



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

MARLON I. BROWN, DPA
DIRECTOR

MICHIGAN BOARD OF PHARMACY February 19, 2025, MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on February 19, 2025, at 611 West Ottawa Street, Upper-Level Conference Room 3, Lansing, Michigan 48933.

CALL TO ORDER

Michael Sleiman, PharmD, Chairperson, called the meeting to order at 10:00 a.m.

ROLL CALL

Members Present: Michael Sleiman, PharmD, Chairperson
Rony Foumia, R.Ph., Vice Chairperson
Keith Binion, BS, C.Ph.T.
Scott Ciarkowski, PharmD, MBA
Kyle McCree, Public Member
Kelli Oldham, Public Member
Grace Sesi, PharmD
Sandra Taylor, R.Ph., M.S.

Members Absent: Pierre Boutros, R.Ph.

Staff Present: Marshall Hooks, Senior Analyst, Compliance Section
Kim Smith, Board Support Technician,
Boards and Committees Section
Jennifer Shaltry, J.D., Departmental Specialist, Boards and
Committees Section
Dena Marks, J.D., Departmental Specialist, Boards and Committees
Section
Shermita Mitchell, Manager, Pharmacy and Drug Monitoring Section
Michele Wagner-Gutkowski, J.D., Assistant Attorney General
Janice Waldmiller, R.Ph., Pharmacy Specialist, Pharmacy and Drug
Monitoring Section.

APPROVAL OF AGENDA

MOTION by Foumia, seconded by Oldham, to approve the agenda as presented.

A voice vote followed.

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Binion seconded by Foumia, to approve the December 18, 2024, meeting minutes as written.

A voice vote followed.

MOTION PREVAILED

Just Culture Presentation from Nicole Chopski

This presentation is attached to the minutes. (Attachment #1)

Pharmacy Inspections: What to Expect and Common Violations

Mitchell and Waldmiller delivered this presentation. This presentation is attached to the minutes. (Attachment #2)

HPRP Annual Report

Marks explained Charlie Mollien is the current Pharmacy representative on the Health Professional Recovery Committee. Marks said that the number of pharmacy licensees in the program is down by 1. Marks also shared that the number of compliant closures has increased, and the number of non-compliant dismissals has decreased.

REGULATORY CONSIDERATIONS

Proposal for Decision

Manuel G. Francia

MOTION by Foumia, seconded by Oldham to discuss the matter.

Voice vote followed

MOTION PREVAILED

Discussion held

MOTION by McCree, seconded by Foumia to accept the Proposal for Decision and deny licensure.

A roll call vote was taken: Yeas: Binion, Ciarkowski, Foumia, McCree, Oldham, Sesi,
Taylor, Sleiman
Nays: None

MOTION PREVAILED

Hien Dien Ha, R. Ph.

MOTION by Taylor, seconded by Foumia to reinstate the license. Petitioner is placed on probation for 1 year with no violation of the Michigan Public Health Code.

A roll call vote was taken: Yeas: Binion, Ciarkowski, Foumia, McCree, Oldham, Sesi,
Taylor, Sleiman
Nays: None

MOTION PREVAILED

NEW BUSINESS

Continuing Education

Ciarkowski stated there were 7 continuing education programs approved this period. Ciarkowski directed the board to the list of continuing education programs for consideration (Attachment #3).

MOTION by Oldham, seconded by McCree to approve the continuing education program list as presented.

A roll call vote was taken: Yeas: Binion, Ciarkowski, Foumia, McCree, Oldham, Sesi,
Taylor, Sleiman
Nays: None

MOTION PREVAILED

Pharmacy Technician Training Program and Examination

Purpose Healthcare Training

MOTION by Foumia, seconded by Sesi to untable the matter.

MOTION PREVAILED

MOTION by Foumia, seconded by Ciarkowski to discuss the matter.

Voice vote followed.

MOTION PREVAILED

Discussion held.

MOTION by Oldham, seconded by McCree, to accept the training program and examination.

A roll call vote was taken: Yeas: Binion, Ciarkowski, Foumia, McCree, Oldham, Sesi,
Taylor, Sleiman
Nays: None

MOTION PREVAILED

Conflict of Interest

Shaltry went over the Conflict-of-Interest policy and form.

Credentials Verification

Shaltry went over the Credentials Verification Form with the board.

Rules Discussion

Shaltry presented the draft Pharmacy – Pharmacist Continuing Education rules.

Discussion was held.

MOTION by Foumia, seconded by Oldham to approve the draft rules as presented.

A roll call vote was taken: Yeas: Binion, Ciarkowski, Foumia, McCree, Oldham, Sesi,
Taylor, Sleiman
Nays: None

MOTION PREVAILED

Chair Report

Sleiman asked that the board members send any conflicts for the next meeting to Smith. Foumia and McCree are not able to attend the next board meeting.

Sesi asked who from the board will be attending the National Association of Boards of Pharmacy (NABP) Meeting in May. Sesi and Binion are planning to attend. The board will discuss the meeting further at the next meeting.

Department Update

Shaltry stated the New Board Member training is March 4, 2025 and encouraged all to attend.

Shaltry explained a new electronic form is being tested to verify attendance for pharmacists seeking continuing education credits.

PUBLIC COMMENT

Nichole Cover encouraged the board to make sure licensees and permit holders have a CQI program in place. Cover shared there was good language used by the state of New Jersey and would like to see it addressed. Cover also commented that licensees should not be required to use CE Broker.

