

Michigan: MAPS Updates and Enforcement

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Presented by

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Michigan Automated Prescription System (MAPS)

Bureau of Professional Licensing

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Bureau of Professional Licensing

- Established in July 2015
- 10 Occupational Licensing/Regulation Boards
- 24 Health Professional Licensing/Regulation Boards
- Boards are advisory and determine sanctions
- License and regulate over 750,000 individuals
- 3 Divisions: Licensing, Investigations & Inspections, Enforcement
- Enforcement Division: Administers Pharmacy and Drug Monitoring Section and Michigan Automated Prescription System (MAPS) Section; investigates overprescribing, over dispensing, and drug diversion



MAPS Background

- Contains over 120 million records
- Data maintained for 5 years
- Required reporting of CS Schedule 2-5 from:
 - Prescribers who dispense CS Schedule 2-5
 - Pharmacists (dispensers)
 - Veterinarians



Controlled Substance Prescriptions Filled in Michigan by Year

	Total CS prescriptions dispensed	% change from previous year
2007	17,007,858	
2008	17,400,640	2.31%
2009	17,876,684	2.74%
2010	18,954,172	6.03%
2011	19,763,680	4.27%
2012	20,991,020	6.21%
2013	20,728,216	-1.25%
2014	20,904,764	0.85%
2015	21,472,326	2.71%
2016	21,092,674	-1.77%
2017	19,943,203	-5.45%
2018	17,642,901	-11.53%



Opioid Prescriptions Filled in Michigan by Year

	Total Opioid Prescriptions Dispensed	% Change from Previous Year
2013	9,920,288	
2014	10,301,142	3.84%
2015	10,833,681	5.17%
2016	10,507,059	-3.01%
2017	9,670,789	-7.96%
2018	8,223,103	-14.97%



Commonly Abused Controlled Substances Filled in Michigan (Summary)

	Alprazolam 1 mg	Alprazolam 2 mg	Carisoprodol 350 mg	Promethazine with Codeine
2015	41,499,216	10,227,915	13,124,785	41,758,634
2016	39,040,420	8,618,772	10,442,641	34,803,234
2017	34,379,472	6,939,880	7,808,190	28,579,490
2018	27,849,498	5,118,689	4,905,115	15,971,635
% Change from 2015 to 2016	-5.92%	-15.73%	-20.44%	-16.66%
% Change from 2016 to 2017	-11.94%	-19.48%	-25.23%	-17.88%
% Change from 2017 to 2018	-18.99%	-26.24%	-37.18%	-44.12%

	Hydrocodone/Acetaminophen 7.5 mg-325mg	Hydrocodone/Acetaminophen 10 mg-325mg	Oxycodone 30 mg	Oxymorphone ER 40 mg
2015	107,776,175	177,326,801	16,666,622	1,165,058
2016	99,473,052	172,038,459	14,859,323	1,358,611
2017	84,705,294	151,080,925	12,306,723	1,502,544
2018	66,741,785	118,239,581	9,456,126	1,040,705
% Change from 2015 to 2016	-7.70%	-2.98%	-10.84%	16.61%
% Change from 2016 to 2017	-14.85%	-12.18%	-17.18%	10.59%
% Change from 2017 to 2018	-21.21%	-21.74%	-23.16%	-30.74%

The numbers in these tables are drug totals dispensed by number of dosage units (e.g. number of tablets, milliliters, etc.)



Enforcement Efforts

Governor's Prescription Drug and Opioid Task Force

- Created in June 2015
- Multiple recommendations by Task Force, included updating or replacing MAPS
- Complete Task Force Recommendation report can be found at:
 - www.Michigan.gov/snyder
 - > Lt. Governor > Initiatives > Prescription Drug & Opioid Task Force
- June 2016 Governor established by EO (2016-15) the Prescription Drug & Opioid Abuse Commission



Enforcement Actions

- Task force recommendation:

“The task force recommends requiring enhanced licensing sanctions for health professionals that violate proper prescribing and dispensing practices.”

- In January 2016, LARA created the “Pilot Program to Reduce Overprescribing.”

