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The Opioid Crisis in Michigan: An Overview of the Issues and Recent Legislation

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Michigan's Opioid Legislation

- ❖ **Ten- bill package signed into law December, 2017, designed to be a comprehensive approach to addressing controlled substance (“CS”) abuse and diversion**
 - ❖ Michigan Automated Prescription System (“MAPS”) queries and reporting
 - ❖ Mandatory opioid education and consent for minor Rx
 - ❖ 7-day limit on opioid prescribing for acute pain
 - ❖ Bona fide prescriber-patient relationship and follow-up requirements
 - ❖ Limitations on initial fills, refills and partial fills of CS prescriptions

Providing SUDS Information for Opioid Overdose

P.A. 250 of 2017; MCL 333.16282

Statutory Requirements: A health profession licensee or registrant who treats a patient for an opioid-related overdose must provide the patient with information on substance use disorder services (“SUDS”- defined term).

Effective Date: March 27, 2018

Providing SUDS Information for Opioid Overdose

P.A. 250 of 2017; MCL 333.16282

❖ Implementation Issues:

- ❖ Unintentional overdoses of opioids in a treatment setting

❖ LARA/MDHHS Guidance:

- ❖ For information on treatment resources, including a list of treatment centers by county, go to www.michigan.gov/stopoverdoses.

Limits on Initial Fill, Refills and Partial Fills of CS

P.A. 251 of 2017; MCL 333.7333

Statutory Requirements: Pharmacist may, consistent with federal law and regs, partially fill in increments a schedule 2 CS prescription. Existing requirements for initial fills and refills of all CS schedules reinforced.

Effective Date: March 27, 2018

Penalty for violation: Professional discipline under MCL 333.16221

Limits on Initial Fill, Refills and Partial Fills of CS

P.A. 251 of 2017; MCL 333.7333

❖ Implementation Issues:

- ❖ Federal statute revised to permit partial fills of schedule 2 CS in broader circumstances, but corresponding federal regulations have not been updated to reflect those changes

❖ LARA/MDHHS Guidance: NONE

Mandatory MAPS Report of CS Dispensing

P.A. 252 of 2017; MCL 333.7333a

Statutory Requirements: A veterinarian, pharmacist or dispensing prescriber must report all dispensing of schedule 2-5 CS to MAPS. A prescriber dispensing buprenorphine or methadone to a patient in a SUDS program (defined term) must report the dispensing to MAPS, unless prohibited under federal law.

Effective Date: March 27, 2018

Penalty for violation: Professional discipline under MCL 333.16221

Mandatory MAPS Report of CS Dispensing

P.A. 252 of 2017; MCL 333.7333a

- ❖ **Exceptions** to MAPS reporting requirement:
 - ❖ Dispensing and administration of the CS to an inpatient in a licensed hospital
 - ❖ Dispensing occurs in a health facility licensed under Article 17 of the Public Health Code by a dispensing prescriber in a quantity adequate to treat the patient for not more than 48 hours
 - ❖ CS is dispensed by a veterinary hospital or clinic that administers the CS to an animal inpatient
 - ❖ Dispensing in a SUDS program where reporting to MAPS is prohibited under federal law

Mandatory MAPS Report of CS Dispensing

P.A. 252 of 2017; MCL 333.7333a

❖ Implementation Issues:

- ❖ Dispensers are accustomed to the existing legal requirement to report CS dispensing, so not many legal issues
 - ❖ Change in exceptions to reporting requirement
- ❖ MAPS transitioned to new vendor Apriss. Some logistical issues with transition, sign-up, interface, etc. are being worked out

Mandatory MAPS Report of CS Dispensing

P.A. 252 of 2017; MCL 333.7333a

❖ LARA/MDHHS Guidance:

- ❖ MAPS users may document MAPS findings and information in their clinical notes (FAQ 19, p. 13)

❖ SAHMSA Guidance:

- ❖ In general, 42 CFR Part 2 prohibits federally-assisted substance use disorder programs from reporting dispensing of CS to prescription drug monitoring programs like MAPS (September 27, 2011 “Dear Colleague” letter from H. Westley Clark, Director, Center for Substance Abuse Treatment, SAMHSA)

Mandatory Registration with MAPS

P.A. 248 of 2017; MCL 333.7303a(4)

Statutory Requirement: Before prescribing or dispensing a CS, a licensed prescriber must register with MAPS.