Eric Roath from the Michigan Pharmacists Association shared concern regarding the Trump administration's recent executive order on diversity, equity, and inclusion initiatives. Roath shared that due to the vagaries associated with the scope and enforcement of these orders, they are doing an internal evaluation to see how to best comply as other associations across the nation. One area of concern that has been identified internally is their status as a provider of implicit bias training. Roath asks that LARA evaluate the continued legality of the implicit bias training requirement under the new executive orders.

ANNOUNCEMENTS

The next regularly scheduled meeting will be held April 16, 2025, at 10:00 a.m. at the Ottawa Building, 611 West Ottawa Street, Upper-Level Conference Center Room 3, Lansing, Michigan 48933.

ADJOURNMENT

MOTION by Foumia, seconded by Ciarkowski, to adjourn the meeting at 11:56 a.m.

A voice vote followed.

MOTION PREVAILED

Michigan Board of Pharmacy
Meeting Minutes
February 19, 2025
Page 6 of 6

Minutes approved by the board on: April 16, 2025

Prepared by:
Kim Smith, Board Support Technician
Bureau of Professional Licensing

February 27, 2025

Establishing a Culture of Safety

Nicki Chopski, PharmD, ANP
Executive Officer Idaho Board of Pharmacy
Bureau Chief Health Professions – Idaho Division of Occupational and Professional Licenses
nicki.chopski@dopl.idaho.gov

1

What is Just Culture?

What is it about?

- Creating a safe learning environment where individuals aren't afraid of speaking up.
- Moving beyond checkbox approach, enhancing education, and getting a holistic view (total picture).
- It's not seeing events as things to be fixed, but as opportunities to improve our understanding of risk whether it's system or behavioral.
- Not a blame or no-blame culture, individuals are held accountable for their choices.
- It is based on the idea that mistakes are inevitable and should be seen as learning opportunities.

2

Just Culture[®] - A Safety Science Framework

- Patient safety is the responsibility of the system and all individuals in the system
- Accountability from regulators is important, but is only one piece of the puzzle
 - What can the organization contribute to improve processes if only individuals are punished?
- A "just culture" balances safety and accountability and avoids blaming and shaming the individual
 - What is responsible versus who is responsible?
 - What can the organization invest in safety if they are not using resources to defend lawsuits?

3

3

Just Culture[®] – Why it matters?

- Accountability alone has unintended consequences
 - Regulators rely on those in the profession they regulate to report information they can act upon to resolve safety issues. Too much accountability results in less disclosure.
- No accountability can negatively impact the public's trust in the profession and the regulators
- A culture of shame and blame leads to burnout, decreased provider well-being (second victim)
- THE ULTIMATE: to prevent harm

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Goal of a Just Culture

- The goal is to create safe systems that will reduce the possibility for human error and capture errors before they reach the patient.
- Safe systems should facilitate those using the system to make good decisions and should make it more difficult to make an error. However, it is up to individuals to manage their behaviors and choices

5

A Model that
Focuses on Three
Duties balanced
against
Organizational and
Individual Values

The Three Duties of Just Culture©

- The duty to avoid causing unjustified risk or harm
- The duty to follow a procedural rule
- The duty to produce an outcome

Organizational and Individual Values

- Safety
- Cost
- Effectiveness
- Dignity

The Just Culture Company. (n.d.). <https://www.justculture.com/>

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Three Duties

Duty to avoid causing unjustifiable risk or harm.

- Values-focused
- “conduct unbecoming”
- Breach of this duty occurs when an individual intentionally harms a patient or acts recklessly.
- Did the employee put an organizational interest or value in harm’s way?

Duty to follow a procedural rule.

- Reliability focused
- “the recipe”
- If the individual knows the proper procedure and it is possible to follow the rule, failure to do so represents a breach of this duty.
- Did the employee breach a duty to follow a procedural rule in a system designed by the employer/organization?

Duty to produce an outcome.

- Mission-focused
- “the cake”
- If an individual knows the desired outcome and should be able to produce it, failure to do so represents breach of this duty.
- Did the employee breach a duty to produce an outcome?

The Just Culture Company. (n.d.). <https://www.justculture.com/>

7

The Five Behaviors

<div style="background-color: #4a7ebb; color: white; padding: 10px; border-radius: 10px; margin-bottom: 10px;">Human Error</div> <p style="font-size: small;">Unintended conduct: where the actor should have done other than what they did</p> <div style="background-color: #f4d03f; padding: 5px; border-radius: 5px; margin-top: 10px;">Accept</div>	<div style="background-color: #4a7ebb; color: white; padding: 10px; border-radius: 10px; margin-bottom: 10px;">At-Risk Behavior</div> <p style="font-size: small;">A choice where risk is not recognized, or is mistakenly believed to be justified</p> <div style="background-color: #f4d03f; padding: 5px; border-radius: 5px; margin-top: 10px;">Coach</div>	<div style="background-color: #4a7ebb; color: white; padding: 10px; border-radius: 10px; margin-bottom: 10px;">Reckless Behavior</div> <p style="font-size: small;">Conscious disregard of a substantial and unjustifiable risk of harm</p> <div style="background-color: #e74c3c; padding: 5px; border-radius: 5px; margin-top: 10px;">Sanction</div>	<div style="background-color: #4a7ebb; color: white; padding: 10px; border-radius: 10px; margin-bottom: 10px;">Knowledge</div> <p style="font-size: small;">Knowingly causing harm (sometimes justified)</p> <div style="background-color: #e74c3c; padding: 5px; border-radius: 5px; margin-top: 10px;">Sanction</div>	<div style="background-color: #4a7ebb; color: white; padding: 10px; border-radius: 10px; margin-bottom: 10px;">Purpose</div> <p style="font-size: small;">A purpose to cause harm (never justified)</p> <div style="background-color: #e74c3c; padding: 5px; border-radius: 5px; margin-top: 10px;">Sanction</div>
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The Just Culture Company. (n.d.). <https://www.justculture.com/>

