

Pharmacy Diversion Awareness Conference
September 12 & 13, 2015
South Portland, Maine



- **Learning Objectives**

- ❑ Gain knowledge of how and when to report drug diversions and thefts by licensed Maine pharmacists, pharmacist interns and pharmacy technicians in accordance with the Maine Pharmacy Practice Act and related rules.
- ❑ Recognize that diversion methods are not what you expect and importance of conducting drug inventories and to question inconsistencies.
- ❑ Learn about today's drug of choice by pharmacists, pharmacist interns and pharmacy technicians.
- ❑ Abridged review of the Maine Pharmacist in Charge responsibilities.

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BOARD OF PHARMACY OVERVIEW OF DRUG DIVERSION, RULES, AND UPDATES

Brad Hamilton, Maine Board of Pharmacy

Overview



- **Red Flag Video- NABP**
- **Diversion Cases & Trends**
- **PIC Responsibilities**
- **Corresponding Responsibility & Refusal to Fill**
- **Reporting/ Notification Requirements**
- **Board Information**

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DIVERSION CASES AND TRENDS UPDATE

Maine – Active Licenses (as of 9/3/2015)



Pharmacists: 2,123, of which 1,091 are Certified to Administer Drugs & Vaccine

Pharmacist Interns: 625

Pharmacy Technicians: 2,572

Pharmacies: 315

Central Fill Pharmacies: 2

Closed Shop Pharmacies: 8

Rural Health Center Pharmacies: 9

Nuclear Pharmacies: 2

Extended Hospital Pharmacies: 2

Mail Order Pharmacies: 537 and Mail Order Contact Lens Suppliers: 4

Opioid Treatment Program Clinics: 8

Retail Supplier of Medical Oxygen and Oxygen Devices: 71

Pharmaceutical Manufacturer: 282

Wholesale Distributors: 716

Maine – Complaints

Covering 1/1/2013 through 9/3/2015



Number of complaint cases opened

(calendar year)

2015 through 9/3/2015: 107

2014: 118

2013: 147

Of the cases above; number of cases involving diversion by license category

(since 1/1/2013)

Pharmacist: 6; license revoked in 5 cases

Pharmacist Intern: 2; license revoked in each case

Pharmacy Technicians: 13; license revoked in each case

Pharmacy Technician Diversions



Drug choice by Pharmacy Technicians continues to be:

- OxyContin
- Oxycodone
- Benzodiazepine
- Suboxone
- Hydrocodone, but since being reclassified in October 2014 as a CII drug, diversion for this drug appears to have decreased

Pharmacist Intern Self-Help



**Calling in a false prescription to a local pharmacy.
Case involved a non controlled drug/nasal inhaler...**

Pharmacist Diversions



Prior years, pharmacists chose prescription opiates. Today's noted trend, pharmacists appear to choose:

- Vyvanse
- Phentermine
- Nuvigil
- Provigil
- Trazodone
- Energy producing drugs to help them with keeping alert during work or personal time
- Sleep aids to off set the energy producing drugs

DIVERSON SCHEMES



- **Will call / pick up / Skimming off the top**
 - ✦ Holding back 1, 2, 3 + pills while filling a prescription/short changing the patient.
 - ✦ Taking pills directly from the stock bottle while filling a prescription.
 - ✦ While the prescription is in the 'will call' area waiting for pick up, technicians/cashiers are siphoning directly from the patient bottle.
 - ✦ Ordering drugs and intercepting the invoice and package upon delivery before the pharmacist could log the receipt of the drug. Suspect in this case diverted well into tens of thousands of prescription drugs.
 - ✦ A pharmacy technician responsible for ordering process in a hospital ordering more hydrocodone tablet than the pharmacy needed and manipulated the inventory to the tune of about 15,000 tablets.
 - ✦ A pharmacy technician accessing the pharmacy's inventory database and decreased the amount of hydrocodone tablets on hand that then notified automatically the wholesaler to ship more hydrocodone tablet that were then diverted upon receipt.
 - ✦ Siphoning liquid prescription opiates and replacing the liquid with water or saline solution.

Oversight & Vigilance



Maine require perpetual inventory for CIIs.
Federal regs require a complete inventory of all controlled drugs every two years.

HOW CAN YOU HELP

Not mandated, but if you do your part in conducting frequent inventory reconciliation of your all controlled drugs (e.g.. annual, PIC change), it will go a long way to you finding/discovering irregularities and likely catch the perpetrator quickly and stop the diversion sooner than later.

