Ohio Law Review
Compliance and What You Need to Know

Ohio Society of Health System Pharmacists
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Disclosure

Relevant Financial Relationships

NONE
Objectives

• Review recent changes to Ohio laws and rules and their impact on institutional care.

• Identify common gaps observed in institutional compounding.

• Illustrate appropriate methods for drug destruction and record keeping.

• Examine methods of identifying diversion in the healthcare setting.
GUIDANCE DOCUMENTS

GENERAL INFORMATION

- Legal Practice of Pharmacy Selected Points - (June 2015)

COMPounding

- Ohio Licensed Outsourcing Facilities
- Drugs Compounded in a Pharmacy Must Adhere to the U.S. Pharmacopoeial Convention Chapters 795 & 797
- Compounding in Ohio
- Terminal Distributor Licensure for Compounded Drugs and Compounding Drugs On-Site
- Compounding for Drug Shortages
- Registering as a 503B Outsourcing Facility

CONTROLLED SUBSTANCES
2017 Presentations

• 2017 CE Law Review:
  – April 26, 2017: Ohio Northern University
  – May 31, 2017: Mercy Health, Cincinnati
  – June 13, 2017: Vern Riffe Center/Columbus
  – August 16, 2017: NEOMED
  – September 20, 2017: University of Findlay
  – October 11, 2017: Cedarville University
  – November 7, 2017: University of Toledo
Recent Law/Rule Changes
OAC 4729-5-05; OAC 4729-5-05

- OAC 4729-5-05/Rescinded: Pharmacists and interns no longer need to sign their identification cards.

- OAC 4729-5-05: Pharmacists must report change of name, address or employer to the Board within 30 days of the change.
OAC 4729-9-08
Change In Description of Facility

• Any change in:
  – Ownership
  – Business or trade name
  – Category
  – Address

• Requires:
  – New application
  – Required fee

*Changes must be reported to the Board within 30 days of the change.
Board may require a pharmacist or pharmacy intern to submit to a mental or physical examination if the board has reasonable cause to believe the person is impaired.

Failure to submit to the examination constitutes admission of the allegations and a suspension order will be entered without testimony or presentation of evidence.
OAC 4729-9-09
Inspections and Corrective Actions

• Any entity licensed/registered by the Board is subject to an on-site inspection with or without notice.

• Submission of an application for a license/registration constitutes permission for entry and on-site inspection.

• Within 30 days of notification of violations, the applicant shall submit to the Board the actions taken to correct violations, or an explanation disputing the observed violations.
A pharmacist shall be the responsible person for no more than one (1) pharmacy unless granted permission by the Board. (Request form available at www.pharmacy.ohio.gov/licensing/TDDD.aspx)

Responsible person is responsible for the practice of pharmacy including supervision, control, record keeping, and compliance with state and federal laws, rules and regulations.
Unless otherwise approved by the Board, no responsible person for a pharmacy may:

1. Have been ever been denied a license by the DEA or appropriate issuing body.

2. Have been the subject of disciplinary action resulting in the suspension or revocation of the pharmacist’s license.

3. Have had disciplinary action based in whole or in part on the pharmacist inappropriate prescribing, dispensing, diverting, administering, storing, compounding, supplying or selling controlled substances or other dangerous drugs.
OAC 4729-5-11
Responsible Person

4. Have been convicted of:
   a. A felony.
   b. A misdemeanor related to, or committed in, the practice of pharmacy.
   c. An act of moral turpitude.
   d. A crime of moral turpitude as defined in ORC 4776.10.
ORC 4729.90 through ORC 4729.96
Pharmacy Technicians

• Registration of pharmacy technicians will be required by April 6, 2018. Application process is pending.

• Technician Rules are still being finalized.

• Three classifications of registration:
  – Pharmacy Technician Trainee
  – Registered Pharmacy Technician
  – Certified Pharmacy Technician

• Application fee will be $50.00, renewable every 24 months. ($25.00/1yr = Technician Trainee)
Registration as a Pharmacy Technician Trainee

• One year, non-renewable registration, Fee of $25.00.

• Must be enrolled on plan to enroll in education and training that will allow the person to meet the requirements of a pharmacy technician.