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Response to Behavior

Human Error	At-Risk Behavior	Reckless Behavior	Knowledge	Purpose
<ul style="list-style-type: none"> • Manage through changes in: <ul style="list-style-type: none"> • Choices, Processes, Procedures, Training, Design, and Environment 	<ul style="list-style-type: none"> • Manage by: <ul style="list-style-type: none"> • Coaching • Creating incentives for healthy behaviors • Increasing situational awareness 	<ul style="list-style-type: none"> • Manage by: <ul style="list-style-type: none"> • Remedial action • Punitive action 	<ul style="list-style-type: none"> • Manage by: <ul style="list-style-type: none"> • Remedial action • Punitive action 	<ul style="list-style-type: none"> • Manage by: <ul style="list-style-type: none"> • Remedial action • Punitive action

The Just Culture Company. (n.d.). <https://www.justculture.com/>

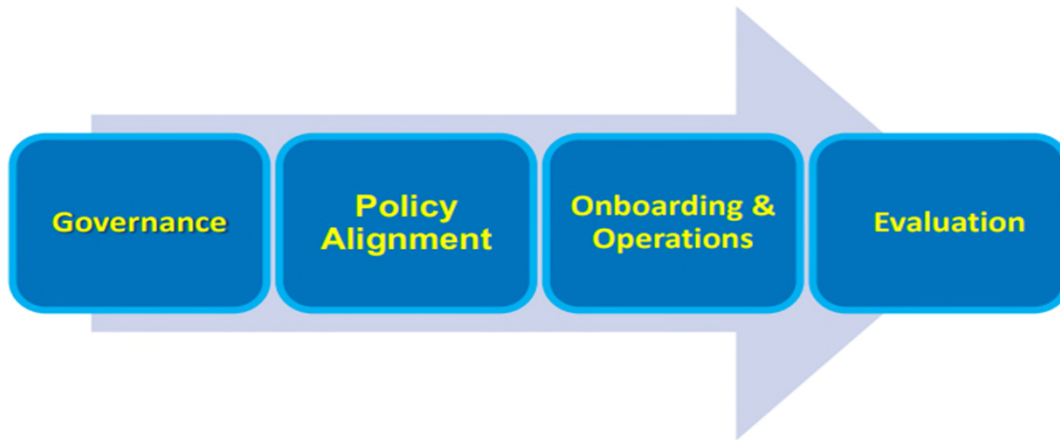
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Organizational Expectations

<div style="background-color: #f4a460; border-radius: 50%; width: 40px; height: 40px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">1</div> <p>Knowing risks</p> <ul style="list-style-type: none"> • Investigating the source of errors and at-risk behaviors • Turning events into an understanding of risk 	<div style="background-color: #c87157; border-radius: 50%; width: 40px; height: 40px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">2</div> <p>Designing safe systems</p> <ul style="list-style-type: none"> • Reduce possibility of errors • Facilitate good decisions 	<div style="background-color: #a69696; border-radius: 50%; width: 40px; height: 40px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">3</div> <p>Facilitating safe choices</p> <ul style="list-style-type: none"> • Consoling • Coaching • Punishing
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Just Culture Implementation: Processes



The Just Culture Company. (n.d.).
<https://www.justculture.com/>

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Individual Expectations



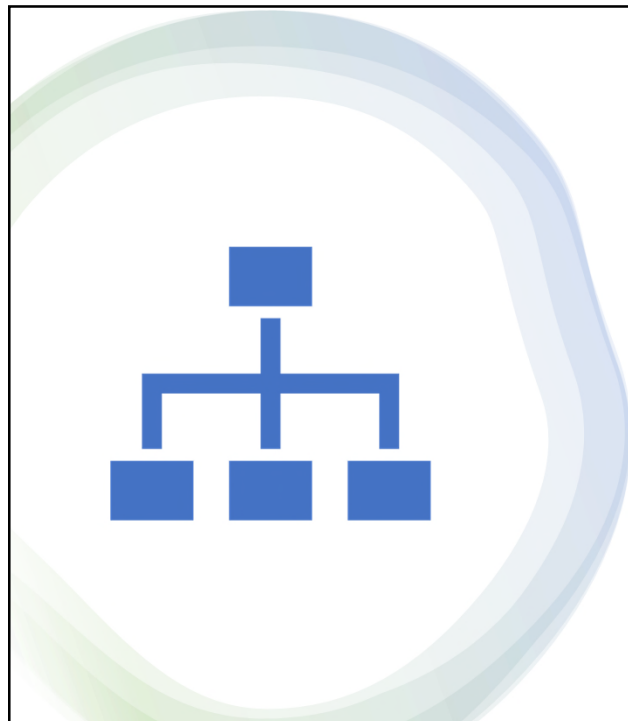
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Just Culture Implementation: People