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PHARMACIST IN CHARGE (PIC) RESPONSIBILITIES

Maine Board of Pharmacy Rules

Chapter 13 Section 3 (2)



The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the retail pharmacy for which the licensee is registered as pharmacist in charge, and for the pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29, Section 1 of the board's rules. The responsibilities of the pharmacist in charge include, but are not limited to...

Maine Board of Pharmacy

Chapter 29 Section 1



1. Federal Food, Drug and Cosmetics Act, 21 USCS §301 et seq. (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)

2. Drug Abuse Prevention and Control law, 21 USCS §801 et seq., including but not limited to the Controlled Substances Act (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)

3. Fair Packaging and Labeling Act, 15 USCS §1451 et seq. (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)

4. Poison Prevention Packaging Act, 15 USCS §1471 et seq. (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)

Maine Board of Pharmacy

Chapter 29 Section 1



5. The following FDA rules, codified in 21 CFR (April 1, 2012)-

Part 200	General
Part 201	Labeling
Part 202	Prescription Drug Advertising
Part 203	Prescription Drug Marketing
Part 205	Guidelines for State Licensing of Wholesale Prescription Drug Distributors
Part 206	Imprinting of Solid Oral Dosage Form Drug Products for Human Use
Part 207	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
Part 208	Medication Guides for Prescription Drug Products
Part 209	Requirement for Authorized Dispensers and Pharmacies to Distribute a Side Effects Statement
Part 210*	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General
Part 211*	Current Good Manufacturing Practice for Finished Pharmaceuticals
Part 212	Current Good Manufacturing Practice for Positron Emission Tomography Drugs
Part 216	Pharmacy Compounding
Part 226	Current Good Manufacturing Practice for Type A Medicated Articles
Part 250	Special Requirements for Specific Human Drugs
Part 290	Controlled Drugs
Part 299	Drugs; Official Names and Established Names

*Does not apply to the compounding of sterile or non-sterile drugs by retail pharmacies pursuant to 32 MRSA §13702-A(4) and Chapter 13, Section 7 and Chapter 37 of the board's rules.

Maine Board of Pharmacy

Chapter 29 Section 1



6. The following DEA rules, codified in 21 CFR (April 1, 2012)—

Part 1300	Definitions
Part 1301	Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances
Part 1302	Labeling and Packaging Requirements for Controlled Substances
Part 1304	Records and Reports of Registrants
Part 1305	Order Forms
Part 1306	Prescriptions
Part 1307	Miscellaneous
Part 1308	Schedules of Controlled Substances
Part 1309	Registration of Manufacturers, Distributors, Importers and Exporters of List I Chemicals
Part 1310	Records and Reports of Listed Chemicals and Certain Machines
Part 1311	Requirements for Electronic Orders and Prescriptions
Part 1312	Importation and Exportation of Controlled Substances
Part 1313	Importation and Exportation of Precursors and Essential Chemicals
Part 1314	Retail Sale of Scheduled Listed Products

Maine Board of Pharmacy

Chapter 29 Section 1



7. The following rules of the Federal Trade Commission, codified in 16 CFR (January 1, 2013)—

Parts 500– 503	Rules, Regulations, Statement of General Policy or Interpretation and Exemptions Under the Fair Packaging and Labeling Act
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8. The following rules of the Consumer Product Safety Commission, codified in 16 CFR (January 1, 2013)—

Parts 1700– 1702	Poison Prevention Packaging Act of 1970 Regulations
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Maine Board of Pharmacy

Chapter 29 Section 1



9. The following law and rules relating to the federal/state Medicaid program (MaineCare), state nursing home licensure, and the state Medicaid plan—

42 USCS §1396r-8(g)	Grants to States for Medical Assistance Programs (drug use review) (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
42 CFR Part 456	Utilization Control (Centers for Medicare & Medicaid Services, Dept. of Health and Human Services, October 1, 2012)
10-144 Chapter 101, Chapter II, Section 80	MaineCare Benefits Manual – Pharmacy Services (Bureau of Medical Services, Dept. of Human Services, January 1, 2013)
Pp. 74a–74c	State Medicaid Plan (State Plan Under Title XIX of the Social Security Act (pp. 74a–74c approved May 24, 1993)
Ch. 110, Ch. 17	Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services (DHHS, February 1, 2001 edition, as amended effective October 15, 2004)

10. The following reference standards of the U.S. Pharmacopeia—

USP <795>	United States Pharmacopeia USP 36-NF 31, General Chapter <795>, Pharmaceutical Compounding – Nonsterile Preparations, 2013-14 edition, Vol. 1, p. 355
USP <797>	United States Pharmacopeia USP 36-NF 31, General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations, 2013-14 edition, Vol. 1, p. 361

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- **CORRESPONDING
RESPONSIBILITY**
- **REFUSAL TO FILL**

What is Corresponding Responsibility?

