The Opioid Epidemic and Changes In Michigan Prescribing Laws

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Speakers and Disclosures

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In 2017,

- 47,600 people died from opioid overdose
- 130+ people died every day in 2017 from opioid-related drug overdose
- 2.1 million people had a opioid use disorder
- 900K used heroin; 81K for the first time
- 15,482 deaths due to heroin overdose
- 11.4 people misused prescription opioids; 2 million people for the first time
- 17K deaths attributed to opioid overdoses on commonly prescribed medications
- 28,466 deaths due to overdoses on synthetic opioids (other than methadone)

COST TO U.S. ECONOMY

|$504 billion

The Opioid Epidemic...by the numbers

1999-2016
• >350,000 died of a opioid overdose

Three waves of the U.S. Opioid Epidemic
• First wave = Increased Prescription Opioid Overdose due to increased Prescribing in early 1990s
• Second wave = Increased Heroin Overdose in the early
• Third wave = Synthetic Opioid Overdoses (e.g., fentanyl)

80% of those who use heroin first misused prescription opioids
In 2017, Michigan ranked 15th out of 51 U.S. States and the District of Columbia in Opioid Overdose Mortality (27.8 deaths per 100,000 people), a 14% increase from 2016.
The Opioid Epidemic...by the numbers

- Number of Michigan fatalities resulting from opioid overdoses has increased exponentially since 1999, accounting for 2,694 deaths in 2017.
- Annual # of opioid overdoses in Michigan now greater either firearm-related deaths or motor vehicle crashes.
- While non-opioid drug overdose deaths have been stable over the past decade, fatal opioid overdoses have been increasing, accounting for >90% of all drug overdose deaths in Michigan in 2017.

Kaiser Family Foundation analysis of Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Multiple Cause of Death 1999-2016 on CDC WONDER Online.
ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, lidocaine in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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The impact of the increase in opioid prescribing observed in the late 1990s and early 2000s was a sharp increase in both opioid pain reliever (OPR) overdose deaths and admissions to hospitals for substance use treatment.
Addressing The Opioid Epidemic

Prescribing Practices
- PDMPs (i.e., MAPS)
- Diversion Control/Safe Disposal

Harm Reduction Strategies
- Naloxone availability
- Needle exchange

Community/Patient Education
Expanded Access to Treatment Services
Improved Data/Research and Surveillance
Michigan Opioid Laws Affecting Providers

Changes coming in 2018
Michigan Opioid Laws Affecting Providers

- Recent package of legislation passed in Michigan for Opioid Epidemic
- Attempt by state government at a comprehensive approach to addressing substance abuse and drug diversion
  - Many elements apply to healthcare providers
- Review of recent legislation and discussion about current guidance regarding their application in clinical practice
- **Caveat:** Interpreting the legal standard is beyond the scope of this talk and there is significant controversy about how providers can best meet all the requirements set forth in these laws as well as ambiguity about how they will be enforced.
Public Act 246 (Effective June 1, 2018)

- Multiple parts to the law (Adult Patients; Minors; Sanctions)
- **Before prescribing an opioid**, information should be provided on the following:
  - The dangers of opioid addiction
  - How to properly dispose of an expired, unused, or unwanted opioid.
  - That delivery (i.e. diversion) of a controlled substance is a felony
  - 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 this information, the prescriber shall obtain the patient’s signature (or the patient's representative) on a **start talking consent form**. The signed form should be kept in the patient's medical record.
- This does not apply if the controlled substance is prescribed for inpatient use.
Start Talking Sample Form (MDHHS)

- [www.michigan.gov/stopoverdoses](http://www.michigan.gov/stopoverdoses)
- English, Spanish, Arabic translations
- Not mandatory to use the state form
- **LARA Guidance**: Prescribers can delegate responsibility for providing education and obtaining a signature to another licensed or unlicensed health professional (if trained).
  - E.g. MD-education; RN-signature
- Form should be used before a new course of treatment (not defined in the law)
- Do not need a new form when changing dose in patient already undergoing treatment
• **Before issuing a new prescription** for a controlled substance to a **minor** (i.e., <18 y/o):
  • Discuss with the minor & parent/guardian **potential risks of addiction and overdose**.
  • Discuss the **increased risk of addiction** to a controlled substance for individuals suffering from **both mental and substance abuse disorders**.
  • Discuss dangers of taking an **opioid** with **benzos, alcohol, or another CNS depressant**.
  • Discuss information in the **patient counseling information section** of the medication label.
  
  • **“Start talking consent form”** must be signed by the minor’s parent or guardian who is consenting to the minor’s treatment (filed in the medical record)
    • If the adult signing the form is not the parent/guardian = **72-hour supply** can be provided
  • Form must contain the signatures, information on the name/quantity of the controlled substance and all the other components of the start talking form (e.g., risks of the drug).
  