• Must comply with ORC 4729.90, ORC 4776.01 and ORC 4776.04

• Pharmacists or pharmacy interns whose license has been denied, revoked, suspended or otherwise restricted by the Board may not be registered as a pharmacy technician trainee.
Registered Pharmacy Technician
Permissible Activities:

- Accepting new written or electronic prescription orders from prescribers or prescriber agents.
- Entering information into and retrieving information from a database or patient profile.
- Preparing and affixing labels.
- Stocking dangerous drugs and retrieving those drugs from inventory.
- Counting and pouring dangerous drugs into containers.
- Placing dangerous drugs into patient storage containers.
- Non-sterile drug compounding as authorized by the State Board of Pharmacy in rule.

Other activities specified by the board in adopted rules.
Certified Pharmacy Technician
Permissible Activities

• All Registered Pharmacy Technician permissible activities and

• Accepting or requesting refill authorizations for dangerous drugs that are not controlled substances from a prescriber or prescriber agent, as long as there is no change from the original prescription.

• Sterile and non-sterile compounding as authorized by the state board of pharmacy in rule.

• Other activities specified by the board in adopted rules.
Pharmacy Technicians

Sanctions/Penalties

- Pharmacy technicians are subject to the same disciplinary actions and proceedings as an Ohio registered pharmacist, including:
  - Revocation of registration
  - Suspension of registration
  - Restrictions on technician duties
  - Fines and other disciplinary action
The Board may designate attorneys at law as hearing examiners.

Hearing examiners will hear and consider evidence introduced and issue findings of fact and conclusions of law to the Board for review within 30 days of the close of the hearing.

The board will render a decision and take action within 90 days of receipt of facts from the hearing examiner.
Obtaining Certificates Prior to Transactions

- Wholesale distributors and terminal distributors, of dangerous drugs must obtain a copy of the current certificate of license prior to making sales/purchases.

- Sole proprietors and sole shareholders exempt from licensure by OSBP must provide their current license to practice. Sole shareholders must provide official documentation showing they are the sole shareholder.

- Entities may utilize the Board’s online registry to confirm licensure.

- If no certificate or confirmation of licensure is obtained prior to purchase/sale both the seller and the purchaser shall be considered in violation of ORC 4729.60.
ORC 4729.45
Administration of Injections

- A licensed pharmacist may administer by prescription the following injections:
  - Opioid antagonists used for the treatment of drug addiction administered in a long-acting or extended-release forms.
  - Antipsychotic drugs administered in a long-acting or extended-release forms.
  - Hydroxyprogesterone caproate.
  - Medroxyprogesterone acetate.
  - Cobalamin.
ORC 4729.45
Administration of Injections

• To administer pharmacists must:

  - Complete a course in administration of drugs.

  - Receive and maintain certification to perform basic life-support (American Red Cross or American Heart Association).

  - Practice in accordance with a protocol by a physician who has a scope of practice that includes treatment of the condition for which the drug is prescribed.
ORC 4729.45
Administration of Injections

• Rules for training and protocol must be adopted by the Board.

• Rules are currently in process.
New Limits of Prescription Opiates for Acute Pain

• Limits are currently **NOT** in effect.

• Medical Board, Nursing Board and Dental Board, and the Pharmacy Board will adopt rules.

• Limits will not apply to opiates prescribed for cancer, palliative care, end-of-life/hospice care, medication-assisted treatment for addiction, chronic pain, or veterinary medical practices.
New Limits of Prescription Opiates for Acute Pain

• General provisions:
  – No more than seven (7) days of opiates prescribed to adults.
  – No more than five (5) days of opiates prescribed to minors.
  – Total morphine equivalent dose may not exceed 30 MED/day.
  – Prescribing in excess of new limits will require documentation in the patient’s medical record.
  – Prescribers will be required to include a diagnosis or procedure code on every controlled substance prescription.
  – Diagnosis codes/procedure codes will be required to be entered into OARRS.
  – Responsibility of adhering to the rules falls to the prescriber.
Other Notable Law/Rule Changes

- ORC 4729.20: Dispensing for Purposes of Medication Synchronization.
- ORC 4720.40: Refill Consolidation.
- ORC 4729.46: Outpatient Prescriptions for Opioid Analgesics.
- OAC 4729-5-26: Partial Dispensing of Schedule II Controlled Substances.
Sterile Compounding Gaps Observed
Sterile Compounding in the Institutional Pharmacy - Gaps

- Policies and procedures:
  - Must be specific
  - Updated annually
  - Followed
  - USP 797 suggests 32 specific policies and procedures
Sterile Compounding in the Institutional Pharmacy - Gaps

• Personnel Training:
  – Hand washing
  – Disinfection of non-sterile compounding surfaces and equipment
  – Protective Garb
  – Training to achieve sterility of CSP in ISO 5 space
  – Ingredient weights and measures
  – BUD policies for SDV and MDV
  – BUD of CSPs
  – Cleaning and verification of compounding devices
  – Measuring, mixing, dilution, packing, labeling
  – Quality Assurance Program

• Training is required annually and must be didactic and observational.