21 C.F.R. Section 1306.04 (a)



- A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately looks the other way when there is reason to believe that the purported prescription has not been issued for a legitimate medical purpose, may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.

Your Responsibilities



- You have a legal responsibility to acquaint yourself with the state and federal requirements for dispensing controlled substances
- You also have a legal and ethical responsibility to uphold these laws and to help protect society from drug abuse
- You have a personal responsibility to protect your practice from becoming an easy target for drug diversion
- You must become aware of the potential situations where drug diversion can occur and safeguards that can be enacted to prevent this diversion

Maine Board of Pharmacy Rules

Chapter 19 Section 11 (2)



Refusal to fill prescription, dispense drug or sell targeted methamphetamine precursor; law enforcement reporting

A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription, dispense any drug or sell any targeted methamphetamine precursor if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription or any person acting on behalf of the patient, or the intention of the customer to use the drug or targeted methamphetamine precursor according to the instructions for use. A pharmacist or person acting at the direction of a pharmacist may make a report to a law enforcement agency when that person has reasonable cause to suspect that a prescription is not legitimate or appropriate, that a person has presented photographic identification that is not valid or that a customer has the intention to use a drug or targeted methamphetamine precursor in a manner inconsistent with the directions for use.

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REPORTING/NOTIFICATION REQUIREMENTS

Maine Board of Pharmacy

Chapter 6-A Subchapter 1 Section 10



Theft or Drug-Related Misconduct of Pharmacy Intern

The preceptor shall notify the board via letter, fax or email of any resignation or discharge from an internship program or termination of employment for any of the following reasons, provided that the report shall be made by a pharmacist in charge or supervising pharmacist if the reason for the resignation, discharge or termination arose outside of the IPPE/APPE.

Notice shall be provided within 48 hours after the termination:

- 1) Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
- 2) Theft of non-drug merchandise; or
- 3) Theft of cash or credit/debit card data

Maine Board of Pharmacy

Chapter 6A Subchapter 2 Section 11



Theft or Drug-Related Misconduct of Pharmacy Intern

The pharmacist in charge or preceptor pharmacist shall notify the board via letter, fax or email of any resignation or discharge from an internship program or termination of employment for any of the following reasons. Notice shall be provided within 48 hours after the termination:

- 1) Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
- 2) Theft of non-drug merchandise; or
- 3) Theft of cash or credit/debit card data

Maine Board of Pharmacy

Chapter 7 Section 1 (5)

Chapter 7 Section 7-B (2)



Notice of Change of Work Site or Contact Address

A pharmacy technician shall notify the board of a change in work site, cessation of employment as a pharmacy technician or a change of contact address via letter, fax or email within 10 days after the change.

Notice of Employment and Non-Employment of Pharmacy Technicians

The pharmacist in charge shall notify the board via letter, fax, email or on line within 10 days after the commencement or cessation of employment of any pharmacy technician at a pharmacy for which the pharmacist in charge is responsible.

Maine Board of Pharmacy

Chapter 7 Section 7-B (3)



Notice of Termination of Employment For Drug-Related Reasons or Theft

The pharmacist in charge or a designee of the pharmacist in charge shall notify the board via letter, fax, email or on line of the termination of employment of a pharmacy technician for any of the following reasons and shall include in the notice the reason for the termination. Notice shall be provided within 7 days after the termination:

- A. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
- B. Theft of non-drug merchandise; or
- C. Theft of cash or credit/debit card data.

Maine Board of Pharmacy

Chapter 8 Section 6-A, Chapter 30 Section 1(26)



Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

A retail pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules:

Failure of a pharmacy to notify the board via letter, fax or email within 7 days of the termination of employment of a pharmacist for any of the following reasons, which must be included in the notice:

- A. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
- B. Theft of non-drug merchandise; or
- C. Theft of cash or credit/debit card data.

Maine Board of Pharmacy

Chapter 13 Section 6 (6)



Security Cameras

A retail pharmacy shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy department, including, at a minimum, the prescription filling area, self-service customer kiosks, dispensing machines that are part of an automated pharmacy system, controlled drug storage areas, the checkout area and compounding area (if applicable). The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A retail pharmacy shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

The requirement of security camera coverage of the compounding area (if applicable) and controlled drug storage areas went into effect on July 1, 2014.