Effective Date: June 1, 2018

Penalties for Violation: Professional discipline under MCL 333.16221(w). Alternately, LARA may issue a “warning letter” that is not considered professional discipline under MCL 333.16221b.

Mandatory Registration with MAPS

P.A. 248 of 2017; MCL 333.7303a(4)

❖ Implementation Issues:

- ❖ Designation and use of “delegate”
- ❖ Register if there is any possibility that you will prescribe or dispense a CS in any quantity

Mandatory Registration with MAPS

P.A. 248 of 2017; MCL 333.7303a(4)

❖ LARA/DHHS Guidance:

- ❖ For information about registering with MAPS, training videos and contact information, see www.michigan.gov/mimapsinfo.
- ❖ Only prescribers who are prescribing or dispensing CS (in any quantity) must register with MAPS (FAQ 8, p. 11)

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

Statutory Requirement: Before prescribing or dispensing a CS in a quantity that exceeds a 3-day supply, a licensed prescriber shall obtain and review a MAPS report for that patient.

Effective Date: June 1, 2018

Penalty for Violation: Professional discipline under MCL 333.16221. Alternately, LARA may issue a “warning letter” that is not considered professional discipline under MCL 333.16221b.

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

- ❖ **Exceptions** to mandatory MAPS query requirement:
 - ❖ Dispensing and administration of the CS occurs in a licensed hospital or FSOF
 - ❖ Patient is an animal and dispensing and administration of the CS takes place in a veterinary clinic or hospital
 - ❖ The CS is prescribed by a veterinarian and will be dispensed by a pharmacist

Mandatory MAPS Query Before CS Prescribing

P.A. 248 of 2017; MCL 333.7303a(3)

❖ **Implementation Issues:**

- ❖ How long “before” prescribing is acceptable?
- ❖ Delegating review of the MAPS report
- ❖ Re-disclosure of MAPS report or patient-identifying information

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ LARA/DHHS Guidance:

- ❖ The MAPS query requirement “*does not apply to a prescriber who orders a schedule 2-5 controlled substance for inpatient administration*” (“administration” is defined term) (FAQ 2.b, p. 9)

❖ **Does this go beyond parameters of the statute?**

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ **LARA/DHHS Guidance:**

- ❖ Vets who dispense (but do not administer) > 3 day CS supply must obtain and review a MAPS report (FAQ 2.c, p. 9)
- ❖ MAPS query requirement applies to patients of all ages (FAQ 12, p. 12)
- ❖ VA practitioners in Michigan are not required to use MAPS per federal law, but many do (FAQ 13, p. 12)

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ LARA/DHHS Guidance:

- ❖ Best practice is to check MAPS “as close to when the prescribing or dispensing occurs” (FAQ 5, p. 10)
- ❖ For serial CS prescriptions, MAPS report review mandate is tied to date the serial prescriptions are issued (not filled) (FAQ 3, p. 10)

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ LARA/DHHS Guidance:

- ❖ Prescriber may designate a “delegate” to access MAPS and obtain a report under prescriber’s name (FAQ 9, p. 11)
- ❖ Delegating MAPS report review? “It is important that the prescriber reviews the MAPS report prior to prescribing or dispensing. . .” (FAQ 9.b, p. 11)

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ LARA/DHHS Guidance:

- ❖ In course of standard medical practice, MAPS reports may be printed (FAQ 17, p. 13)
- ❖ MAPS reports may be maintained in HTML format in an EHR, but must be segregated from other information in the record, so that the patient or other unauthorized users may not access the MAPS report (FAQ 20, pgs. 13-14)

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ **LARA/DHHS Guidance:**

- ❖ Practitioner may request a MAPS report only about an individual who is their bona fide patient (FAQ 16, p. 13)
- ❖ Practitioners may document MAPS information in their records and discuss with patient (FAQ 18, p. 13)
- ❖ Practitioner may not give patient a copy of MAPS report (FAQs 18 and 20, pgs 13-14)

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ LARA/DHHS Guidance:

- ❖ Practitioner may discuss MAPS information with other practitioners treating the patient during normal course of coordinating the patient's care (FAQ 21, p. 14)
- ❖ Practitioner may not give a copy of the MAPS report to law enforcement, but may notify law enforcement about suspicious activity. Law enforcement may request report from MAPS through a bona fide investigation (FAQ 22, p. 14)

Mandatory MAPS Query Before Prescribing CS

P.A. 248 of 2017; MCL 333.7303a(3)

❖ LARA/DHHS Guidance:

- ❖ MAPS system maintains detailed user records which may be audited to track prescriber/dispenser compliance (FAQ 10, p. 12)
- ❖ If the internet connection or MAPS is inoperable, document the issue and all reportable actions taken in patient's record. LARA will ensure licenses not adversely impacted by legitimate inability to report/query (FAQ 15, p. 13)

Consent for Opioid Prescription for a Minor

P.A. 246 of 2017; MCL 333.7303b

- ❖ **Statutory Requirement:** Before issuing to a minor the first prescription for an opioid in a single course of treatment, the prescriber shall provide the parent/guardian/another adult authorized to consent to treatment (defined term) specified information and obtain the dated signature of the parent/guardian/another authorized adult on a start talking form. The prescriber must also sign the form and place it into the minor's record.

Effective Date: June 1, 2018

Penalty for violation: Professional discipline under MCL 333.16221(x)

Consent for Opioid Prescription for a Minor

P.A. 246 of 2017; MCL 333.7303b

- ❖ **Information** that must be discussed with parent/guardian/authorized adult:
 - ❖ The risks of addiction and overdose with CS
 - ❖ Increased risk of addiction for an individual suffering with both mental and substance use disorders
 - ❖ Danger of taking an opioid with a benzodiazepine, alcohol or other central nervous system depressant
 - ❖ Other information from the patient counseling section of the federally-mandated CS label

Consent for Opioid Prescription for a Minor

P.A. 246 of 2017; MCL 333.7303b

❖ Start Talking Form required elements:

- ❖ Form must be separate from all other consent forms used
- ❖ Must contain name, quantity and initial dose of prescribed opioid, and number of refills, if any
- ❖ Must state that a CS is a drug that the DEA has identified as having a potential for abuse
- ❖ Must include statement certifying the prescriber discussed the required information with minor and the minor's parent/guardian/another authorized adult
- ❖ Must have space for signature of parent/guardian/another authorized adult and date signed

Consent for Opioid Prescription for a Minor

P.A. 246 of 2017; MCL 333.7303b

- ❖ **Exceptions** to “minor consent” requirement:
 - ❖ Minor’s treatment is associated with/incident to a “medical emergency” (defined term)
 - ❖ Minor’s treatment is associated with/incident to surgery (inpatient or outpatient)
 - ❖ Minor is being treated in or discharged from a licensed hospice or an oncology department of a licensed hospital
 - ❖ In prescriber’s professional judgment, obtaining consent would be detrimental to minor’s health or safety
 - ❖ The consent of the minor’s parent/guardian is not legally required for the minor to obtain treatment

Consent for Opioid Prescription for a Minor

P.A. 246 of 2017; MCL 333.7303b

- ❖ **Limitation** – if the person signing the minor consent form is another authorized adult (not the parent, guardian or minor)
- ❖ Prescriber shall not prescribe more than a 72-hour supply of the opioid for the minor

Opioid Education Requirement

P.A. 246 of 2017; MCL 333.7303c

Statutory Requirement: Before prescribing an opioid (for minor or adult), a licensed prescriber or another health professional (defined term) must obtain the patient's/patient's representative's (defined term) signature on a form prescribed by DHHS, indicating the patient/patient's representative received specified information. The form must be retained in the patient's record.