Objectives:

- Reduce prescription drug abuse and drug-related overdose deaths
- Develop best practices and protocols for identifying, investigating, and taking administrative action against overprescribers
- Determine ways to best collaborate with law enforcement and other local, state, and federal agencies.



Enforcement Actions

- In August 2016, LARA created a permanent Drug Monitoring Section to identify, investigate, and pursue administrative actions against health professionals who overprescribe, overdispense, and divert controlled substances.
 - Focused on supply reduction of medically unnecessary controlled substances that feed addiction and overdose.
- Due to success and progress made, the Drug Monitoring Section split into two sections in August 2018: MAPS and the Pharmacy and Drug Monitoring Section.



Definitions

- "Drug diversion" means obtaining, possessing, or attempting to obtain or possess a controlled substance without lawful authority; or selling, prescribing, giving away, or administering controlled substances for other than lawful diagnostic or therapeutic purposes.
- "Overprescribing" means prescribing controlled substances in greater amounts, in higher strengths, or on more occasions than required by medical necessity.
- "Overdispensing" means dispensing controlled substances without proper legal authority (e.g., a prescription) or dispensing controlled substances without applying sufficient scrutiny to controlled substance prescriptions.



Note

- The vast majority of health professionals are competent practitioners.
- LARA is not seeking to intervene the doctor-patient relationship or to punish practitioners just because they prescribe controlled substances.
- The health professional boards, composed largely of practitioners, have been supportive of administrative action.
- The process shields good practitioners.



