



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:
 - No permanent or secure mailing address
 - Require special handling
 - Delivered where they shall be administered
 - Filled under Medicare and/or Medicaid for End Stage Renal Disease (ESRD) program
 - Radiopharmaceuticals
 - Compounded medications

Pharmacy

- Written Policy and Procedure manual
 - https://www.ok.gov/pharmacy/documents/DRUG%20DIVERSION%20D%26P_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 repackagers 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 \leq 30 days
- Water-containing oral \leq 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 rxs 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://elciwd.xara.hosting>
- OBNDL 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
 - http://deadiversion.usdoj.gov/drug_disposal/index.html
- OBNDD Take-Back Boxes
 - <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
- OBND – Any CDS-related misdemeanor or any felony. Includes finding of guilt, guilty plea, nolo contendere plea, deferred 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:
 - **OBND**
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 (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 rx's do not have to be signed
- Cannot be transferred

Verify Licenses/File Complaints

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

Schedule II Rx's

- | | |
|--|---|
| <ul style="list-style-type: none"> • Can Add <ul style="list-style-type: none"> ◦ Dosage Form ◦ Strength ◦ Quantity ◦ Directions ◦ Pt address ◦ Generic ◦ Compounded | <ul style="list-style-type: none"> • Cannot Add <ul style="list-style-type: none"> ◦ Patient name ◦ Date ◦ Drug name ◦ Physician signature <p>Do NOT CHANGE anything on CII prescription. Prescriber must issue new rx if an error is made.</p> |
|--|---|

What about DEA number?
YES, after confirming with prescriber



- 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:
 - If pharmacy doesn't have it all, has 72 hours to complete
 - Call prescriber if unable to supply all
 - If LTCF or hospice, may partial fill for up to 60 days
- Partial filling of CIII-V:
 - May partial fill for up to 6 months
 - 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
 - PA (up to 30 days, but no refills)
 - 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 \leq 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 OBNDD
- Newsletter/Fax Blasts/Website
- The "Road to Nowhere" video

Questions??

- OK State Board of Pharmacy
- 2920 Lincoln Blvd, Ste. A
- OKC, OK 73105
- (405) 521-3815
- www.ok.gov/pharmacy
- pharmacy@pharmacy.ok.gov