The Just Culture Company. (n.d.).
<https://www.justculture.com/>

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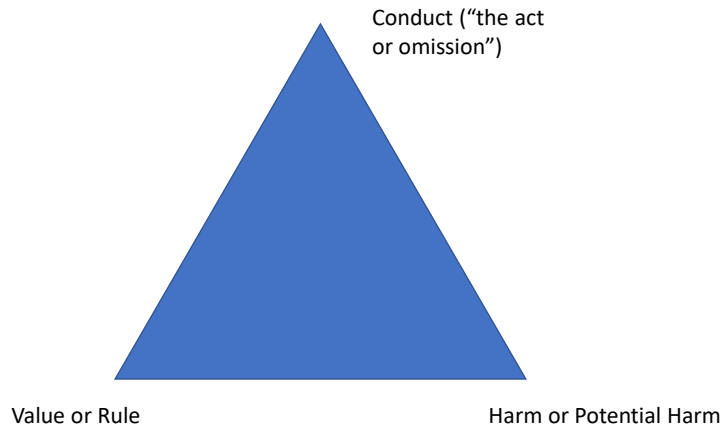
Just Culture Algorithm™

- Three sets of algorithms dependent on the duty breached.
- Within these algorithms are the five behaviors.
- They are a guide on how to address situations that may arise.

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Before Algorithm

“Magic Triangle”



Threshold Investigation

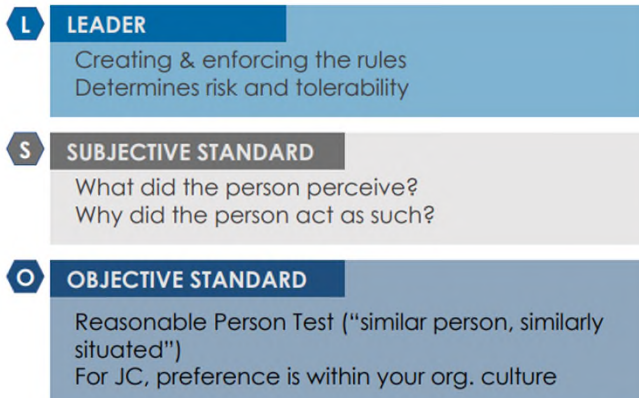
- What happened?
- What normally happens?
- What does procedure require?
- Why did it happen?
- How was the organization managing the risk?

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Before Algorithm Continued

- **Leader**
 - Perspective in the organization who deals with rules and their enforcement.
 - Was there a greater good or social benefit that exceeded risk of deviating from the rule?
- **Subjective Standard**
 - The person in the situation.
 - What they know and think about the situation that occurred.
- **Objective Standard**
 - Why did a person’s choices make sense on a given day?
 - Would someone else have done the same?

The Three “Voices”



The Just Culture Company. (n.d.).
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Example of Using Algorithm

Duty to Avoid Causing Unjustifiable Risk or Harm

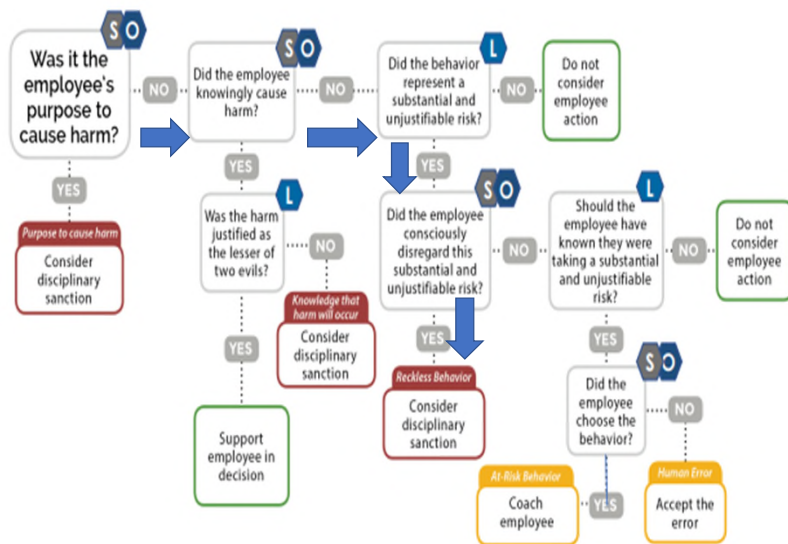
Scenario:

- A veterinarian issued a hard copy prescription for potassium bromide 1000 mg oral suspension daily for a canine with a seizure disorder. Pharmacist dispensed potassium chloride because potassium bromide isn't stocked by the pharmacy. The pharmacist assumed that the substitution could be made and did not reach out to the veterinarian to get authorization to make the change. Patient did not get treated for the seizure disorder and the pharmacist put the patient at risk for suffering from unnecessary amounts of potassium.

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Duty to Avoid Causing Unjustifiable Risk or Harm



The Just Culture Company. (n.d.).
<https://www.justculture.com/>

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What is Expected in a Board Investigation in ID?

- Analysis of the quality of the decision making, not the quality of the outcome
- All parties are to respond (organization, pharmacist, +/- tech)
- Creative, innovated solutions to the problem that can be implemented
 - Additional policy, review of policy, and “retraining” is not enough
- Authentic organizational engagement to drive problem solving

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So, how's it going and what's been learned?

