

# Licensee Complaint and Enforcement

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# Learning Objectives

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This presentation will enable participants to:

- Understand the structure of the Bureau of Professional Licensing and its role in enforcing Michigan's Public Health Code
- Identify red flags for drug diversion / overprescribing through case examples.



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# The structure of the Bureau of Professional Licensing and its role in enforcing Michigan's Public Health Code



# Department of Licensing and Regulatory Affairs – Bureau of Professional Licensing

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- -10 Occupational Licensing/Regulation Boards
- -26 Health Professional Licensing/Regulation Boards
- -License and regulate over 758,000 individuals
- -3 Divisions: Licensing, Investigations & Inspections, Enforcement
- -Pharmacy and Drug Monitoring Section:
  - Investigates overprescribing, over dispensing, and drug diversion by licensed health professionals;
  - Conducts prelicensure inspections for pharmacies and other entities applying for a controlled substance license
  - Issues administrative complaints and executes orders of summary suspension
  - Conducts compliance conferences with licensees and their attorneys to resolve pending administrative complaints



# Michigan Automated Prescription System (MAPS)

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- 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

## Q: Does a licensed health professional have to report a colleague who may have violated the Public Health Code?

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### MCL 333.16222(1)

- A licensee or registrant who has knowledge that another licensee or registrant has committed a violation under section 16221, article 7, or article 8 or a rule promulgated under article 7 or article 8 **shall** report the conduct and the name of the subject of the report to the department.
- Failure of a licensee or registrant to make a report under this subsection **does not give rise to a civil cause of action** for damages against the licensee or registrant, but the licensee or registrant **is subject to administrative action** under sections 16221 and 16226.

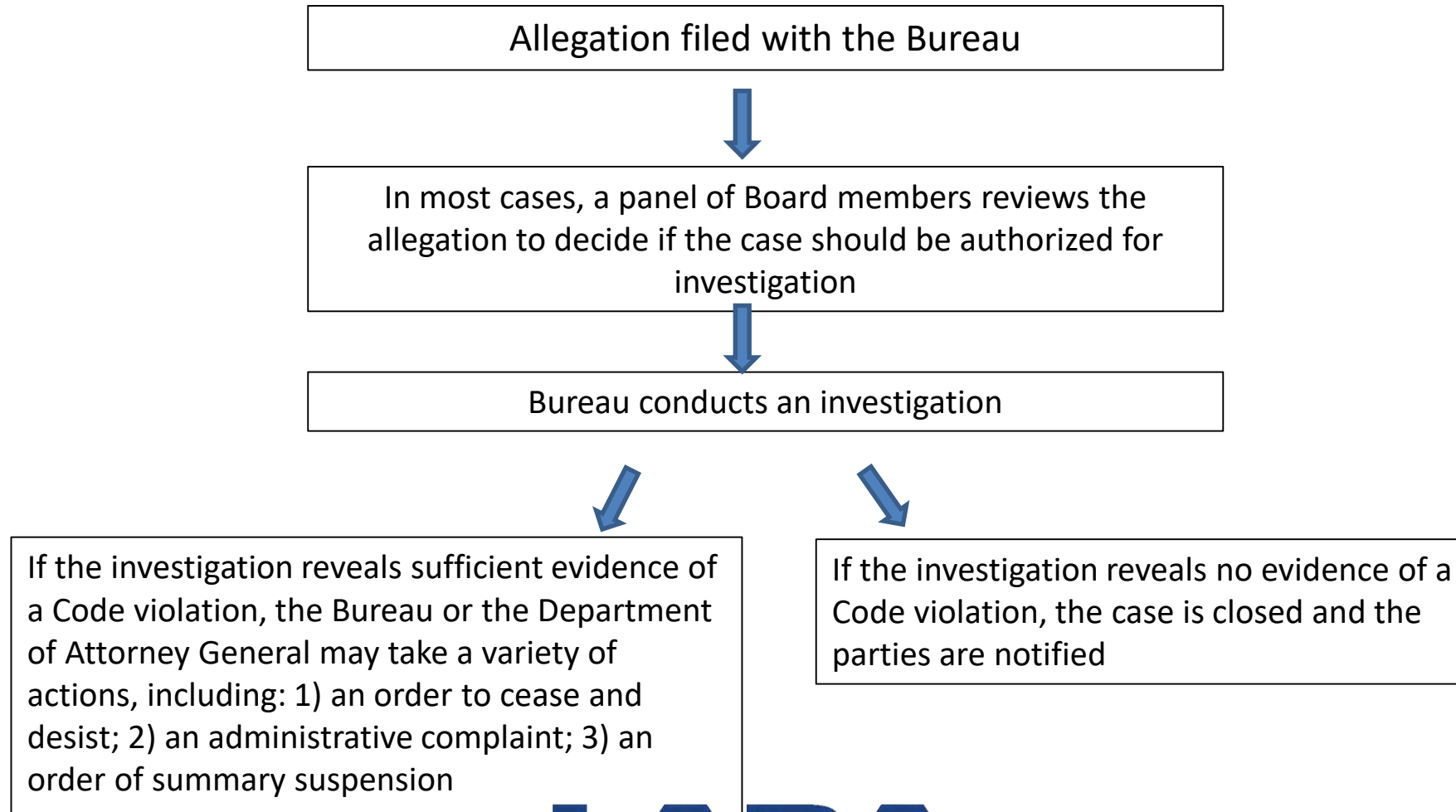
# Does a licensed health professional have to report a colleague who may be impaired?

