2-5 controlled substance that exceeds a 3-day supply. What constitutes "before"; is there a suggested timeframe for checking MAPS prior to prescribing or dispensing?
  - a. It is best practice to check MAPS as close to when the prescribing or dispensing of a schedule 2-5 controlled substance occurs.
- 6. Are licensees subject to a sanction for failing to register to MAPS prior to prescribing or dispensing a schedule 2-5 controlled substance?
  - a. The law is effective on June 1, 2018 and the Bureau of Professional Licensing (BPL) within LARA may issue a letter to a licensed prescriber notifying the licensee that he/she may be in violation of the PA 248 of 2017 (mandated registration and use of MAPS). Receiving this letter is not considered discipline.
  - b. However, pursuant to the provisions contained in <a href="MCL 333.16221(w)">MCL 333.16221(w)</a> and <a href="MCL 333.16226(1)(w)">MCL 333.16226(1)(w)</a>, also effective on June 1, 2018, licensees who fail to register with MAPS prior to prescribing or dispensing a controlled substance to a patient, may be subject to board sanctions against their license that include: denial, fine, reprimand, probation, limitation, suspension, revocation, or permanent revocation.
- 7. Are licensees subject to sanctions for failing to request and review a MAPS report, prior to prescribing or dispensing a schedule 2-5 controlled substance that exceeds a 3-day supply?
  - a. The law is effective on June 1, 2018 and BPL has the option to issue a letter to a licensed prescriber notifying the licensee that they he/she may be in violation of the requirement to obtain and review a MAPS report prior to prescribing or dispensing a schedule 2-5 controlled substance that exceeds a 3-day supply. Receiving this letter is not considered discipline.
  - b. However, pursuant to the provisions contained in <a href="MCL 333.16221(w)">MCL 333.16221(w)</a> and <a href="MCL 333.16226(1)(w)">MCL 333.16221(w)</a> and <a href="MCL 333.16221(w)">MCL 333.16221(w)</a> and <a href="MCL 33





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- 8. Are all practitioners required to register with MAPS, even if they do not anticipate prescribing or dispensing controlled substances?
  - a. The law is effective on June 1, 2018 and prescribers are only required to register with MAPS if they are prescribing or dispensing controlled substances, in any quantity.
- 9. Many prescribers have staff (e.g. Registered Nurse, Office Administrator) checking MAPS for them. Will this be in compliance with new regulations as long as the prescriber checked MAPS, even if they did not personally run MAPS?
  - a. If a user is registered as a prescriber delegate and requests a MAPS report on the prescriber's behalf for the prescriber to review, this will be in compliance with new regulations. A prescriber delegate must select the prescriber for whom he/she are requesting a MAPS report.
  - b. 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. Please note, "Delegate Users" under MAPS are not necessarily the same as the term "Delegate", or "by Delegation", as defined under the Public Health Code, MCL 333.16215, which prohibits PAs and other subfield providers from delegating functions within their scope of practice. In the MAPS user context, "Delegate" is a term used to describe the user role within the MAPS program, a role which assists with an administrative function, and is not referring to the delegation provision under MCL 333.16215.
  - d. Please be aware, for the purposes of using MAPS, a prescriber may have 10 active delegate users, while a delegate user may run MAPS reports on behalf of 30 active licensed users (prescribers).

#### 10. How does the Department know when MAPS has been queried?

a. MAPS software maintains detailed user records of MAPS usage for each user account and the system itself maintains audit trails. The Bureau has the ability to audit a licensee's MAPS account to review and verify user data to determine compliance.





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# 11. Is the MAPS requirement met if a provider runs a MAPS report for a patient pre-op and dispenses a controlled substance at hospital discharge?

a. This depends on when the MAPS report was run. If the patient is admitted to a hospital, they will not be filling their own prescription, therefore a MAPS review at admission is adequate. In an outpatient setting, checking MAPS should occur as close to when the schedule 2-5 controlled substance is prescribed and/or dispensed to the patient. Please refer to the answer provided under question 4 on page 8.