Maine Board of Pharmacy

Chapter 23 Section 3



Reporting of Theft, Loss and Unresolved Inventory Discrepancies of Controlled Drugs

A pharmacist shall report any significant theft, loss or unresolved inventory discrepancy of controlled drugs to the board. The pharmacist shall make the report no later than 7 days after discovery of the theft, loss or inventory discrepancy. The report may be made via letter, facsimile transmission or email, must be signed by the pharmacist in charge or other pharmacist with knowledge of the situation, and must list the controlled drugs and quantities of same that were lost or stolen or cannot be accounted for. A pharmacist may satisfy the reporting obligation for controlled substances by filing Form 106 with the DEA and sending a copy to the board.

Maine Board of Pharmacy

Chapter 23 Section 3 Continued



When determining if a theft, loss or unresolved inventory discrepancy is “significant,” a pharmacist should consider, among others, the following factors:

- 1. The actual quantity of controlled substances lost in relating to the type of business;**
- 2. The specific controlled substances lost;**
- 3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;**
- 4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,**
- 5. Whether the specific controlled substances are likely candidates for diversion; and**
- 6. Local trends and other indicators of the diversion potential of the missing controlled substance.**

Maine Board of Pharmacy

Chapter 30 Section 1 (13,14)



Failing to establish and maintain effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels.

Being unable to practice pharmacy or perform the duties of a pharmacy intern or pharmacy technician with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition. A licensee affected under this subsection shall at reasonable intervals be afforded an opportunity to demonstrate that the licensee can resume the competent practice of pharmacy or competent performance of licensed duties with reasonable skill and safety to patients.

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BOARD INFORMATION

Maine Board of Pharmacy

Chapter 8 Section 6



Change of Owner, Location, or Pharmacist in Charge; Change in Other Registration Information

.... Upon a change of pharmacist in charge, the retail pharmacy shall file a new application with the board by registered mail no later than 7 days after the change....

Collaborative Drug Therapy Rules



Maine licensed pharmacists who meets the qualifications and requirements specified under 32 MRS §13842 and rules adopted by the board may engage in collaborative drug therapy management pursuant to a collaborative practice agreement with a practitioner.

The Board is actively working with the Maine Board of Licensure in Medicine on adopting a joint rule to implement collaborative drug therapy management. Expectation is that the joint proposed rule will be available for public comment later this Fall. Watch our website on the notice of proposed rulemaking.



**Maine Department of
Professional & Financial
Regulation**

**Office of Professional &
Occupational Regulation**

Board of Pharmacy

www.maine.gov/professionallicensing

**pharmacy.lic@maine.gov
(Licensing)**

**Pharmacy.board@maine.gov
(Board Business)**

Licensing (207) 624-8620

Complaints (207) 624-8621

Inspections/Investigations (207) 624-8604

Board Agendas (207) 624-8600

Board Administrator (207) 624-8625

Questions and Answers



1. Which two of the following drugs may be subject to pharmacist diversion given today's trend?
 - a) Trazodone
 - b) Morphine
 - c) Hydrocodone
 - d) Phentermine

2. Which of the following does not have to be reported to the Maine Board of Pharmacy?
 - a) Licensed employee terminated for theft
 - b) A licensee is conviction for operating under the influence
 - c) Traffic speed infraction
 - d) Significant loss of controlled drugs by a pharmacy

Questions and Answers, Con't



3. A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription, dispense any drug or sell any targeted methamphetamine precursor if unsatisfied for which of the following:
- a) The legitimacy or the appropriateness of a prescription presented
 - b) Validity of a photographic identification or the identify of a patient presenting a prescription or any person acting on behalf of the patient
 - c) Intention of the customer to use the drug or targeted methamphetamine precursor according to the instructions for use
 - d) All of the above
4. Upon discovery of a significant theft, loss or unresolved inventory discrepancy of controlled drugs, the pharmacist must file a report the Maine Board of Pharmacy no later than?
- a) 23 hours after discovery of the theft, loss or inventory discrepancy
 - b) 7 days after discovery of the theft, loss or inventory discrepancy
 - c) 10 days after discover of the theft, loss or inventory discrepancy
 - d) Not required to report the Maine Board of Pharmacy if reported to DEA on a Form DEA-106, Report of Theft or Loss of Controlled