Case Example – Prescriber D

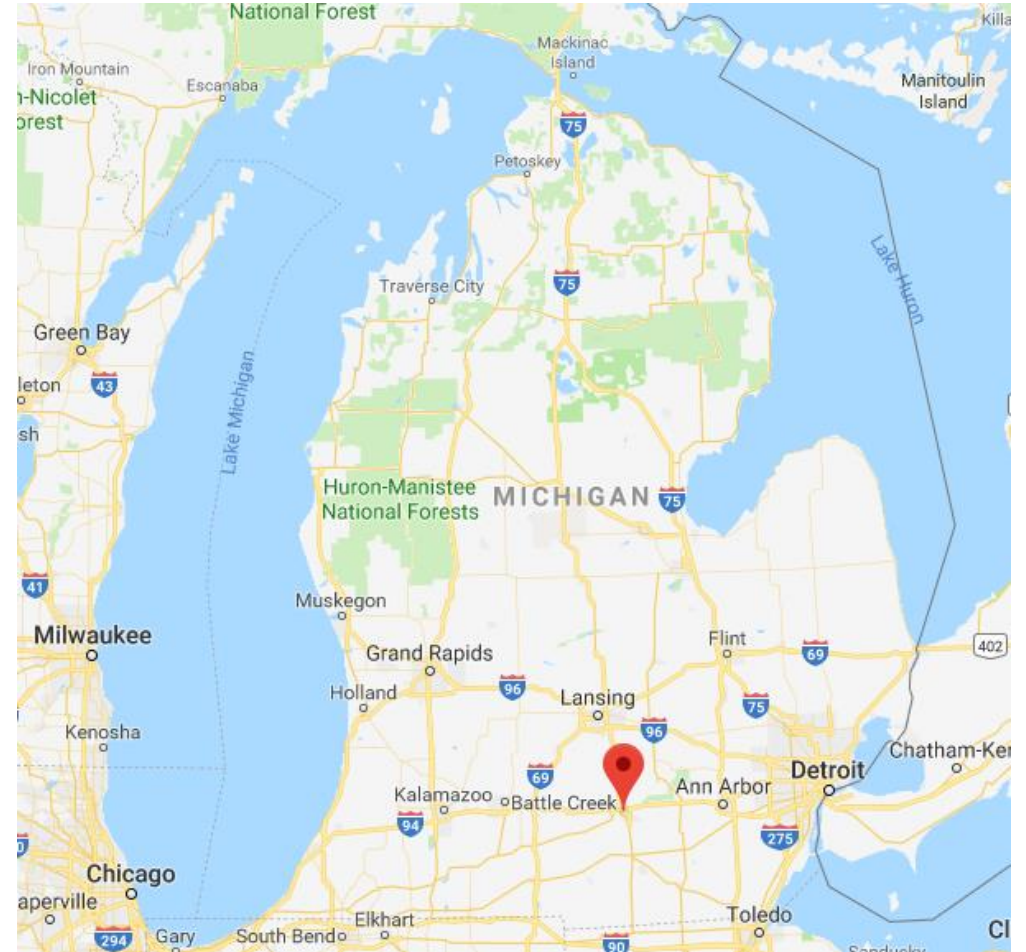
Prescriber D

- Practiced from an office in Jackson, MI
- Specialty: Family Medicine

Jackson, MI (Jackson County)

- 2017 Population:
 - County Population: 158,640
 - City Population: 32,704

Source: United States Census Bureau



Case Example – Prescriber D

MAPS Data:

- First case using county rankings

Drug	2017 Jackson County Rank	Medication Dosage Units
Carisoprodol 350mg	1	18,260
Methadone (all strengths)	3	67,492
Promethazine w Codeine	1	40,015

Case Example – Prescriber D

Investigation and results:

- LARA subpoenaed medical records of 10 patients
- Prescriber consistently outranked other providers in Jackson county in terms of volume of prescriptions for commonly abused and diverted drugs.
- Prescriber issued more prescriptions for promethazine with codeine than the next three ranked Jackson county prescribers combined.
- Prescriber indicated he was not familiar with Michigan Guidelines on Prescribing of Controlled Substances.
- Prescriber indicated he was not familiar with “red flags” associated with drug diversion.
- Prescriber stated he was not familiar with informed consent regarding risks and benefits of pain medications.
- Prescriber had an “office girl” run MAPS reports for him.
- Prescriber estimated 1% of his patients had no insurance coverage, but MAPS data revealed over 10% of his patients pay cash for prescriptions.
- Prescriber acknowledged he had received phone calls from family members of patients regarding concerns for the patients’ controlled substance regimens.
- Prescriber reported that after LARA subpoenaed records, he began obtaining drug screens, pain contracts, and MAPS reports on his patients
 - Prescriber reported that because he implemented drug screens, he had discharged two patients, however MAPS data showed that he continued to issue controlled substance prescriptions for these patients.



Case Example – Prescriber D

- The department obtained an expert to review the case.
- The expert reviewed the medical records and provided their findings. Examples include, but are not limited to:
 - Prescriber failed to document patient histories and failed to obtain medical records from previous providers
 - Medical records lack critical information regarding patient’s history, pain, functional status, medication efficacy, medication side effects, or psychiatric status
 - Prescriber frequently prescribed opioids and benzodiazepine combinations
 - Prescriber did not document any rationale for treatment and failed to provide justification for the medications he prescribed or any subsequent dosage changes. The expert noted that many of the changes in medications seemed “random” and showed a clear lack of knowledge of appropriate opioid dosing.

Case Example – Prescriber D

- Expert review found deficiencies in patient care in individual patient files. Examples include, but are not limited to:
 - Patient 1
 - Prescribed 27 methadone 10mg per day. The expert noted this is dangerous and “beyond ridiculous.”
 - Prescribed 450 days-worth of Benzphetamine over a 200-day period. The expert noted this is an indicator of a person involved in drug diversion.
 - Patient 2
 - Prescribed a dangerous combination, including two different strengths of OxyContin, hydrocodone, and 250mg of fentanyl. This equated to a MME of 980.

