



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

MARLON I. BROWN, DPA
ACTING DIRECTOR

MICHIGAN BOARD OF PHARMACY FEBRUARY 14, 2024, MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on February 14, 2024, at 611 West Ottawa Street, Upper-Level Conference Room 3, Lansing, Michigan 48933.

CALL TO ORDER

Grace Sesi, PharmD, Chairperson, called the meeting to order at 10:02 a.m.

ROLL CALL

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

Members Absent: None

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

APPROVAL OF AGENDA

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

A voice vote followed.

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Oldham, seconded by McCree, to approve the December 20, 2023, meeting minutes as written.

A voice vote followed.

MOTION PREVAILED

HPRP Annual Report

Marks supplied a brief overview of the HPRP program and presented the HPRP Executive Summary: October 1, 2022, through September 30, 2023.

Pharmacy & Drug Monitoring Section Presentation

Mitchell and Waldmiller gave a presentation titled "Pharmacy Inspections: What to Expect and Common Violations" (Attachment #1).

REGULATORY CONSIDERATIONS

None

OLD BUSINESS

None

NEW BUSINESS

Conflict of Interest

Shaltry provided an overview of Policy G-06, Conflict of Interest for Boards, Commissions, Authorities, and Committees. Shaltry and Wysack helped the members with completion of the Disclosure of Interest form (C-46).

Credentials Verification

Shaltry stated that to keep accurate records, the department was asking for verification of credentials of all board members.

Continuing Education

Foumia directed the board to the list of continuing education programs for consideration (Attachment #2).

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

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

MOTION PREVAILED

Pharmacy Technician Programs and/or Examinations

Thunder Bay Pharmacy

Binion recused.

Ciarkowski stated that the pharmacy technician committee recommended approval of the pharmacy technician program and examination.

MOTION by Fournia, seconded by Taylor, to accept the recommendation of the committee and approve the pharmacy technician training program and examination.

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

MOTION PREVAILED

Pharmacy Technician Examination Modification

HealthMart Systems, Inc.

Binion recused.

Ciarkowski stated that the pharmacy technician committee recommended approval of the pharmacy technician examination modification.

MOTION by Boutros, seconded by McCree, to accept the recommendation of the committee to approve the pharmacy technician examination modification.

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

MOTION PREVAILED

Chair Report

Sesi stated that a voting delegate needed to be selected for the 120th NABP Annual meeting will be held on May 14 – 17, 2024 in Fort Worth, Texas. Foumia will be the voting delegate with Binion as the alternate delegate.

Sesi encouraged board members to attend the 2024 91st Annual District IV meeting that will be held from September 18 – 20, 2024, in Detroit, Michigan.

Department Update

Shaltry stated that the Pharmacy – General Rules are currently with the Joint Committee on Administrative Rules (JCAR), the Controlled Substance rules are with Legislative Service Bureau (LSB), and the Program for Utilization of Unused Prescription Drugs rules are being prepared for the second public hearing.

Shaltry stated that the bureau will hold the next board member training on February 20, 2024, via Zoom. All board members are welcome to attend.

Wysack reminded board members to check their state email on a regular basis as this is the form of communication with the department.

Wagner-Gutkowski reminded board members to be cognizant of quorum, which is six members, when attending the 120th NABP Annual meeting and having conversations.

Wysack announced to the board that she had taken a promotion within the bureau and that today would be her last meeting with them.

PUBLIC COMMENT

None

ANNOUNCEMENTS

The next regularly scheduled meeting will be held April 23, 2024, 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 Boutros, seconded by Fournia, to adjourn the meeting at 11:00 a.m.

A voice vote followed.

MOTION PREVAILED

Minutes approved by the Board on April 23, 2024.

Prepared by:
Stephanie Wysack, Board Support Technician
Bureau of Professional Licensing

February 14, 2024

Pharmacy Inspections: What to Expect and Common Violations

February 14, 2024 Presented by:
Shermita Mitchell, Manager
Janice Waldmiller, R.Ph.
Pharmacy Specialist Pharmacy
and Drug Monitoring Section
Bureau of Professional Licensing



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.



