Pharmacy Law Update
Oklahoma State Board of Pharmacy
OPhA District Meeting
Fall 2016

Overview
• Updates
• Immunizations
• Compounding
• Common Issues

Delivery to Prescriber
• Patient-specific filled prescriptions:
  o No permanent or secure mailing address
  o Require special handling
  o Delivered where they shall be administered
  o Filled under Medicare and/or Medicaid for End Stage Renal Disease (ESRD) program
  o Radiopharmaceuticals
  o Compounded medications
Pharmacy

• Written Policy and Procedure manual
  o https://www.ok.gov/pharmacy/documents/DRUG%20DIVERSION%20D&P GUIDE.pdf
• Invoices for non-CDS drugs may be maintained electronically
• Phantom PICs

Pharmacy

• OSBP may require up to 3 hours of CE on a specific topic.
• OSBP may review, approve, or disapprove intern hours worked in ACPE-approved out-of-state COP if that state’s BOP doesn’t track or report earned intern hours.

Storing Vaccines

• No dorm-size refrigerator allowed
• May use full-size refrigerator
• Need separate freezer
• Remove crisper bins and place water bottles in bottom of refrigerator
• Calibrated thermometers
• Record temperatures twice a day
• Must comply if participating in VFC program

http://www.cdc.gov/vaccines/recs/storage/default.htm
Immunizations
• May be on pt-specific order or protocol
• Logs on refrigerators/freezers
• Techs can’t give immunizations
• Maintain current CPR
• Date MDV vial when opened, BUD 28 days unless manufacturer states otherwise (i.e. Merck)
• Administration vs. Immunization

Technician Training
• Must be updated annually
• Documentation must be available in the pharmacy
• Type of training determined by PIC

Technician Duties
• Technician may take refill authorization from prescriber’s office when no changes made to non-CDS Rx
• Pharmacist must take refill authorization when there are changes made to a non-CDS Rx
• Pharmacist must take refill authorization for any CDS Rx
**Drug Supplier Permit**

- To supply legend drugs to licensed practitioners for office use and/or hospitals for dispensing
- Not selling to wholesalers, manufacturers, 3PL’s, repackager, outsourcing facility, etc. (returns to wholesalers allowed)
- Does not apply to repackers where ownership of pharmacy’s drug doesn’t change hands
- Online swap sites...selling out of state?

**Sterile Compounding**

- **503(a)**
  - Compounding pharmacies
  - OK licensed PIC
  - Sterile compounding permit required
  - Sterile office use **NOT** permitted
  - Non-sterile office use permitted
  - Pt-specific rx’s
  - USP 797 standards

- **503(b)**
  - Outsourcing facilities
  - OK licensed PIC
  - Sterile products
  - Non-patient specific, for office use
  - FDA registered
  - CGMP standards
  - May also have pharmacy license

**Sterile Compounding**

- Injectables, irrigation solutions, inhalation solutions, ophthalmics
- Must have sterile compounding permit
- Must comply with applicable USP standards
Sterile Compounding

- Intern Training
- Cleaning logs
- Cleaning schedule
  - Work area: Each shift, prior to each batch, after spills, every 30 min when used continuously, when known or suspected contamination occurs
  - Counters, work surfaces, and floors: daily
  - Walls, ceilings, and shelving: monthly

Sterile Compounding

- Equipment calibration log
- Records
  - FDA approved drugs
  - Purchased from OSBP licensed entities
- May no longer compound “for office use”

Non-Sterile Compounding

- Equipment calibration log
- Cleaning logs
- Intern training documented
- Commercially-available products
- Billing for commercial products
**NS Beyond Use Dates**

- Water-containing topical ≤ 30 days
- Water-containing oral ≤ 14 days refrigerated
- All other compounds = earliest EXP date of API or 6 months whichever is less.
- BUD must not exceed EXP date of any ingredient.
- Extending BUD must have supporting scientific data

**USP <800>**

- Published February 1, 2016
- Enforceable **JULY 1, 2018**
- New guidelines for hazardous drugs
- Includes the preparation, storage, transportation, and administration of HD
- Non-sterile and sterile preparations
- NIOSH listing
- Separate storing and handling
- Negative pressure rooms
- BSC or CACI vented to outdoors

**Unethical Conduct**

- Dividing fees or private formulas between registrant and prescriber
- No automatic refills without patient consent
- No agreements between any licensee and prescriber to require where rx is filled
- Pre-populated CDS rx or refills
Non-Resident Pharmacies

- Must have OK-licensed PIC after November 1
- Must provide inspection within past 24 months
  - By pharmacy's state board
  - Other Board-approved entity (i.e. NABP or ACHC)

Oklahoma PMP Aware

- Went live on August 30, 2016.
- New PMP System
  - https://oklahoma.pmpaware.net
- Previous PMP System
  - https://portal.obn.ok.gov
- Oklahoma PMP Aware Information Portal
  - http://elclwd.xara.hosting
- OBND Website
  - http://www.ok.gov/obndd

Prescribers and PMP

- Prescribers to check PMP for new patients or existing patients every 180 days who are being prescribed:
  - Opiates, carisoprodol, benzodiazepines
- Doesn’t apply to hospice or LTCF
- Must be documented in patient’s chart
- Enforced by their licensing board
- Cannot be delegated to pharmacy
Acceptable ID’s