Effective Date: June 1, 2018

Penalty for Violation: Professional discipline under MCL 333.16221

Opioid Education Requirement

P.A. 246 of 2017; MCL 333.7303c

- ❖ **Information** that must be provided to the patient:
 - ❖ The danger of opioid addiction
 - ❖ How to dispose properly of an unused, expired or unwanted CS
 - ❖ That delivery of a CS is a felony under Michigan law
 - ❖ If the patient is pregnant or a female of reproductive age, the short- and long-term effects of exposing a fetus to a CS, including, but not limited to, neonatal abstinence syndrome

Opioid Education Requirement

P.A. 246 of 2017; MCL 333.7303c

❖ Key Definitions

- ❖ **Health professional** means an individual licensed, registered or otherwise authorized to engage in a health profession under Article 15 of the Michigan Public Health Code
- ❖ **Patient's representative** means a guardian, a parent, or a person acting in loco parentis for a minor (missing – patient advocate, person acting under durable power of attorney for health care)

Opioid Education Requirement

P.A. 246 of 2017; MCL 333.7303c

❖ **Exceptions** to the opioid education requirement:

- ❖ The opioid is “prescribed for inpatient use” (not defined)

Michigan's Opioid Start Talking Form

P.A. 246 of 2017; MCL 333.7303b and 333.7303c

- ❖ LARA and DHHS created the Opioid Start Talking Form to address the minor consent and opioid education requirements of P.A. 246 of 2017
- ❖ Form MDHHS-5730 (4-18a)
- ❖ Available under the “Prescriber’s” tab on the MDHHS website at https://www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_79584---,00.html.
- ❖ Available in English, Spanish and Arabic

Michigan's Opioid Start Talking Form

P.A. 246 of 2017; MCL 333.7303b and 333.7303c

❖ Implementation Issues:

- ❖ Use with minors vs. adults
- ❖ Use for multiple prescriptions and serial prescriptions
- ❖ Pregnant minors
- ❖ Who may sign the form
- ❖ Delegation by APRNs and PAs
- ❖ What is “inpatient use”?
- ❖ In whose medical record is the form retained – prescriber or facility?

Michigan's Opioid Start Talking Form

P.A. 246 of 2017; MCL 333.7303b and 333.7303c

❖ LARA/MDHHS Guidance:

- ❖ Providers not required to use state's form, but form used must comply with PA 246 of 2017 (FAQs 2 and 3, p.5)
- ❖ Requirement only applies on/after 6-1-18 (FAQ 7.a, p. 6)
- ❖ Prescriber may delegate opioid education to a licensed or unlicensed person with appropriate training and background (FAQs 5 and 6, p. 6)

Michigan's Opioid Start Talking Form

P.A. 246 of 2017; MCL 333.7303b and 333.7303c

❖ LARA/MDHHS Guidance:

- ❖ New form not required for a minor when opioid dosage changed (FAQ 7.b, p. 6)
- ❖ New form not required for an adult when opioid dosage changed or new opioid started on same patient who already signed a form (FAQ 7.c, pgs. 6-7)
- ❖ Form not required when opioid administered (defined term) to an adult during an inpatient stay within, but not limited to a hospital, FSOH, SNF, hospice, home for the aged, etc. (FAQ 8.a, p. 7)
- ❖ Form not required for veterinary practice (FAQ 9, p.7)

7-Day Limit on Opioid Prescription for Acute Pain

P.A. 251 of 2017; MCL 333.7333b

- ❖ **Statutory Requirement:** When treating a patient for acute pain, a prescriber shall not prescribe more than a 7-day supply of an opioid within a 7-day period. “Acute pain” means pain that is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus, typically associated with invasive procedures, trauma and disease, usually lasting for a limited time.

Effective Date: July 1, 2018

Penalty for violation: Professional discipline under MCL 333.16221

7-Day Limit on Opioid Prescription for Acute Pain

P.A. 251 of 2017; MCL 333.7333b

❖ Implementation Issues:

- ❖ No exception for inpatient prescriptions
- ❖ Acute pain (defined) vs. chronic pain (not defined)
- ❖ Application to serial prescriptions

7-Day Limit on Opioid Prescription for Acute Pain

P.A. 251 of 2017; MCL 333.7333b

❖ LARA/MDHHS Guidance:

- ❖ The 7-day limit does not apply to prescriptions to treat chronic pain (FAQ 1, p.14-15)
- ❖ Individual practitioners must make a professional judgment about whether or not they are prescribing for acute pain (FAQ 2, p. 15)
- ❖ 7-day limitation does not apply to veterinary practice (FAQ 3, p. 15)

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

Statutory Requirement: Except as provided in rules, a prescriber must be in bona fide prescriber-patient relationship with a patient before prescribing schedule 2-5 CS. Prescriber must also provide follow-up care to monitor efficacy of CS in treating the patient's medical condition, or refer to patient to his/her primary care provider (“PCP”) for follow-up. If no PCP, must refer patient to a licensed prescriber who is geographically accessible to the patient.