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## MCL 333.16223

- . . . a licensee or registrant who has reasonable cause to believe that a licensee, registrant, or applicant is impaired ***shall*** report that fact to the department.
- A licensee or registrant who fails to report under this subsection is ***not liable in a civil action*** for damages resulting from the failure to report, but the licensee or registrant ***is subject to administrative action*** under sections 16221 and 16226.
- A licensee or registrant who in good faith complies with this section is ***not liable for damages in a civil action or subject to prosecution in a criminal proceeding as a result of the compliance.***

# Overview of a Health Licensing Case





## What happens after an administrative complaint is issued?

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The licensee may choose to meet with a Bureau representative for a compliance conference. A Board member may attend at the Bureau's discretion. The parties will attempt to resolve the case and submit terms for resolution to the Board for approval.



If the parties cannot resolve the case, an administrative hearing is scheduled at the Michigan Administrative Hearings System



Administrative Law Judge issues a proposal for decision (PFD)  
\*Except for a decision on a summary suspension, neither the findings of fact nor the conclusions of law are binding on the Board

## What happens after an administrative hearing?

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The Board considers the PFD along with the evidence presented at hearing and determines whether the Bureau has proven a Code violation and what, if any, sanctions are appropriate



Sanctioned licensees have an appeal by right to the Court of Appeals

# BPL's authority to obtain and use PHI

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- MCL 333.16244 (2): “The physician-patient privilege created in section 2157 of the revised judicature act of 1961, Act No. 236 of the Public Acts of 1961, being section 600.2175 of the Michigan Compiled Laws, does not apply in an investigation or proceeding by a board or task force, a disciplinary subcommittee, a hearings examiner, the committee, or the department acting within the scope of its authorization.”
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- LARA – BPL is a health oversight agency and pursuant to HIPAA, 45 CFR 164.512(d), a covered entity is permitted to disclose protected health information to LARA – BPL for the department’s oversight activities, including investigations, inspections, and administrative proceedings.



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# Red flags for drug diversion / overprescribing



# Case example: Prescriber R

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- MAPS data for January 1, 2015, through March 31, 2017, indicated the following:
  - 79.28% of the controlled substance prescriptions issued by Prescriber R were for Alprazolam, Carisoprodol, Hydrocodone 10mg, or Promethazine with Codeine
  - 42% of the controlled substance prescriptions written by Prescriber R were filled by patients who paid cash
  - 42% of the controlled substance prescriptions issued by Prescriber R were filled at the same independent pharmacy
- Additionally, Prescriber R had a history of prescribing to “doctor-shopping” patients, did not regularly request MAPS data on his patients, and had a known history of mental illness.



# Case example: Prescriber R

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- LARA Pre-Investigation/MAPS Review:
  - Requested authorization for investigation due to possible overprescribing
- Investigation:
  - Investigation authorized
  - Medical records subpoenaed and Prescriber X interviewed
  - Expert review of medical records revealed numerous deviations from the standard of care
- Outcome:
  - Complaint drafted
  - Summary suspension served
  - Prescriber X agreed to permanently surrender his controlled substance license and agreed to an 18-month suspension of his license to practice medicine



# Case example: Prescriber D

## LARA Pre-Investigation/MAPS Review:

Drug	2015 ranking	2016 Q3 ranking	2016 Q4 ranking
Alprazolam 1 mg	N/R	3	4
Carisoprodol	6	4	2
Promethazine with codeine syrup	73	20	11
Hydrocodone 10 mg	N/R	7	4
All controlled substances	N/R	43	19

# Case example: Prescriber D

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# Case example: Prescriber D

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- MAPS data for January 1, 2015 through August 14, 2017 indicated the following:
  - Nearly 22% of the controlled substance prescriptions written by Prescriber D were filled by patients who paid cash
  - Nearly 10% of the controlled substance prescriptions Prescriber D wrote were for patients who traveled from more than 70 miles away
- Additionally, expert review of a sampling of Prescriber D's medical records showed he did not perform adequate pain assessments, failed to assess patients for risk of addiction, and failed to take adequate safeguards to detect misuse, abuse, or diversion of controlled substances.

