2015 Law & Rule Changes
DEA Pharmacy Diversion Awareness Conference
July 27-28, 2015
SB787

- Statutes vs. Rules
- Statutes, effective November 1, 2015
- Rules, effective about August 27, 2015
Definitions

- Third-party logistics provider (3PL) and virtual 3PL’s: Does not include shippers and USPS
- Virtual manufacturers
- Virtual wholesalers
- Non-resident pharmacies-OK licensed PIC
- Non-resident pharmacies-Inspection
Outsourcing Facilities

- 503(a) vs. 503(b)
- Sterile products for office use
- Non-sterile products for office use
- Patient-specific, additional license as pharmacy
- OK licensed PIC
Definitions

- Pharmacy: place regularly licensed by BOP in which prescriptions, drugs, medicines, chemicals and poisons are compounded or dispensed or such place where pharmacists practice the profession of pharmacy, or a Pharmacy operated by the OK Dept of Veterans Affairs.
Practice of Pharmacy

- Interpretation and evaluation of prescription orders
- Participation in drug selection & DUR
- Counseling and providing information
Statutes

- Must have written drug diversion detection & prevention policy
- Pharmacy may not sell drugs to wholesaler
- Wholesaler may not buy drugs from pharmacy
- Pharmacist can’t refuse to transfer rx
- Prescriber can’t refuse to transmit rx to pharmacy of patient’s choice
Rule Changes

- Practitioner changed to prescriber
- Parenteral changed to sterile compounded preparation
- Notification of DR supervisors to Board
- DR Dispensing Formulary
  - Removed Hydrocodone products (CII’s)
  - Added Tramadol and Codeine-containing cough syrup
Rule Changes

- Drug Supplier Permit
  - 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
Sterile Compounding

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

- Equipment calibration log
- Cleaning logs
- Intern training documented
Sterile Compounding

- Intern Training
- Cleaning logs
- Cleaning schedule
  - Work area: Each shift, prior to each batch, after spills, nlt 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”
Clarify Tech 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
Tech Training

- Must be updated annually
- Must be available in the pharmacy
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 rx’s sent only to that business
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)
Facilities

- Outsourcing facilities
- 3PL's
- Shipping only to address on license
- Receiving only at address on license
- Not operating at place of residence
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 of possession of U.S., D.C., or foreign nation
- Tribal ID’s?
  - Cherokee
  - Muscogee-Creek
Non-acceptable ID’s

- Consulate
- Conceal Carry
- Most Tribal ID’s
- California DL stating “Federal Limits Apply”
Odds & Ends

- Out-of-state mid-level practitioners
- Optometrists-Hydrocodone
- Disposal of Medications
- Fraudulent Prescription Form
Questions???

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**Compliance Officers present today**