- More than 30 caps issued in FY2022
- Initial hesitancy by companies to engage improving
- Overall system improvement; although difficult to quantify
- Pharmacists - no formal discipline
- Process must involve tech, pharmacist, and facility to make meaningful change

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Summary: How does this help the front line?

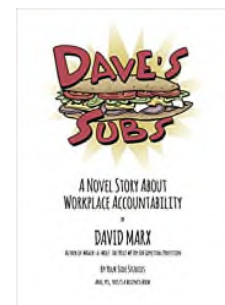
- Encourage safety culture within individual and organizational practice
- Propose process improvement
- Engage with a PSO if not already; Ask for analysis of data
- Respectfully approach the organization or BOP with suggestion

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Resources

- [The Just Culture Company – The Learning Resource for Just Culture Proficiency](#)
- [Just Culture in Health Care | Balancing Safety and Accountability](#)
- [Institute for Safe Medication Practices](#)
- [Assess-ERR™ Medication System Worksheets](#)
- [Center for Patient Safety](#)
- [Patient Safety Organizations](#)
- [NABP Task Force Report: Safety Sensitive Measures to Review Medication Errors](#)



Whack
· a ·
Mole

THE PRICE WE PAY
FOR EXPECTING PERFECTION

David Marx

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References

- [The Just Culture Company – The Learning Resource for Just Culture Proficiency](#)
- [Just Culture in Health Care | Balancing Safety and Accountability](#)
- [Cohort 3.3 2023 e-Learning Three Day Handouts.pdf](#)

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Questions?

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Pharmacy Inspections: What to Expect and Common Violations

February 19, 2025

Presented by:

Shermita Mitchell, Manager
Janice Waldmiller, R.Ph. Pharmacy Specialist
Pharmacy and Drug Monitoring Section
Bureau of Professional Licensing

1



Speaker Introduction Shermita Mitchell and Janice Waldmiller



In June 2014, Shermita Mitchell began working with the Bureau of Professional Licensing as a Departmental Analyst in the Regulation Section. In 2016, she became a Regulation Agent with the Pharmacy and Drug Monitoring Section (PDMS) and in 2023, she became the manager of the section. Ms. Mitchell holds a Master of Business Administration (MBA) from Wayne State University. Additionally, Ms. Mitchell is matriculating at Liberty University to obtain her Doctorate of Business Administration (DBA) – healthcare administration .

After graduating from Ferris State University College of Pharmacy in 1995, Janice Waldmiller worked in the retail practice setting of pharmacy. Ms. Waldmiller began working for the State of Michigan as a Pharmacy Specialist in 2010. Ms. Waldmiller's current responsibilities are conducting inspections of multiple practice settings and types, conducting investigations and analyzing MAPS data.

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Introduction

Pharmacy & Drug Monitoring Section

- Field staff consists of 6 pharmacy specialists and 5 regulation agents
- Responsibilities include but are not limited to:
 - Investigations - on behalf of several boards (Pharmacy, Medicine, Osteopathic Medicine, Physician Assistants, and Nursing, Dentistry, and Veterinary Medicine)
 - Drug diversion
 - Overprescribing of controlled substances
 - Overdispensing of controlled substances
 - Substandard practice of pharmacy (ex. health care fraud, dispensing errors)
 - Inspections



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Inspections

- PDMS personnel conduct site inspections for all new in-state pharmacy and wholesaler applicants (pre-licensure) which includes relocations
 - Caution: do not move to a new location without DEA approval and Department approval
 - Certificate of Occupancy required in most instances to ensure the building is suitable for a pharmacy
 - Verification of PIC
- Animal shelter applicants or relocation applicants are site-inspected when applying for licenses to use pentobarbital & Rx tranquilizers
- Research and analytical lab applicants inspected as appropriate on a case-by-case basis
- Random inspections of retail and long-term care pharmacies on a county-by-county basis
- Sterile and non-sterile compounding inspections on a county-by-county basis
- Drug Control License (DCL) inspections as appropriate
- During an authorized investigations, inspections are routinely performed, particularly if the allegation relates to inappropriate dispensing or fraud
- Disciplinary monitoring inspections of licensees on probation are conducted as dictated by Board order



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Other Entities Who Conduct Inspections

- Sterile compounders must obtain a Board-approved accreditation (always includes an inspection) every other year in most cases. R 338.534a – within 6 months after initial licensure, shall obtain and provide to the Department an inspection to assess USP compliance
- FDA conducts some inspections of Pharmacies – FDA has jurisdiction due to interstate commerce. LARA may accompany or receive referral letter from FDA.
 - FDA may notify the Bureau, who may participate or observe these inspections
- Insurance Companies and PBMs – Department Notified of the Results
 - Fraud Waste and Abuse
 - Concerns with controlled substance storage and potential diversion



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Regulations and Rules

- Michigan Public Health Code (MCL) – statutes (laws)
- Article 15 of Public Health Code – covers General Provisions for all Health Professions
- Article 7 of Public Health Code – covers controlled substances
- Administrative Rules for the Board of Pharmacy – rules clarifying statute



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What to Expect During Inspection