  • **Exceptions** = Emergent condition or surgical intervention, Detrimental to minor’s health or safety; Treatment is in hospital or an oncology department of a hospital (or at time of discharge from such), or if consent is not legally required for the minor to obtain treatment.
Public Act 247

- Licensed prescriber shall not prescribe a controlled substance (S2-5) unless they have a **bona-fide prescriber-patient relationship**.
  - **Bona-fide relationship** = treatment/counseling relationship with both criteria:
    - Prescriber has **reviewed patient’s medical record and completed an assessment** of medical history and condition in-person or via telehealth
    - Prescriber has created and maintained a **proper medical record**
  - Prescriber will provide **follow-up care** (to assess efficacy; follow-up care not defined) or refer to PCP (or licensed MD in a geographically accessible region)
  - Originally set to take effect March 31, 2018; Delayed to **March 31, 2019**
  - By **December 27, 2018**: LARA in consultation with Michigan Medical and Surgical Boards will promulgate **rules describing circumstances where bona-fide relationship is not required** for purposes of prescribing controlled substances and/or additional requirements for these circumstances
LARA Clarification on Bona-Fide Physician-Patient Relationship Parameters

- **Public Act 101 of 2018**
  - Pushed back the effective data for Public Act 247 to 3/31/2019 and forced the development of rules/alternatives to the prescriber-patient relationship

- **Alternatives to a bona-fide physician-patient relationship:**
  - Providing on-call coverage or cross-coverage for another prescriber who is not available, but has an established prescriber-patient relationship
  - **Modifying the orders** of a prescriber who has an established bona-fide prescriber-provider relationship and provides documentation in the patient's medical record in accordance with standard of care.
  - Prescribing for a patient admitted to a licensed nursing care facility or in hospice and documents such in medical record.
  - Prescriber is treating a patient in a “medical emergency,” a situation that in the prescribers good faith professional judgement creates an immediate threat of serious risk to the life or health of the patient.
Public Act 248 & 249 (Effective June 1, 2018)

- Licensed prescribers must be registered with MAPS before prescribing or dispensing a controlled substance.
- Before prescribing or dispensing a controlled substance that exceeds a **3-day supply**, licensed prescribers shall obtain and review a **MAPS report**.
- Before prescribing/dispensing a controlled substance, prescribers must **ask the patient about other controlled substances they may be using** and record the **patient response in the medical record**.

**Exceptions**
- If **dispensing** and **administration** occurs in a hospital or freestanding surgical outpatient facility.
- If the **dispensing** and **administration** occurs in a veterinary hospital/clinic (if the patient is an animal) OR If the controlled substance is prescribed by a veterinarian and the controlled substance will be dispensed by a pharmacist.
• A licensee or registrant who treats a patient for an opioid-related overdose shall provide information to the patient on substance use disorder services. (Effective March 27th, 2018)

• Substance use disorder treatments include:
  • Early intervention and crisis intervention counseling services for individuals who are current or former individuals with substance use disorder
  • Referral services for individuals with substance use disorder, their families, and the general public
  • Planned treatment services, including counseling, or rehabilitation for individuals physiologically or psychologically dependent upon or abusing alcohol or drugs
• If a prescriber is treating a patient for acute pain, that prescriber should not prescribe the patient more than a 7-day supply of an opioid within a 7-day period. (Effective July 1, 2018)

• **Acute pain** is defined as pain that is the normal, predicted physiological response to a noxious chemical or mechanical stimulus and is typically associated with invasive procedures and trauma. Acute pain usually lasts for a limited time.

• A pharmacist, consistent with federal law and regulations on the partial filling of a controlled substance included in S2, may partially fill in increments, a prescription for a controlled substance. (Effective March 27, 2018)
Amended current law to **rescind substance use treatment exemption for obtaining a MAPS report** (unless prohibited by federal laws):

1. **Before** dispensing or prescribing buprenorphine or a drug containing buprenorphine or methadone to a patient in a SUD program, the prescriber shall **obtain and review a MAPS report on the patient**.

2. Physicians who dispense buprenorphine or methadone on premises, as part of an approved substance use disorder program, are **required to report data** associated with the encounter to MAPS.
- **Act 253**: Amends PA 280 (the Social Welfare Act): An eligible individual may receive medically necessary acute medical detoxification for opioid disorder, medically necessary inpatient care at an approved facility, or care in an appropriately licensed substance use disorder residential treatment facility. (i.e., Codifies Medicaid coverage for detox programs)

- **Act 254**: The prescription drug and opioid abuse commission shall develop or adopt, and make available to the Michigan Department of Education (MDE), recommendations for the instruction of pupils on prescription drug abuse.

- **Act 255**: Beginning the 2019-2020 school year, MDE shall ensure that the state model academic standards for health education include instruction of prescription opioid drug abuse and make available to school districts and public school academies a grade- and age- appropriate model program of instruction on prescription opioid drug abuse based on the recommendations under Act 254.
LARA Guidance

LICENSING AND REGULATORY AFFAIRS

LARA / BUREAU LIST / PROFESSIONAL LICENSING

Laws/Regulations

LAWS AND REGULATIONS

Recently passed laws require prescribers to obtain and review a patient's prescription history in the Michigan Automated Prescription System prior to prescribing controlled substances to patients. The bills also create disciplinary action for prescribers who fail to use MAPS. Below is a summary of the new acts.

<table>
<thead>
<tr>
<th>Public Acts</th>
<th>Description</th>
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<tbody>
<tr>
<td>Public Act 246 of 2017</td>
<td>Requires the disclosure of prescription opioid information and risks to minors and patients, beginning 6/1/18. Required “Start Talking” form.</td>
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<tr>
<td>Public Act 247 of 2017</td>
<td>Requires prescribers to be in a bona fide prescriber-patient relationship prior to prescribing Schedules 2-5 controlled substances. These provisions were due to take effect on 3/31/18, however the implementation date has been pushed back by Public Act 101 of 2018.</td>
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Tools and Resources

Additional resources that are available for providers and patients:

- Posters
- Fact Sheets
- Checklists
- Education on Epidemic

Access the full CDC guideline for prescribing opioids for chronic pain at:

https://www.cdc.gov/drugoverdose/index.html

https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html

https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
Questions?

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