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
 - Certificate of Occupancy required in most instances to ensure the building is suitable for a pharmacy under Michigan Admin Code, R 338.482
 - 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

Other Entities Who Conduct Inspections

- Sterile compounders must obtain a Board-approved accreditation (always includes an inspection) every other year in most cases.
- 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



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

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
- Inspection emailed later

Common Inspection Violations

- Licenses Displayed and Individuals Licensed
 - MCL 333.16191(2) - licenses shall be displayed “prominently and where visible to the public”
 - MCL 333.17739(2) Technicians must be licensed.
 - 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.





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



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 monitoring
 - Expired medications
 - 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)

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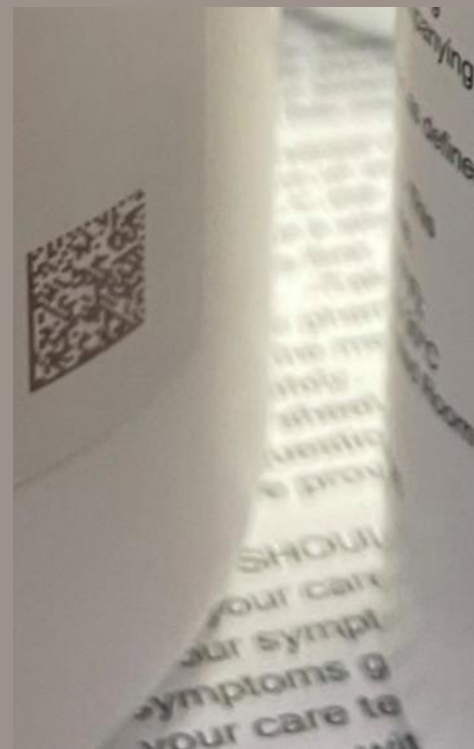
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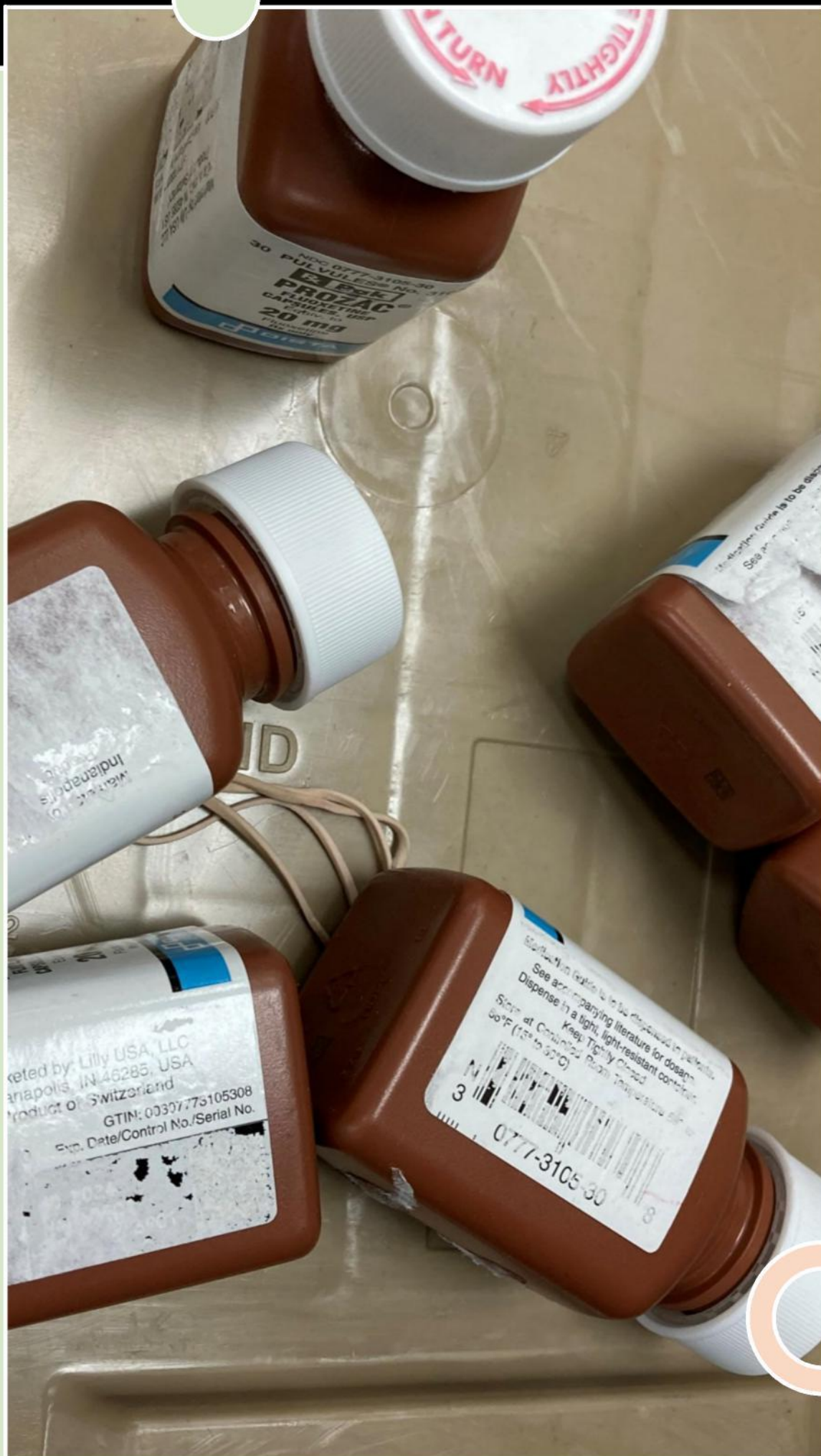