- Inspector provides identification and business card
- Tour of the pharmacy
- Observations
- Document review including policy and procedures
- Questions specific to the inspection
- Audits of controlled substances and prescriptions in will call
- Feedback regarding deficiencies found during inspection
- Inspection emailed later



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Common Inspection Violations

- Licenses Displayed and Individuals Licensed
 - MCL 333.16191(2) - licenses shall be displayed “prominently and where visible to the public” and current
 - MCL 333.17739(2) - Technicians must be licensed
 - R 338.3655(4) – maintain records of technician training program: name, DOB, starting date
 - R 338.3655(5) – completed technician training program within 2 years
 - R 338.589 (5)(c) – Delegation policy and procedures
 - MCL 333.17739a(3) – A pharmacist shall not allow an unlicensed individual to work as a technician; note that this applies to any pharmacist, not just the PIC



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Common Inspection Violations

- Pharmacist-in-Charge

- MCL 333.17748(4) Change in PIC not reported to Department within 30 days
 - This can be done directly by logging into MiPlus Account, no paper changes.
 - Can also send email to bplhelp@Michigan.gov
 - Displayed on LARA Public Website
- R 338.531(2)(d) – if PIC unable to fulfill duties for 120 consecutive days, shall appoint a new PIC and notify the Department



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Common Inspection Violations

- Quality and Purity of medications
 - R 338.589(1) A Pharmacist has the professional responsibility for the strength, quality, purity and labeling of all drugs...
 - Temperature and humidity monitoring
 - excursion plan
 - R 338.537(2)(b) - ...temperatures must be monitored at all times for out-of-range...during business closure
 - Expired medications
 - including a labeled quarantine area
 - Unlabeled and incorrectly labeled medications in general stock
 - Return to stock medications placed in stock bottle and missing information required (manufacture, expiration date, name and strength of medication)
 - MCL 333.17762(1) – misbranded medications

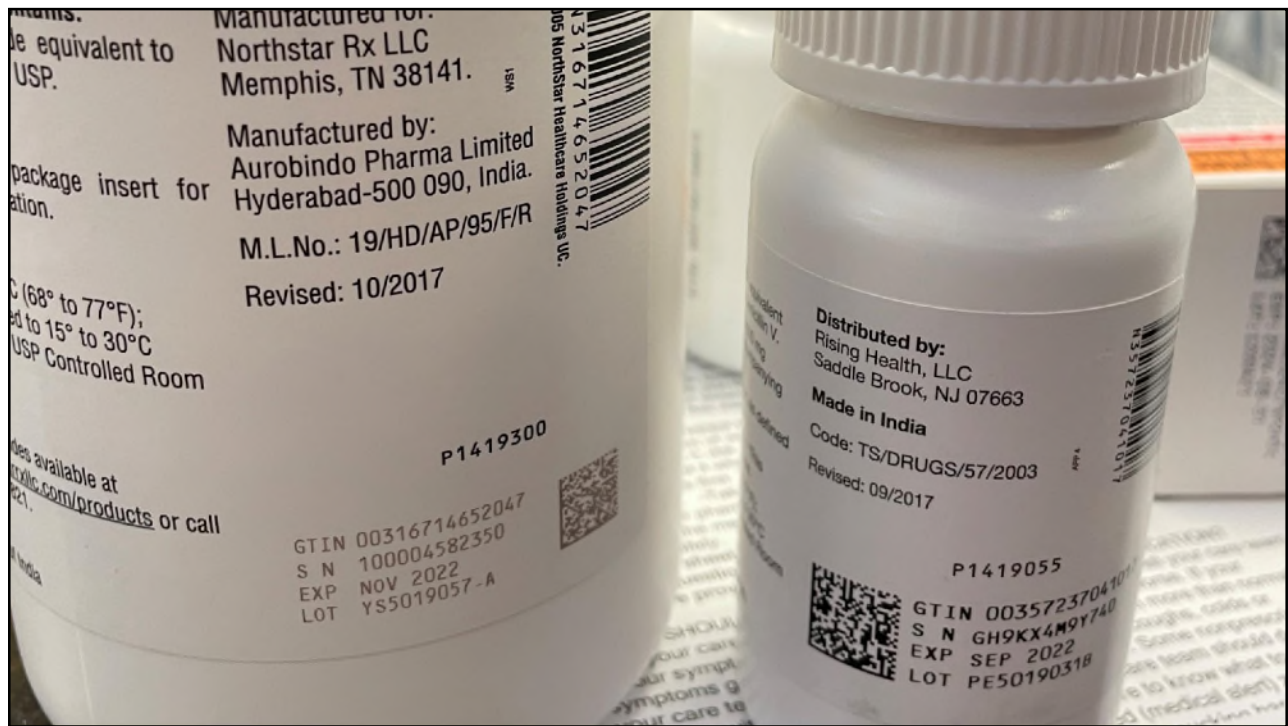


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Common Inspection Violations

- Quality and Purity of medications
 - R 338.585 Custom Patient Medication Packages (CPMP) - a package which is prepared by a pharmacist for a specific patient and which contains 2 or more prescribed solid oral dosage forms.
 - (2)(a)(i) - serial number must be recorded on labels.
 - (2)(a)(vi) - 60-day expiration date (or earlier).
 - (2)(g) - log for each CPMP shall be made and filed
 - patient name/address
 - serial number
 - date & expiration date
 - label
 - Pharmacist's initials
 - Blister packaging (Bingo cards) – six month expiration date, if not labeled as unit dose (full manufacture information on the back of each tablet)



