OhioHealth Pharmacy Services 2021 Law Update

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Disclosures

- Laura Duvall – Nothing to disclose
- Heidi Haldiman – Nothing to disclose
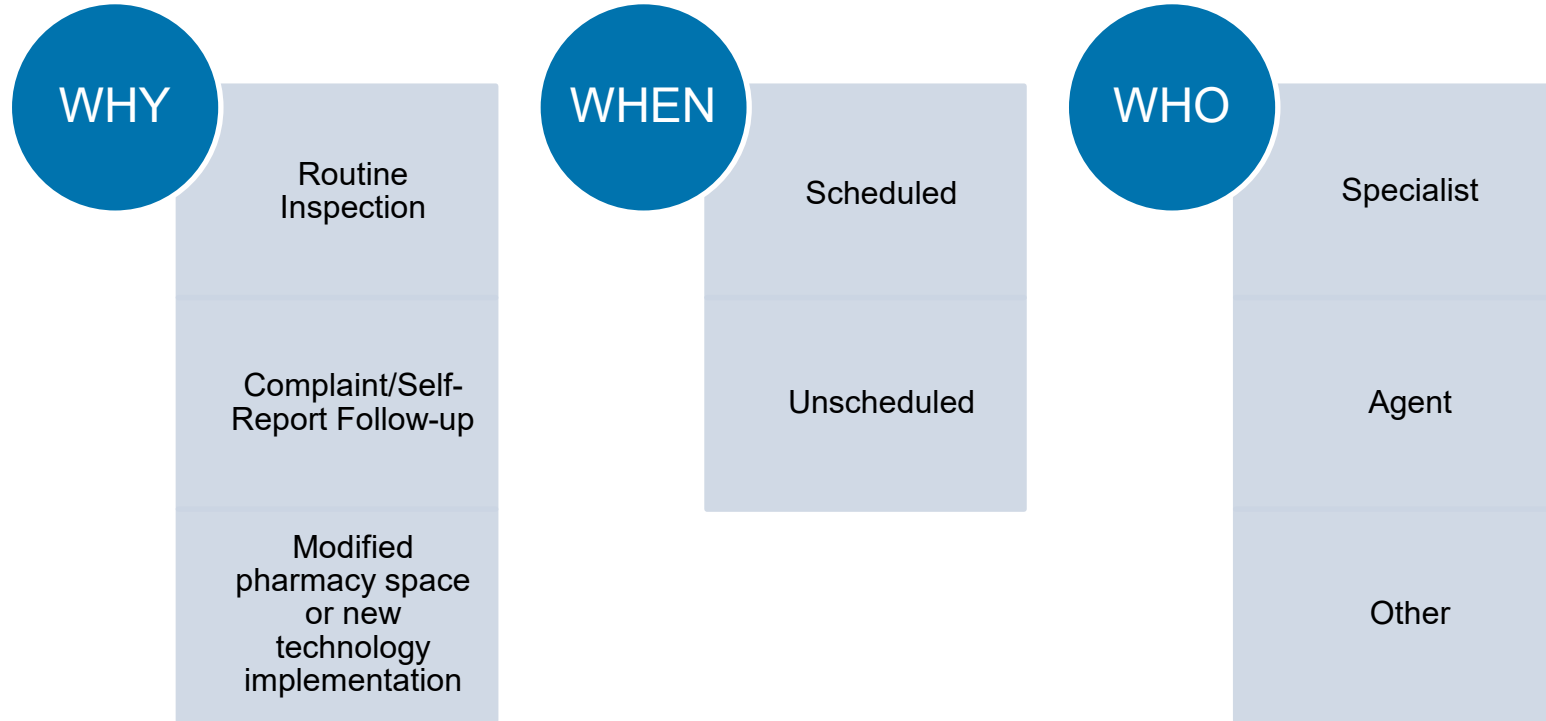- Elizabeth Dallman – Nothing to disclose

Learning Objectives

- Describe what to expect during a board of pharmacy site visit or inspection

- State the deadline for pharmacist license renewal in 2021

Board Visits / Inspections

The Ohio Board of Pharmacy

- Agency responsible for administering and enforcing laws governing the practice of pharmacy and the legal distribution of drugs in Ohio

- OAC vs. ORC

Board of Pharmacy Visits

WHY

- Routine Inspection
- Complaint/Self-Report Follow-up
- Modified pharmacy space or new technology implementation

WHEN

- Scheduled
- Unscheduled

WHO

- Specialist
- Agent
- Other

What will be inspected?