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Common Inspection Violations

- 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



Reorder



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
 - (2) – Daily attest statements along with 21 CFR 1305.22(f)(3)
 - (3) – Annual inventory not available for inspection
 - R 338.3153- invoices not signed (or electronically signed) and dated by a Licensee (pharmacist)

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SUB TOTAL	4.44
GRAND TOTAL	4.44
TOTAL DUE BY	07/10/2022

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

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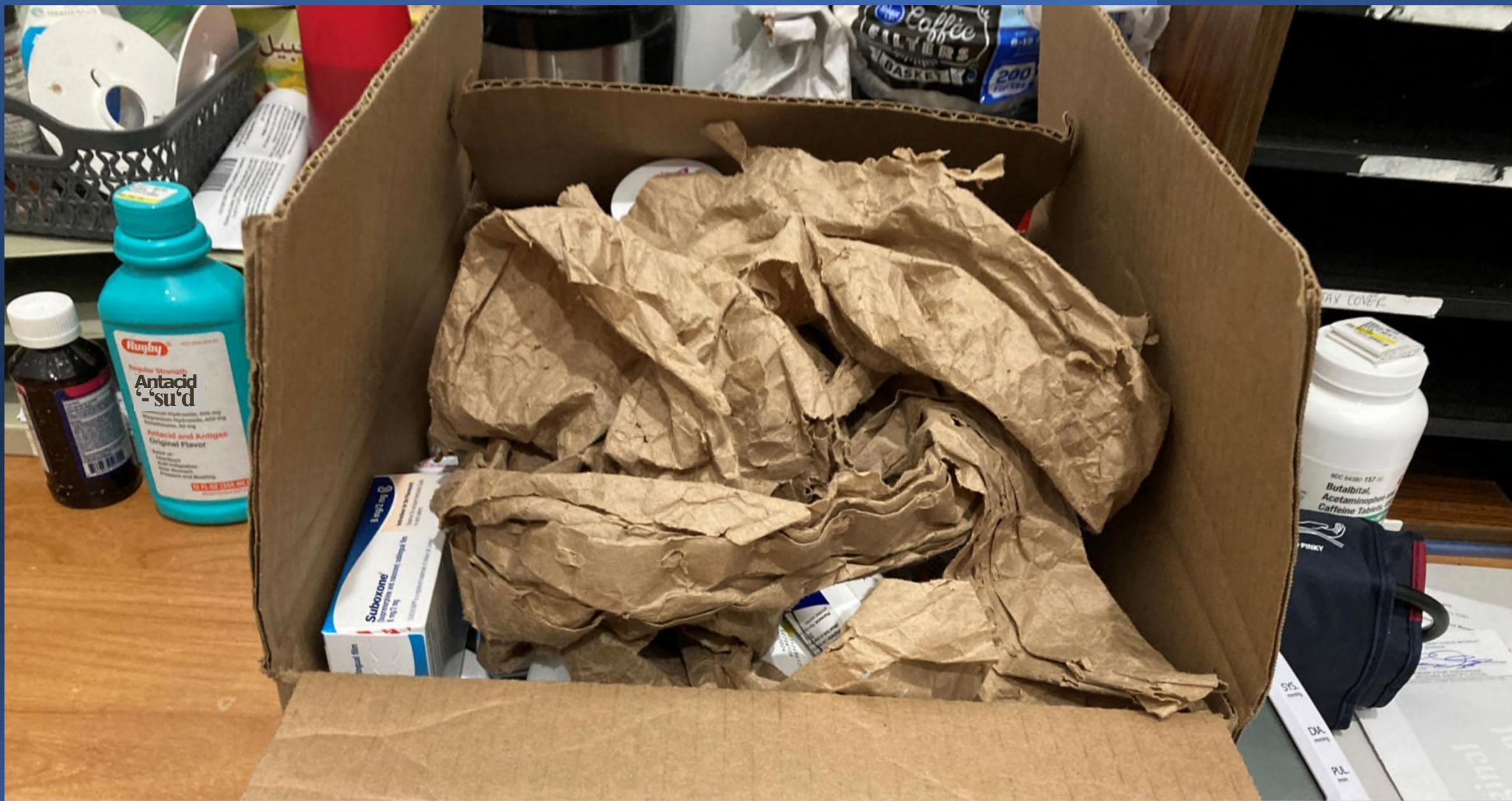


Common Inspection Violations

- 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(2) – report of theft or loss within 10 days to the Department (State of Michigan) by submitting DEA 106 form
 - Ability to reconcile controlled substances
 - Theft/Loss
 - audit



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Questions?

Thank you!



PHARMACY CONTINUING EDUCATION REVIEW

February 14, 2024

RECOMMENDED APPROVAL(S)

Approval from February 14, 2024 to February 28, 2027.

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

Ascension St. John Hospital, Department of Inpatient Services

- Use of Direct Oral Anticoagulants in Special Populations (pharmacists) for 0.5 hours
- An Update on SGLT2 Inhibitors (pharmacists) for 0.5 hours
- Management of Cirrhosis and Related Complications (pharmacists) for 0.5 hours
- A Comprehensive Overview of Opioid Use Disorder and Medication-Assisted Treatment (pharmacists) for 0.5 hours

Ascension Genesys Hospital

- Beyond Benzodiazepines: Exploring the Role of Phenobarbital for Alcohol Withdrawal Syndrome (pharmacists and pharmacy technicians) for 1 hour
- Chilling Out for a Better Outcome: Exploring Targeted Temperature Management After Cardiac Arrest (pharmacists and pharmacy technicians) for 1 hour
- Dialogue Dynamics: Mastering Crucial Conversations for Continued Growth (pharmacists and pharmacy technicians) for 1 hour
- Uses of Tenecteplase for Ischemic Stroke: A Guideline Update (pharmacists and pharmacy technicians) for 1 hour

Ascension Providence Hospital, Department of Pharmacy Services

- Know Your Role – An Introduction to Gen Z & How to Precept Your Pharmacy Students (pharmacists) for 1 hour