Effective Date: Earlier of March 27, 2019, or effective date of implementing regulations

Penalty for Violations: Professional misconduct under MCL 333.16221(v)

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

Bona Fide Prescriber-Patient Relationship means a treatment or counseling relationship between prescriber and patient in which both of the following are present:

- 1) Prescriber has reviewed the patient's relevant clinical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant medical evaluation conducted in person or by telehealth
- 2) Prescriber has created and maintained records of the patient's condition in accordance with medically accepted standards

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

❖ LARA Proposed Bona Fide Relationship Rule:

- ❖ Statute authorizes LARA to consult with boards of medicine, osteopathic medicine, dentistry, nursing, optometry and PA task force to promulgate rules describing circumstances under which a bona fide relationship is not required
- ❖ Statute permits the rules to include an alternative requirement when a bona fide relationship is not required

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

❖ LARA Proposed Bona Fide Relationship Rule:

- ❖ LARA issued proposed rule and held public hearing on May 23, 2018
- ❖ Original proposed rule only described ability to delegate the elements of a bona fide relationship under MCL 333.16215
- ❖ Original proposed rule did not state when bona fide relationship is not required, per statutory authorization

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

- ❖ **LARA Proposed Bona Fide Relationship Rule:**
 - ❖ Considerable commentary on proposed rule as not providing for reasonable exceptions
 - ❖ LARA informally reported that it would revise the proposed rule to address the commentators' concerns and suggested exceptions
 - ❖ LARA sent a revised proposed rule to JCAR on 8/31/18, but has not yet otherwise posted the revised version or scheduled any further hearings

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

❖ Implementation Issues:

- ❖ “Delegation” language in revised proposed rule is problematic as it does not reference MCL 333.16215, and is not really an “exception” to the bona fide relationship requirement
- ❖ Language suggested by commentators and used in revised proposed rule is not always clear

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

❖ LARA/MDHHS Guidance:

- ❖ No guidelines on follow-up care. Each prescriber must make good-faith effort to provide follow-up care, taking into consideration the patient's individual needs and the standard of care (FAQ 2, p. 8)
- ❖ If the primary physician has a bona fide relationship, she may delegate refill authority to a covering physician under MCL 333.16215 (FAQ 3, p. 8)

Bona Fide Relationship and Follow-Up Care

P.A. 249 of 2017; MCL 333.7303a(2)

❖ LARA/MDHHS Guidance:

- ❖ Telephone consult will qualify as telehealth medical exam only if the prescriber can examine the patient via real-time interactive video and/or audio (FAQ 4, p. 8)

Medicaid Coverage for SUDS

P.A. 253 of 2017; MCL 400.109

Statutory Requirement: Medicaid beneficiaries may receive medically necessary treatment for substance use disorders, including medical detoxification and residential care.

Effective Date: March 27, 2018

Opioid Abuse Education Program for Schools

P.A.s 254 and 255 of 2017; MCL 333.7113a.

Statutory Requirements: Prescription Drug and Opioid Abuse Commission (PDOAC) develops/recommends to the Department of Education (DOE) a model program for instruction on dangers of opioid drug abuse. DOE provides model program to schools and ensures schools' health curriculum includes the PDOAC recommendations.

Effective Dates:

July 1, 2018: PDOAC recommendations due to DOE

July 1, 2019: DOE provides model program to schools

2019-2020 School Year: DOE implements curriculum requirements

Resources

- ❖ **MAPS Help Phone:** 517-373-1737
- ❖ **MAPS Fax:** 517-241-5072
- ❖ **MAPS email:** BPL-MAPS@michigan.gov
- ❖ **MAPS Information:** www.michigan.gov/mimapsinfo.
- ❖ **LARA/MDHHS Opioid FAQs (7-3-18):**
https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf.
- ❖ **Michigan Opioid Start Talking Form:**
https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf

THANK YOU

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