Case Example – Prescriber D

Outcome:

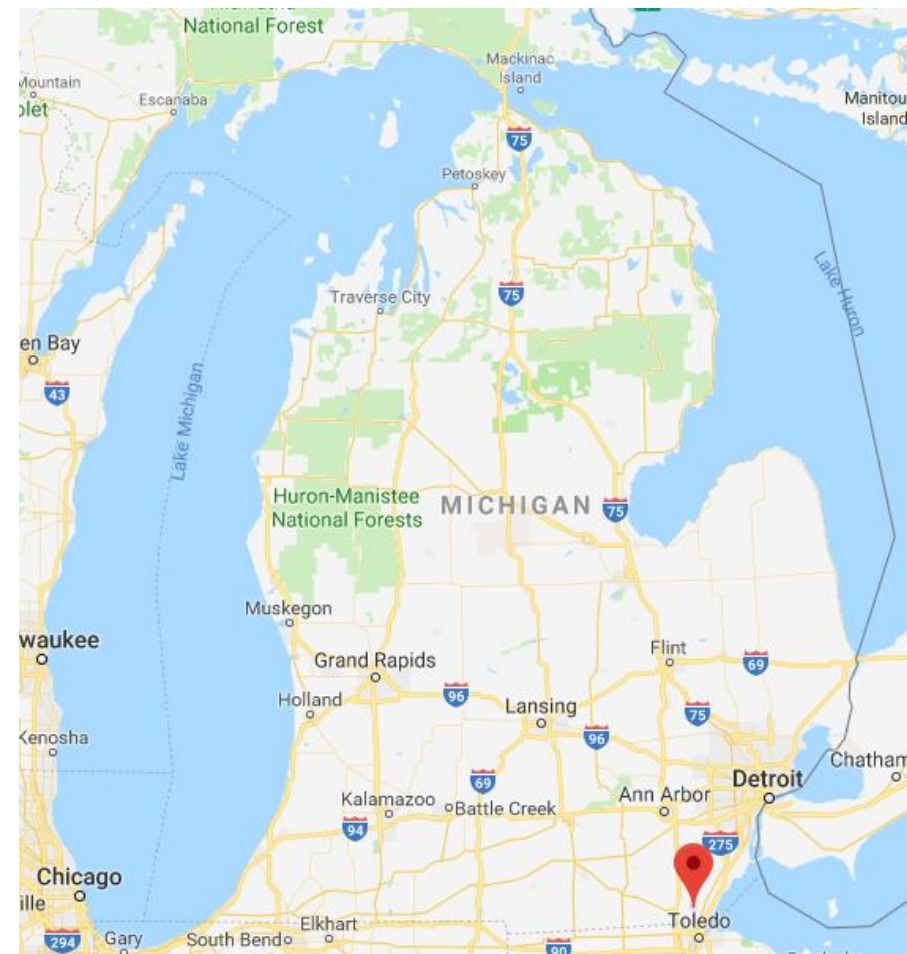
- Violations of Michigan Public Health Code
 - MCL 333.16221(a) – conduct violates general duty, consisting of negligence or failure to exercise due care
 - MCL 333.16221(b)(i) – conduct fails to conform to minimal standards of acceptable, prevailing practice for the health profession
 - MCL 333.16221(c)(iv) – conduct constitutes selling, prescribing, giving away, or administering drugs for other than lawful diagnostic or therapeutic purposes
- Prescriber was summarily suspended in May 2018
- Prescriber was fined \$25,000
- Prescriber held a limited license, with a limitation to not obtain, possess, prescribe, dispense or administer any drug designated as a controlled substance under the Public Health Code or its counterpart in federal law (unless prescribed or dispensed to Prescriber as a patient), and was also not allowed to issue any Medical Marijuana certifications (patient or caregiver).
- Once the limited license period ended, Prescriber was put on probation with specific terms and conditions



Case Example – Pharmacy A

Pharmacy A

- Located in Temperance, MI



Case Example – Pharmacy A

MAPS Data:

Drug	2016 Q3	2016 Q4	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2
Oxymorphone ER 40mg	40	29	25	30	21	19	22	17
Oxymorphone (all strengths)	57	29	38	40	30	22	27	22

- Between January 1, 2016 and June 30, 2018, data shows:
 - Over 40% of prescriptions were paid for by cash
 - Nearly 80% of the oxycodone 30mg prescriptions were paid for by cash
 - Nearly 90% of the oxymorphone ER 40mg prescriptions were paid for by cash
 - Pharmacy dispensed prescriptions for numerous prescribers that were prescribing same medications to numerous patients (pattern prescribing).
 - Several of the providers had recently been disciplined by the State of Michigan.
 - MAPS review of these prescribers showed self-proclaimed healthcare specialties that would not warrant such high volume of oxycodone 30mg or oxymorphone ER 40mg prescriptions.



