



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

HB1948-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 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"

Intelligence Alert

CALIFORNIA DRIVER LICENSE

DL I1234562
EXP 01/01/2020
LN LASTNAME
FN FIRST
1234 ANY STREET
CITY, CA 00000
DOB 10/31/1977
RSTR NONE
SEX M HAIR BLK EYES BRN
HGT 5'-08" WGT 150 lb
DD 00000000NNNANAFDYY 01/01/2015

FEDERAL
LIMITS
APPLY
CLASS C
END NONE

These licenses will have the phrase "Federal Limits Apply" on the front of the card, and a longer advisory on the back.

This card is not acceptable for official federal purposes. This license is issued only as a license to drive a motor vehicle. It does not establish eligibility for employment, voter registration, or public benefits.

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Odds & Ends

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

Questions???

OK State Board of Pharmacy

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**Compliance Officers present today