- Drivers License
- Military ID
- Passport
- State-issued ID
  - Definition of State: any state, territory or possession of U.S., D.C., or foreign nation
- Tribal IDs
  - Cherokee
  - Muscogee-Creek

Non-Acceptable ID’s

- Consulate
- Conceal Carry
- Most Tribal ID’s
- California DL stating “Federal Limits Apply"

Drug Disposal

- Federal guidelines
- Register as authorized DEA Collector
- OBNDD Take-Back Boxes
  - [https://portal.obn.ok.gov/takeback/default.aspx](https://portal.obn.ok.gov/takeback/default.aspx)
- Only for patient-dispensed meds.
- Registrants must use reverse distributors/wholesalers
Naloxone

- May be distributed by physician protocol or patient-specific RX (NOT OTC)
- May use local physician or contact State Medical Director
- Sample protocols, educational tools, etc.: http://takeasprescribed.org/pharmacy-provider-resources

Naloxone

- Educate patient/family must still seek medication attention as opiate effect may last longer than Naloxone.
- More info: Jessica Hawkins, Director of Prevention
  OK Dept. of Mental Health & Substance Abuse Services
  405-522-5952
  jhawkins@odmhsas.org

Epinephrine

- May be sold to schools or businesses without a specific patient’s name
- Prescriber writes a prescription for entity (e.g. YMCA, Eisenhower HS) for Epinephrine #24.
- Pharmacy may fill under the entity name and dispense an appropriate quantity each time and refill as directed by prescriber.
- Prescriber is responsible to ensure that the entity has P&P in place for proper usage.
Waivers

- Must be obtained by employer
  - Site specific
- OBNDD - Any CDS-related misdemeanor or any felony. Includes finding of guilt, guilty plea, nolo contendere plea, defamed or suspended sentences, or probation.
- DEA - Any CDS-related felony or has surrendered a registration for cause or in lieu of prosecution.
- May affect your bonding insurance

Reporting Losses

- DEA 106 form (electronic)
  - Link available on our website
- Send copy to:
  - OBNDD
    - 419 NE 38th Terrace
    - OKC, OK 73105
  - OSBP
    - 2920 Lincoln Blvd, Ste A
    - OKC, OK 73105
- Keep copy for yourself

E-Prescribing

- [www.surescripts.com](http://www.surescripts.com) (verification of certified pharmacies and prescribers)
- CII’s are allowed
- Electronic rx’s should be stored electronically
E-Prescribing

- Faxes, emails are not same as electronic
- If not electronic, CDS must be manually signed
- Non-CDS rxs do not have to be signed
- Cannot be transferred

Verify Licenses/File Complaints

- OK Board of Medical Licensure & Supervision
  - [http://www.okmedicalboard.org/](http://www.okmedicalboard.org/)
- OK State Board of Osteopathic Examiners
  - [http://www.ok.gov/osboe/](http://www.ok.gov/osboe/)
- OK Board of Nursing
  - [http://www.ok.gov/nursing/](http://www.ok.gov/nursing/)
- OK Bureau of Narcotics
  - [http://www.ok.gov/obndd/](http://www.ok.gov/obndd/)

Schedule II Rx’s

- **Can Add**
  - Dosage Form
  - Strength
  - Quantity
  - Directions
  - Pt. address
  - Generic
  - Compounded

- **Cannot Add**
  - Patient name
  - Date
  - Drug name
  - Physician signature

What about DEA number?

**YES**, after confirming with prescriber

Do **NOT CHANGE** anything on CII prescription. Prescriber must issue new rx if an error is made.
• Valid for 30 days, with Day #1 being the first day after the date of issuance
• Multiple Rx’s written on same day no longer valid per OBND
• Split billing allowed, must document and must be obtained at one transaction (any not obtained is void)
• No days’ supply limitation on CDS rx quantity
• Optometrists may prescribe ≤5 days supply of Hydrocodone (no other CII)

Partial Filling

• Partial filling of CII:
  o If pharmacy doesn’t have it all, has 72 hours to complete
  o Call prescriber if unable to supply all
  o If LTC or hospice, may partial fill for up to 60 days
• Partial filling of CIII-V:
  o May partial fill for up to 6 months
  o May exceed 5 transactions
• Proper documentation

Mid-Level Practitioners

• No out-of-state PA’s or ARNP’s
• Must be licensed in OK and be supervised by OK licensed physician
• CDS III-V: ≤30 day supply
  o PA (up to 30 days, but no refills)
  o APRN (any combination of original + refills up to 30 days)
Hospital Practice

- PA
  - CII’s limited to immediate or ongoing administration on-site through written protocol

- APRN
  - No CII’s
  - Must be within scope of practice
  - Exclusionary Formulary list

Return to Stock

- Do not return to stock bottles
- Redact patient name
- EXP date ≤ 1 year
- Lot number not required
- Recall procedure
- Do not place new label over previous

Odds & Ends

- Compliance w/ OK Tax Commission
- Checking Medicare Exclusion List for employees monthly
- Red flag for CDS prescriptions
- Fraudulent Prescription Form from OBND
- Newsletter/Fax Blasts/Website
- The “Road to Nowhere” video
Questions??

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- www.ok.gov/pharmacy
- pharmacy@pharmacy.ok.gov