- Routine Inspections → will use applicable inspection guides
- Complaint/Issue Follow-ups → likely more targeted
- Pharmacy modifications/new implementations → likely more targeted

Once they are in the door, anything is fair game

What will occur during the visit?

Tour

Policy Review

Q&A

Demonstration

Observation

Staff Interviews

Common Topics

- Pharmacy security
- Controlled substances
- Positive ID
- Labeling
- Sterile compounding

Common Findings

- General
  - Unlicensed technicians
  - Technicians practicing beyond their scope
  - Missing required records and documentation
  - Not capturing positive ID

- Sterile Compounding
  - Break in aseptic technique
  - Improper response to failed room certifications & excursions
  - Lack of documented training & competencies
  - Improper response to failed media-fill tests and gloved fingertip sampling

The Basics – What YOU Can Do

YOU

Wear your name badge

Keep food & drinks away from medications

Know & follow policies

Be courteous & respectful

Keeping Yourself Informed

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Pharmacy Record Keeping

General Record Keeping Requirements

- Required records must be kept for **3 years.**
- Records must be kept **on-site** OR have approval from the board to store elsewhere.
- Records are kept under supervision & restricted access.
- Computerized records must have daily back-up functionality

NOTE: Controlled substance (DEA) records must be kept separately

Types of Records ** Not All Inclusive

Medication Use Process POSITIVE ID

- Receiving/Stocking CII-CV
- Actions Taken as Part of a Consult Agreement
- Order Entry
- Repackaging/Compounding
- Barcode Creation/Association
- Product Verification Prior to Distribution (Both Patient Specific & Non-Patient Specific)
- Drug Administration

Movement of Drug

- Receipt of all Drugs Purchased
- Transfers to other Terminal Distributors
- Storage Conditions (Temperature)
- CS Inventory
- Distribution of Non-Patient Specific Drugs Throughout Institution (Including Pyxis Transaction Information)
- Drug Destruction/Disposal

Other Records

- Licensure/Registration (Pharmacy AND Staff)
- Staff Training
- Compounding Area Maintenance (Facility Certification, Cleaning, Excursion Remediation)

CS = Controlled Substance

What is POSITIVE ID?

A method of identifying a person that does not rely on the use a personal identifier such as a password

Should be used to document **all activities relating to the practice of pharmacy.**

- Manual Signature
- Magnetic Card Reader*
- Bar Code Reader*
- Biometric Method
- Proximity Badge Reader*
- Randomly Generated Personal Questions*

Why Does the Board of Pharmacy REQUIRE These Records?

Licensee Demographics

Patient Safety

Medication Security

Verify Compliance w/Rules

Challenges in Documentation/Record Keeping

- Multiple record keeping platforms (including PAPER) coordinated b/w multiple care-sites.
  - # of Contributing Personnel
  - Accessibility and Interpretation of Records
- Positive ID Limitations
- Space (secure location to store records)
- Time for documentation

Be Vigilant in These Spaces

Controlled Substance Chain of Custody

Inventory Records

Temperature Monitoring

Compounding Area Related Maintenance

Completion of Training

What Happens When a Surveying Body Identifies Missing/Incomplete Records?

QUESTIONS, QUESTIONS, & more QUESTIONS

Identify Missing Cleaning Records	BOP Asks to See Cleanroom Remediation Plans	BOP Asks to See Compounding Records	BOP Asks to See Recall Process
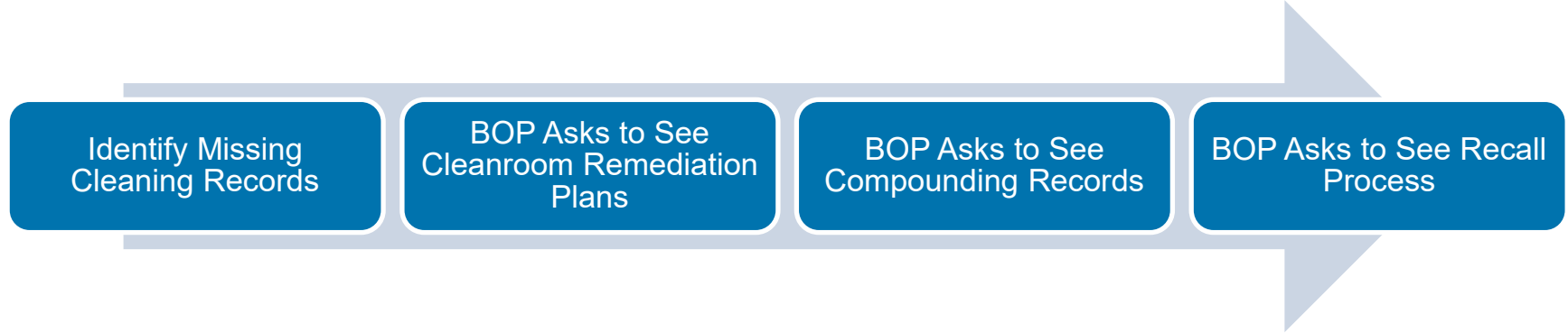
What YOU Can Do

Protect your personnel identifiers.