# 12. Are prescribers required to check MAPS for all patients, regardless of age? Are there exemptions for infants or toddlers?

a. The MAPS requirements apply to all patients, regardless of age.

# 13. Are VA practitioners in Michigan required to comply with the registration and MAPS report requirements?

a. No, while not required under federal law to use MAPS, in many instances the VA is using MAPS.

# 14. What happens if MAPS is down or an internet connection cannot be established to check MAPS? Is there a suggested protocol to follow?

- a. If the licensed prescriber's internet connection is down, making it so the licensee cannot run a MAPS report, it is advised that the licensee document or note such issues and make the best possible clinical judgement on how to appropriately treat the patient.
- b. If MAPS is down or there is an outage of the system, BPL will work with its vendor, Appriss Health, to get the system resumed. Also, through the system audit trail, BPL will make sure that licensees are not impacted if they are questioned about not checking MAPS during the timeframe of a possible outage of MAPS.
- c. If licensees experience any difficulty accessing MAPS, they may also contact the MAPS support team at <a href="mailto:BPL-MAPS@michigan.gov">BPL-MAPS@michigan.gov</a> or visiting www.michigan.gov/mimapsinfo.





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# 15. What happens if MAPS is down or an internet connection cannot be established to report data to MAPS? Is there a suggested protocol to follow?

- a. Licensed dispensers are required to report data to MAPS and if the licensee's IT system is down or they have no internet connection, it is advised that the licensed dispenser take note of all reportable actions that have occurred while MAPS is down and input the data into MAPS when normal functionality resumes.
- b. If MAPS is down or there is an outage of the system, BPL will work with its vendor, Appriss Health, to get the system resumed. Also, through the system audit trail, BPL will make sure that licensed dispensers are not impacted if they are questioned about not reporting to MAPS during the timeframe of a possible outage of MAPS.

### 16. Can a practitioner request a MAPS report on any individual?

a. No. Pursuant to MCL 333.7333a MAPS reports can only be requested for individuals who are a bona-fide current patient of the licensed practitioner.

### 17. Are prescribers and dispensers permitted to print out MAPS reports on each patient?

 Yes, throughout the course of standard medical practice, MAPS reports can be printed out for each patient.

# 18. Are prescribers and dispensers permitted to discuss MAPS report information with patients when relevant or appropriate?

a. Yes, when relevant, MAPS information can be discussed with the patient. An example of a relevant application would be going over the MAPS data with the patient. Further, pursuant to <a href="MCL333.7333a">MCL333.7333a</a>, patients are not permitted to obtain a copy of their MAPS report.

# 19. Are prescribers and dispensers permitted to document MAPS findings and information within their notes?

a. Yes, MAPS users are permitted to document MAPS findings and information within their notes.

### 20. Can prescribers and dispensers maintain records from MAPS directly in the EHR?

a. Yes. MAPS users can maintain a MAPS report (HTML format) in the EHR or EMR. However, the prescriber or EHR/EMR vendor cannot pull the data from the report and upload the data in a way where the data is combined with other data sets within the EHR/EMR. If a prescriber saves the MAPS report in the EHR/EMR, the





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- prescriber will need to make sure it is saved in a way where the patient or other unauthorized users of the EHR/EMR cannot access the report.
- b. Please note, prescribers and dispensers are not required to save a copy of the MAPS report, whether electronic or hard copy, as the software system that MAPS operates on also has audit trail capabilities.
- 21. Can prescribers and dispensers discuss MAPS report information with other physicians treating the patient? Is the answer to the question dependent on if the other physician is listed as a prescriber on the MAPS report that was run?
  - a. BPL cannot advise on federal privacy protections that may apply; however, prescribers and dispensers can discuss MAPS report information with other physicians treating the patient during the normal course of coordinating care for the patient.
- 22. If a practitioner requests a MAPS report and detects possible illegal activity, can the practitioner give the MAPS report to a law enforcement agency?
  - a. No, however the practitioner can notify law enforcement and law enforcement could then open a bona-fide drug related investigation and request a MAPS report for the specific case through BPL.