# Case example: Prescriber D

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- LARA Pre-Investigation/MAPS Review:
  - Requested authorization for investigation due to possible overprescribing
- Investigation:
  - Investigation authorized
  - Medical records subpoenaed and Prescriber D interviewed
  - Expert review of medical records revealed numerous deviations from the standard of care
- Outcome:
  - Complaint drafted
  - Summary suspension served in coordination with MSP executing a search warrant and taking Prescriber D into custody
  - Prescriber D failed to answer LARA's pleadings. Thus, the Board of Medicine defaulted him and revoked his license.



# Case example: Pharmacy B

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## LARA Pre-Investigation/MAPS Review:

Drug	2016 ranking	2017 Q2 ranking
Promethazine with codeine syrup	18	6
Oxycodone 30 mg	22	6
Oxymorphone 40 mg	18	20

# Case example: Pharmacy B

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# Case example: Pharmacy B

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- LARA Pre-Investigation/MAPS Review:
  - Requested authorization for investigation due to possible over-dispensing
- Investigation:
  - Investigation authorized
  - Inspection & audit conducted
  - Interviewed PIC
  - Contacted wholesale distributors
  - Compiled all info → drafted investigation report → approved
- Outcome:
  - Complaint drafted
  - Summary suspension served/seizure of controlled substances in August 2017
  - Pharmacy agreed to permanently surrender its controlled substance license in February 2018



# Good faith

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## MCL 333.7333 definition:

- “...the prescribing or dispensing of a controlled substance by a practitioner licensed under section 7303 in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance...”
- The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:
  - (a) Lack of consistency in the doctor-patient relationship.
  - (b) Frequency of prescriptions for the same drug by 1 prescriber for larger numbers of patients.
  - (c) Quantities beyond those normally prescribed for the same drug.
  - (d) Unusual dosages.
  - (e) Unusual geographic distances between patient, pharmacist, and prescriber.



# Enforcement Actions - Outcomes

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Since 2016, LARA and the AG have taken disciplinary action against 97 prescribers.

- 36 of those actions included summary suspensions of the professional license because the public health, safety, and welfare, required emergency action.



# Controlled Substance Prescriptions Filled in Michigan by Year

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*	17,644,265	-11.53%

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\*2018 numbers are provisional as of 2/14/19  
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# Controlled Substances Filled in Michigan by Drug

Year	Alprazolam 2 mg	Alprazolam 1 mg	Hydrocodone 10 mg	Hydrocodone 7.5 mg
2015	10,227,915	41,499,216	177,326,801	107,776,175
2016	8,618,772	39,040,420	172,038,459	99,473,052
2017	6,939,880	34,379,472	151,080,925	84,705,294
2018*	3,511,238	27,845,017	118,224,505	66,733,496
% Change from 2015 to 2016	-15.73%	-5.92%	-2.98%	-7.70%
% Change from 2016 to 2017	-19.48%	-11.94%	-12.18%	-14.85%
% Change from 2017 to 2018	-49.40%	-19.01%	-21.75%	-21.22%

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

\*2018 numbers are provisional as of 2/14/19



# Controlled Substances Filled in Michigan by Drug

Year	Carisoprodol 350 mg	Oxycodone 30 mg	Oxymorphone 40 mg	Promethazine with Codeine
2015	13,124,785	16,666,622	1,165,058	41,758,634
2016	10,442,641	14,859,323	1,358,611	34,803,234
2017	7,808,190	12,306,723	1,502,544	28,579,490
2018*	4,903,581	9,450,473	1,040,601	15,967,775
% Change from 2015 to 2016	-20.44%	-10.84%	16.61%	-16.66%
% Change from 2016 to 2017	-25.23%	-17.18%	10.59%	-17.88%
% Change from 2017 to 2018	-37.20%	-23.21%	-30.74%	-44.13%

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

\*2018 numbers are provisional as of 2/14/19

# Questions?

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*Thank You!*



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