Document activities relating to the practice of pharmacy truthfully to the best of your knowledge.

Target to complete all documentation AS YOU COMPLETE EACH ACTIVITY.

If you identify missing records, go back and complete as soon as possible OR document why activity was missed.

When in doubt…document it. **If you don't document it, it didn't happen.**

Licensing

License Renewals

- Bi-annual renewals depending on your role

- All renewals are electronic via the eLicense Ohio online licensing portal

Pharmacists	Pharmacy Technicians
Renew on ODD years	Renew on EVEN years
$250 + $3.50 fee	$50 + $3.50 fee
40h CE (4 CEU) •2h med errors / patient safety •2h jurisprudence	10h CE (1 CEU) •2h med errors / patient safety •2h jurisprudence
Must renew by September 15th	Must renew by March 31st

License Renewals

- Continuing Pharmacy Education (CPE) Exceptions
  - Pharmacists with Board Certification
  - Certified Pharmacy Technicians

Common Renewal Mistakes

- Missing required law and/or safety CPE

- Not enough CPE

- CPE was not earned within the recertification cycle

- Completing pharmacist specific CPE instead of pharmacy technician specific CPE
  - Note: PTCB now allows up to 5 hours CPE with pharmacist designation

CPhT Specific Common Renewal Mistakes

- Certified pharmacy technicians
  - Certification renewals do not occur at the same time as the Ohio Board of Pharmacy renewals
  - Email notices of delinquency post-renewal
    - It is **critical** to keep a **current and accurate email address** on file with the Board of Pharmacy AND the national certification organization (PTCB/NHA)
  - Duty to report to lapse in certification

Examples of CPE Designations

- Technician approved course:
  - 0123-0123-12-123-H01-**T**
- Pharmacist approved course:
  - 0123-123-12-123-H01-**P**
- Law approved course:
  - 0123-0123-12-123-H**03**-T
- Medication safety approved course:
  - 0123-0123-12-123-H**05**-T

License Renewals
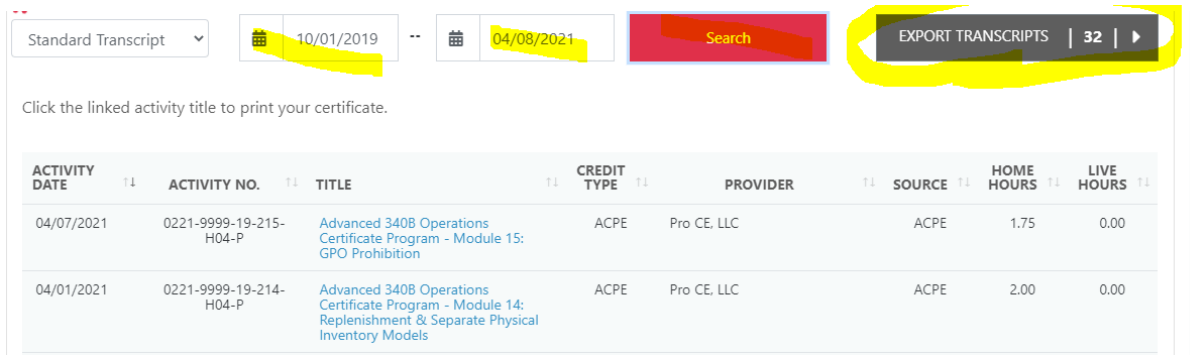
- Audits
  - Board of Pharmacy
  - PTCB/NHA

- Documentation
  - Keep a record of proof of CPE activities for **2 years.**

Verifying Your CPE Monitor

- Review your CPE monitor before renewing your certifications

- Accessing the NABP CPE Monitor:
  - Website: https://nabp.pharmacy/
    - e-Profile ID login
    - Once logged in, click on the CPE Monitor

Verifying Your CPE Monitor

- Select the appropriate date range (Remember to filter to dates within the recertification cycle)

- Review transcript to verify all CPE requirements are met *__BEFORE RENEWAL__*

Takeaways

- Complete renewals and recertifications on time
- Maintain accurate contact information
- Know the CPE requirements
- Maintain CPE documentation

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