

# Pharmacy Law Update



Oklahoma State Board of Pharmacy  
OPhA District Meeting  
Fall 2016

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## Overview

- Updates
- Immunizations
- Compounding
- Common Issues



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## 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

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## Pharmacy

- Written Policy and Procedure manual
  - [https://www.ok.gov/pharmacy/documents/DRUG%20DIVERSION%20D%26P\\_GUIDE.pdf](https://www.ok.gov/pharmacy/documents/DRUG%20DIVERSION%20D%26P_GUIDE.pdf)
- Invoices for non-CDS drugs may be maintained electronically
- Phantom PICs

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## 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.

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## 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>

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## 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

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## Technician Training

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

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## 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

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## 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?

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## 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

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## Sterile Compounding

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

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## 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

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## Sterile Compounding

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

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## Non-Sterile Compounding

- Equipment calibration log
- Cleaning logs
- Intern training documented
- Commercially-available products
- Billing for commercial products

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## 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

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## 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

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## 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

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## 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)

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## 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>

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## 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

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## 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

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## Non-Acceptable ID's

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



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## Drug Disposal

- Federal guidelines
- Register as authorized DEA Collector
  - [http://deادiversion.usdoj.gov/drug\\_disposal/index.html](http://deادiversion.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

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## 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/>

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## 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](mailto:jhawkins@odmhsas.org)

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## 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.

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## 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

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## Reporting Losses

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

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## 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

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## 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

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## 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/obnodd/>

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## Schedule II Rx's

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

What about DEA number?  
**YES**, after confirming with prescriber

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- 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  $\leq 5$  days supply of Hydrocodone (no other CII)

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## 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

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## 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:  $\leq 30$  day supply
  - PA (up to 30 days, but no refills)
  - APRN (any combination of original + refills up to 30 days)

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## 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

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## 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

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## 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

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## Questions??

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

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