Case Example – Pharmacy A

MAPS Data – Patient Examples

- Patient 1: Regularly received oxycodone, oxymorphone, and promethazine with codeine prescriptions filled by Pharmacy.
 - MMEs as high as 440
 - Received prescriptions from 7 different prescribers
 - Felony convictions for controlled substance violations
 - Resides 58 miles from Pharmacy
- Patient 2: Regularly received oxycodone and oxymorphone prescriptions filled by Pharmacy.
 - MMEs as high as 270
 - Convicted felon
 - Resides 55 miles from Pharmacy
- Patient 3: Regularly received oxycodone and oxymorphone prescriptions filled by Pharmacy.
 - MMEs as high as 350
 - Convicted felon
 - Resides 51 miles from Pharmacy



Case Example – Pharmacy A

MAPS Data – Patient Examples

- Patient 4: Regularly received oxycodone and oxymorphone prescriptions filled by Pharmacy.
 - MMEs as high as 340
 - Convicted felon
 - Resides 49 miles from Pharmacy
- Patient 5: Regularly received oxycodone and oxymorphone prescriptions filled by Pharmacy.
 - MMEs as high as 400
 - Received prescriptions from 7 different prescribers
 - Felony convictions for controlled substance violations
 - Resides 62 miles from Pharmacy
- Patient 6: Regularly received oxycodone and oxymorphone prescriptions filled by Pharmacy.
 - MMEs as high as 450
 - Received prescriptions from 8 different prescribers
 - Resides 65 miles from Pharmacy



Case Example – Pharmacy A

MAPS Data – Patient Examples

- Patient 7: Regularly received oxycodone and oxymorphone prescriptions filled by Pharmacy.
 - MMEs as high as 300
 - Received prescriptions from 6 different prescribers
 - Resides 52 miles from Pharmacy
- Patient 8: Regularly received oxycodone and oxymorphone prescriptions.
 - MMEs as high as 460
 - Received prescriptions from 8 different prescribers and filled at 4 different pharmacies
 - Resides 55 miles from Pharmacy (same household as Patient 9)
- Patient 9: Regularly received oxycodone and oxymorphone prescriptions.
 - MMEs as high as 420
 - Received prescriptions from 8 different prescribers and filled at 4 different pharmacies
 - Resides 55 miles from Pharmacy (same household as Patient 8)



Case Example – Pharmacy A

MAPS Data – Patient Examples

- Patient 10: Regularly received oxycodone and oxymorphone prescriptions filled by Pharmacy.
 - MMEs as high as 370
 - Received prescriptions from 6 different prescribers
 - Resides 40 miles from Licensee
- Patient 11: Regularly received oxycodone and oxymorphone prescriptions.
 - MMEs as high as 350
 - Received prescriptions from 7 different prescribers and filled at 3 different pharmacies
 - Resides 62 miles from Pharmacy
- Patient 12: Regularly received oxycodone and oxymorphone prescriptions, in addition to several prescriptions for alprazolam and promethazine with codeine.
 - MMEs as high as 510
 - Received prescriptions from 14 different prescribers and filled at 6 different pharmacies
 - Resides 67 miles from Pharmacy



Case Example – Pharmacy A

Investigation:

➤ Pattern prescribers:

- Pharmacy dispensed oxycodone 30mg and oxymorphone ER 40mg prescription combinations to patients, some issued by previously disciplined prescribers.
- One “pattern prescriber” had contacted Pharmacy and indicated they had closed their office and the prescriptions were fraudulent. Pharmacy continued to fill them for two months.
- Another “pattern prescriber” indicated these were fraudulent prescriptions and never prescribes oxymorphone. The prescriber had notified police. Pharmacy told the prescriber they called the prescriber’s office and spoke with “Jennifer” to verify prescriptions, but there was actually no Jennifer at that office. Pharmacy knew there were fraudulent prescriptions issued under this prescriber’s name and continued to fill for these patients under different providers afterwards.
- Two other “pattern prescribers” were mentioned and interviewed, with the prescribers indicating the prescriptions were fraudulent.