• Non-pharmacy personnel performing cleaning, packaging, handling must also be trained annually.
Sterile Compounding in the Institutional Pharmacy - Gaps

• Media Fills:
  – Most difficult level of compounding
  – Record must stand alone

• Gloved Fingertip testing:
  – Three times prior to initial compounding
  – Annual re-test required
  – ZERO CFU’s permitted
  – Test performed when sterile gloves are donned in the ISO 7 or ISO 5 space, prior to compounding and prior to wiping gloved hands with Sterile 70% IPA.
  – Record must stand alone
Sterile Compounding in the Institutional Pharmacy - Gaps

• Gowning and Garbing:
  – Garbing in the correct order (shoes/head/face-then handwashing/gown- then move to ISO 7)
  – Nail Picks
  – No visible jewelry (rings/earrings)
  – Glasses cleaner

• Hood Certification:
  – Tests must be under dynamic conditions including use of particle generating equipment located in ante/buffer areas
  – In situ air pattern analysis/smoke studies must be conducted
Sterile Compounding in the Institutional Pharmacy - Gaps

• Equipment:
  – Documentation of maintenance
  – Documentation of calibration
  – Throughout the life of the product

• Compounding Environment:
  – Continuous operation of primary engineering controls
  – Temperature and humidity monitoring
  – Anteroom has a line of demarcation
  – Pressure differentials are monitored
  – Compounding environments not compliant with USP 797 = low risk 12hr BUD compounding only in a segregated compounding area
Sterile Compounding in the Institutional Pharmacy - Gaps

• Cleaning
  – PECs must be cleaned with sterile 70% IPA at the beginning of each shift, before each batch, every 30 minutes during compounding, after spills
  – Cleaning log to include disinfectant used
  – Logs document mixing and BUD of cleaning solutions if not using pre-mixed products
  – Dedicated cleaning equipment must be used

• Beyond-Use dating:
  – Follow USP 797 or
  – Complete independent sterility/stability/endotoxin testing
Compounding Records:
A record of all drugs compounded which shall include at least the following:

- Name of drug, strength, and dosage form
- Quantity of drug(s) added to each container
- Disposition of unused drug(s) and amount (does not apply to hospitals)
- Manufacturer lot or distributor control number
- Manufacturer or distributor name (if generic)
- Pharmacy control number if prepared in anticipation of need
- Date compounded
- Manufacturer/distributor expiration date
- Expiration/Beyond-use date
- Positive identification of the pharmacist/prescriber responsible for verifying the compounded product
Drug Destruction and Record Keeping
OAC 4729-9-06
Controlled Substance Drug Disposal

“Non-retrievable"

A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.
Non-retrievable DOES NOT include:

- Flushing in sinks or toilets
- Depositing in sharps containers
- Mixing in kitty litter or coffee grounds.
OAC 4729-9-06
Controlled Substance Drug Disposal

• Controlled substances must be disposed of in accordance with 21 C.F.R. 1317
  – Registrant Disposal:
    • Transfer/delivery to a reverse distributor for return or recall.
    • Delivery to the registered person from who the drug was obtained.
    • Delivery to a manufacturer, or registrant authorized to accept returns.
    • On-site destruction.
OAC 4729-9-06
Controlled Substance Drug Disposal

• Records of controlled substance destructions must be maintained in accordance with 21 C.F.R. 1304:
  – DEA Form 41
  – Shall be maintained for a minimum of 3 years.

*See OAC 4729-9-06 for record keeping requirements in long-term care facilities.
Destruction of Ultimate User Controlled Substances:

- Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, retail pharmacies.

- All entities collecting ultimate user controlled substances must be registered with the DEA as authorized collectors.