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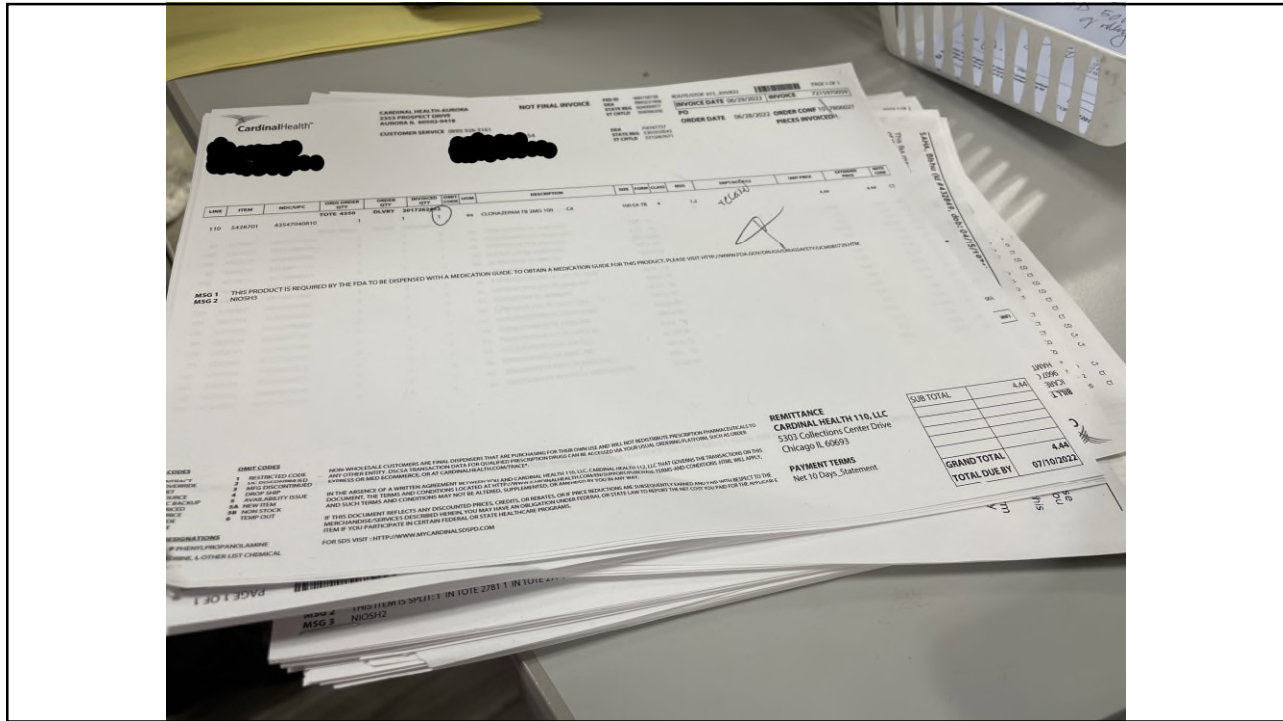
Common Inspection Violations

- Controlled Substance Records
 - MCL 333.7321 Compliance with controlled substance records (per Federal and State regulations)
 - (1) – DEA form 222 not complete – incomplete CSOS records on computer
 - (2) – Daily attest statements along with 21 CFR 1305.22(f)(3) –sign at end of day
 - (3) – Annual inventory not available for inspection – signed, dated, time of day
 - R 338.3151(3) - change in PIC inventories
 - R 338.3153- invoices not signed (or electronically signed) and dated by a Licensee (pharmacist)



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Common Inspection Violations

- Equipment, Supplies, references, and housing
 - R 338.536 – Housing
 - Clean and sanitary surroundings
 - Sufficient counter space and free movement
 - Floor to ceiling partitions
 - R 338.537(1)(b) – two current references and able to access laws and rules of this state
 - R 338.537(2)(b) – personal or food items must not be store in refrigerator