#### **Public Act 250 of 2017 – Substance Use Disorder Services:**

- 1. Will the Department be providing health registrants and licensees who treat a patient for an opioid-related overdose, with suggested resources for providing the patient with information on substance use disorder services?
  - a. Health professionals are encouraged to visit the DHHS website that provides resources for providers: <a href="www.michigan.gov/stopoverdoses">www.michigan.gov/stopoverdoses</a>. This site contains information related to treatment resources, including a list of treatment programs compiled for each county in the state.

#### Public Act 251 of 2017 – 7 Day Supply of an Opioid for Acute Pain:

- 1. Are there new requirements that exist for practitioners treating patients with acute pain? How is acute pain defined in the new law?
  - a. Yes. Starting on July 1, 2018, if a licensed prescriber is treating a patient for acute pain, the prescriber shall not prescribe more than a 7-day supply of an opioid within a 7-day period.





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- b. Public Act 251 of 2017 defines acute pain as pain that is the normal, predicted physiological response to a noxious chemical or mechanical stimulus and is typically associated with invasive procedures, trauma, and disease, and usually lasts for a limited amount of time.
- c. This law does not apply to chronic pain.
- 2. With regard to the new requirements for treating acute pain, a majority of surgeries will only require a patient to be prescribed up to a 7-day supply of opioids. However, does the 7-day requirement apply to larger, and more complex surgeries, which may result in a patient needing more than a 7-day supply of opioids?
  - a. In instances involving major surgery, providers should review the definition of acute pain, and the patient's prognosis, and determine whether circumstances justify prescribing beyond a seven-day supply.
- 3. Does the 7-day supply of an opioid for acute pain apply to Veterinarian Medicine?
  - a. No, this law only applies to patients that are human.

<u>Public Act 252 of 2017 – Review MAPS prior to Prescribing or Dispensing Buprenorphine or Methodone:</u>

- 1. Are practitioners dispensing or prescribing buprenorphine or a drug containing buprenorphine or methadone subject to MAPS requirements?
  - a. Beginning March 27, 2018, before dispensing or prescribing buprenorphine, or a drug containing buprenorphine or methadone, to a patient in a substance use disorder program, a prescriber shall obtain and review a MAPS report concerning that patient.

Public Act 253 of 2017 - Medicaid Eligibility for Substance Use Disorder Services:

- 1. Is Michigan's Medicaid population eligible for medically necessary treatment for opioid use disorders?
  - a. Public Act 253 of 2017 codifies within Michigan's Social Welfare Act, that eligible Medicaid individuals may receive medically necessary acute medical detoxification for opioid use disorders, medically necessary inpatient care at an approved facility, or care in an appropriately licensed substance use disorder residential treatment facility.





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#### Public Act 254 of 2017 & Public Act 255 of 2017 – Opioid Education Curriculum:

- 1. Is the Prescription Drug and Opioid Abuse Commission (PDOAC) developing educational tools that will help to inform youth of the potential dangers associated with opioids?
  - a. Yes. By July 1, 2018, the PDOAC is required to develop or adopt for Michigan's Department of Education (MDE), recommendations for the instruction of pupils regarding the dangers of prescription opioid drug abuse.
  - b. No later than July 1, 2019, MDE shall make available to school districts the model program of instruction on the dangers of prescription opioid drug abuse, developed or adopted by the PDOAC. Beginning in the 2019-2020 school year, the MDE shall ensure that the state model of academic standards for health education includes instruction on prescription opioid drug abuse, including at least the recommendations made by the PDOAC.
  - c. These recommendations are also being developed with the support and assistance of DHHS.