- Pharmacies may maintain collection receptacles at long-term care facilities.
Law Enforcement

- Federal, State, tribal or local law enforcement may collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property.

- Take Back Events
- Mail Back Programs
- Collection Receptacles inside law enforcement’s physical address.
Drug Diversion in the Health Care Setting
Substance Abuse Disorder in Health Care

- From 2008-2012

- Overall rate of past year substance use disorder among full-time workers age 18-64 in Health Care and Social Assistance Fields: 5.7%

- SAMHSA, Center for Behavioral Health Statistics and Quality, National Surveys on Drug Use and Health (NSDUHs) 2008-2010 (revised March 2012) and 2011 to 2012.

Drug Diversion

- Increased risk of patient harm
- Inadequate relief of pain
- Inaccurate documentation of care
- Exposure to infectious disease
- Impaired healthcare worker performance
- Regulatory and legal risks to the facility
- Fraudulent billing
- Liability for damages
- Decreased community confidence
Monitoring and Surveillance

• Monitor trends and variances
• Include self-audits and external audits.

• Procurement Audits:
  – Verify Power of Attorney for controlled substance ordering annually.
  – Audit order volume/patterns comparing variations to facility changes.
  – Compare invoices to orders and receipt to perpetual inventory.
  – Reconcile statements to wholesale purchase history reports.
  – Inspect pharmacy stock for evidence of tampering.
  – Verification of perpetual inventory (including infrequently used items).
  – Reconcile transactions of controlled substance movement throughout the facility. (Request/Delivery/Receipt)
  – Identify and audit look-alike drugs.
Monitoring and Surveillance

• Preparation and Dispensing:
  – Controlled substance overfill is considered unusable/waste product and is documented in accordance with procedures.
  – Overfill waste is made irretrievable.
  – Packages are inspected for integrity of contents.
  – Verification/reconciliation of perpetual inventory by multiple individuals.
Monitoring and Surveillance

- Prescribing:
  - Monitor prescribing/ordering practices of physician employees.
  - Evaluate prescribing trends and address significant variation from peers.
  - Evaluate documentation practices. Failure to document, corrections to documentation/ADMs, failure to waste with a witness, removing meds prior to need.
  - Assess prescriber positive ID is in place.
Monitoring and Surveillance

• Administration:
  – Compare ADM activity with medication administration records.
  – Evaluate patient response to medication.
  – Compare nurse administration to other health care workers on subsequent days/shifts.
  – Conduct random patient interviews- verify patients received medications, medication response, compare to nurse notes/MAR records.
  – Periodically audit/supervise shift counts.
  – Evaluate documentation practices.
  – Monitor medication removal for same patient from multiple ADMs.
  – Compare doses given to prescriber order. (too much given/ no order/ patient discharged).
  – Routinely monitor ADM/medication access privileges.
  – Ensure ADM time-out is in place (60 seconds max)
Monitoring and Surveillance

• Waste and Removal:

  – Review waste documentation: all waste must have a witness.
  
  – Is waste appropriate? (Removing larger size/strength to create waste. Waste reconciles with documentation of dose dispensed.)
  
  – Randomly assay waste from high-risk/high volume areas.
  
  – Controlled substance waste is not deposited in unsecure or unintended containers. (Waste is made irretrievable)
  
  – Waste occurs by two licensed health care professionals immediately at the time of administration- one being the person who administered the medication.
  
  – Pharmacy return processes include auditable verification of delivery and receipt. (Pharmacy returns from patient care areas, pharmacy returns to vendor, destructions, etc.).
  
  – Expired controlled substances are securely stored until destruction/distribution to a reverse distributor. Reconcile quantities transferred to reverse distributors against facility records.
Reporting Theft or Loss

- Policy for unresolved discrepancies.
- Report to Ohio State Board of Pharmacy (OAC 4729-9-15)- required upon discovery by telephone, follow-up with DEA 106.
- Local Law Enforcement (ORC 2921.22).
- DEA for controlled substances.
Employee Responsibility

• 21 CFR 1301.91
  – Employee responsibility to report drug diversion

  – “...employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer”

  – “The employer shall inform all employees concerning this policy”
Failure to Report

- Facilitates addiction
- Prevents/delays rehabilitation
- Endangers patients
- Possible criminal offense:
  - CFR 1301.76 (b)
  - ORC 2921.22
- Possible administrative offense
  - OAC 4729-09-15
Questions?