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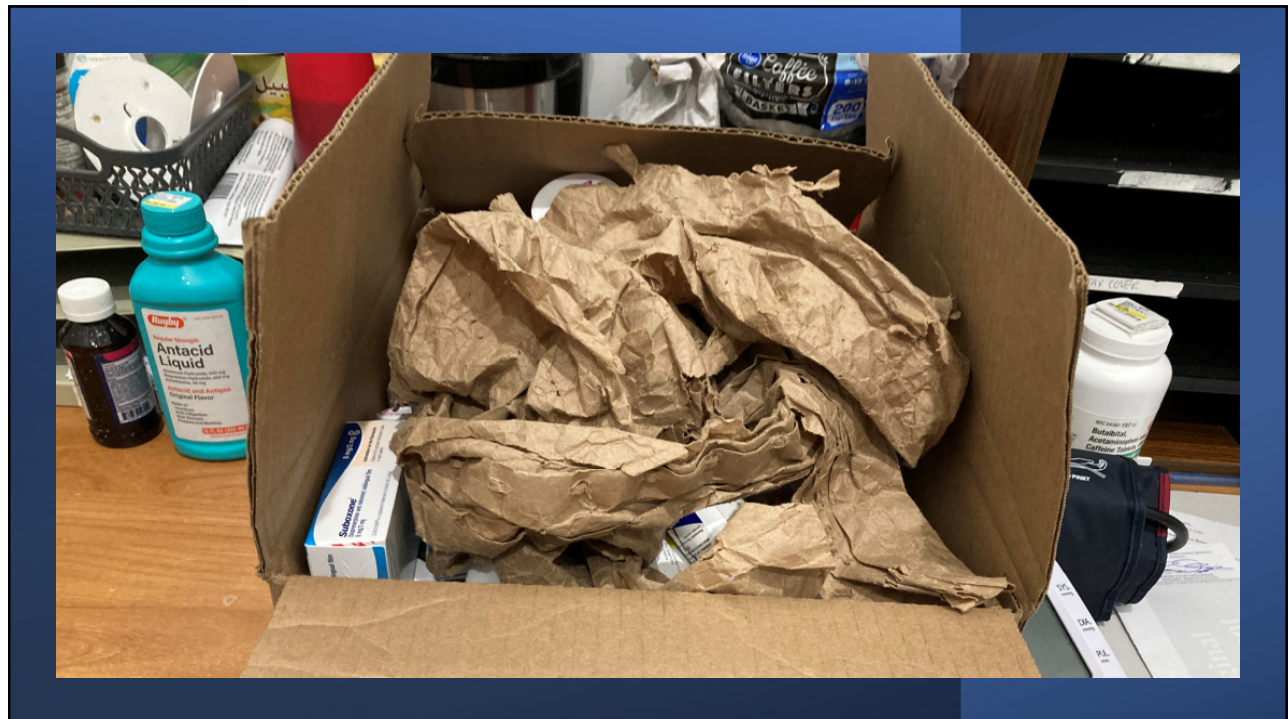
Common Inspection Violations

- Security of Pharmacy and Effective Controls
 - R 338.3141(1) Security of pharmacy and effective controls against theft and diversion
 - MCL 333.17741 – A pharmacy open for business shall be under the personal charge of a pharmacist
 - R 338.3141(3) – report of significant theft or loss of controlled substance within 45 days after completion of an investigation to the Department (State of Michigan) by submitting DEA 106 form
 - Ability to reconcile controlled substances
 - Theft/Loss
 - Audit
 - R 338.3143(2) – storage of schedule II controlled substances, locked or dispersed



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Common Inspection Violations

- Compounding
 - R 338.533(1) and (3) – compliance with USP
 - USP 795
 - Training – Section 2
 - Documentation/Records – Section 7
 - Labeling – Section 9
 - Lot number and expiration date – Section 7
 - USP 797
 - Integrity of the surfaces, peeling paint, rusting equipment – Section 4.3.1
 - Dusty areas in clean room – Section 7
 - Total volume – Section 11.2 Box 10
 - Updated BUDs
 - Visual description and inspection – Section 12.1
 - Time of preparation, lot number and expiration date – Section 11.2 Box 10 and 13
 - USP 800
 - Labeling of Hazardous Area – Section 5



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Common Inspection Violations

- Miscellaneous
 - R 338.538(1) – ceasing operations shall provide the Department with written notification, not less than 15 days before closing
 - Date of closing
 - Disposition of controlled and non-controlled substances
 - Location of prescription files to be stored
 - R 338.538(3) – records maintained for same amount of time if pharmacy was still open
 - R 338.503(1) – drugs dispensed and left the control of the pharmacist must not be returned or exchanged for resale – including for destruction



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Common Inspection Violations

- Miscellaneous
 - MCL 333.17741(3) – responsible for compliance with federal and state laws regarding distribution of drugs and practice of pharmacy
 - DSCSA (Drug Supply Chain Security Act)
 - Aware of
 - Know your suppliers
 - Able to show how to locate product tracing
 - How to handle suspected illegitimate drugs
 - Policy and procedures
 - [Pharmacists: Utilize DSCSA Requirements to Protect Your Patients | FDA](#)
 - R 338.486(4)(g) – medical institution inspection all areas of medication storage, safe use and storage conditions
 - Security and temperature monitoring
 - R 338.536(3) – rx only drugs only obtainable when pharmacist present



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Thank you!



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PHARMACY CONTINUING EDUCATION REVIEW

February 19, 2025

RECOMMENDED APPROVAL(S)

Approval from February 19, 2025 – February 28, 2028.

* Each program listed under the sponsor's name will be given a separate approval number.

Ascension Genesys Hospital

- *Flavors of Special K: Understanding Ketamine's Role in Rapid Sequence Intubation, Sedation, and Pain Management* (for pharmacists and pharmacy technicians) for 1 hour.
- *In the Grip of Seizures: A Closer Look at Status Epilepticus* (for pharmacists and pharmacy technicians) for 1 hour.

Henry Ford St. John Hospital

- *Factor in the Solution: A Review of Blood Factors & treatment of Acute Bleeding* (for pharmacists) for 0.5 hour.
- *Resistance Isn't Futile – Resistant Hypertension* (for pharmacists) for 0.5 hour.
- *Reversal Showdown – Andexxa vs. Kcentra in Anticoagulation Reversal* (for pharmacists and pharmacy technicians) for 0.5 hour.
- *SOS Strategies for Substance Use Disorder Treatment* (for pharmacists) for 0.5 hour.

Michigan Center for Rural Health

- *Pharmacy Grand Rounds: Mash IT, Not Nash It* (for pharmacists and pharmacy technicians) for 1.0 hour.