Case Example – Pharmacy A

Investigation Interview of Staff Pharmacist:

- Pharmacy filled prescriptions on multiple occasions for oxycodone 30mg and oxymorphone ER 40mg from the same provider for Detroit-area patients.
 - Prescriptions were in near sequential order
 - Pharmacist stated a single “caregiver” would receive monthly prescriptions for these patients
- Pharmacist reported that patients who paid cash for oxycodone 30mg and oxymorphone ER 40mg paid:
 - \$176 for 90-count oxycodone 30mg and \$840 for 60-count oxymorphone ER 40mg
 - Investigators found through inspection that Pharmacy was actually receiving \$220.47 for 90-count oxycodone 30mg and \$1,232.31 for 60-count oxymorphone ER 40mg.
- Indicated pharmacists checked MAPS to make sure patients were not “doctor shopping” and contacted physician’s offices to verify prescriptions
- Could not explain why customers traveled long distances to prescribers’ offices and then to Pharmacy.



Case Example – Pharmacy A

Investigation Interview of Pharmacist in Charge (PIC):

- PIC confirmed a “caregiver” would bring in prescriptions for patients. The PIC also confirmed most of these were paid for by cash and he believed it was not a good idea for Pharmacy to dispense these prescriptions.
- PIC believed patients traveled long distances because this pharmacy’s prices were cheaper.
- PIC was unaware of any potential drug diversion and that deciding which prescriptions were appropriate to fill was a “headache” for him and he considered himself neither a “policeman” nor a “judge.”

Case Example – Pharmacy A

Outcome:

➤ Violations of Michigan Public Health Code

- MCL 333.7311(1)(e) – failed to maintain effective controls against drug diversion of controlled substances to other than legitimate and professionally recognized therapeutic, scientific, or industrial uses
- MCL 333.7311(1)(g) – dispensed controlled substances for other than legitimate or professionally recognized therapeutic, scientific, or industrial purposes, or outside the scope of practice
- MCL 333.7311(1)(h) – dispensed controlled substances without good faith
- MCL 333.7311(1)(h) – failed to maintain invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 in a separate file, contrary to R 338.3153(2)(a)
- MCL 333.7311(1)(h) – failed to keep records and maintain inventories in conformance with the record-keeping and inventory requirements of 21 U.S.C. § 827 and 21 C.F.R. 1304, contrary to MCL 333.7321(1)
- MCL 333.7311(1)(h) – did not possess required pharmacy reference texts, contrary to R 338.481(2)
- MCL 333.17768(1) – premises lacked clean and sanitary surroundings, contrary to R 338.482(1)
- MCL 333.17768(1) – possessed drugs not labeled correctly, contrary to MCL 333.17762(1)
- MCL 333.17768(1) – conduct evidences a failure to maintain the necessary quality of the drugs being dispensed, contrary to R 338.490(1)
- MCL 333.7311(1)(h) – failed to date and create initial invoices and other acquisition records of all controlled substances, contrary to R 338.3153(3)



Case Example – Pharmacy A

Outcome:

- Pharmacy was summarily suspended in October 2018
 - Department seized drugs and were ultimately forfeited
- Pharmacy permanently surrendered pharmacy and controlled substance license
- Pharmacy was fined \$10,000

- Pharmacist in Charge was summarily suspended in October 2018
 - Must petition for reinstatement upon conclusion of suspension period for both pharmacist and controlled substance licenses
- Pharmacist in Charge was fined \$10,000



Enforcement - Outcomes

Since March 2016, LARA has summarily suspended 61 Licenses:

- 38 prescribers
- 25 pharmacies and pharmacists



Questions?

Thank you!



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