



# Idaho Pharmacy Law 2015

**Jurisprudence  
Continuing Education**

**Mark Johnston, R.Ph**

# Idaho State Board of Pharmacy

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# 2015 Statute Changes

- Prescription Monitoring Program:
  - Subpoenas must be issued by judges, not attorneys who are too often fishing for data.
- Fingerprinting:
  - Exception to fingerprinting requirement for licensees or registrants that have lapsed for less than a year.

# 2015 Statute Change

- CS Registration (continued)
  - Restrict, not just suspend or revoke
  - Enforce a Board order
  - Fine

Other non-substantive housekeeping

# 2015 Statute Change

- Controlled Substance Registration
  - Separates administering and prescribing from the definition of dispensing.
  - Harmonizes in all places that a CS registration is required for persons that manufacture, distribute, prescribe, administer (independently), dispense, or conduct research.

# 2015 Statute Changes

- Tramadol: CIV
- Hydrocodone: rescheduled to CII
- Perampnenel: CIII
- Suvorexant: CIV

# 2015 Statute Change

- Wholesaling
  - Started with the need to strike all pedigree law, as required by DQSA
  - Cleaned up the Idaho Drug Distribution Act
  - Updated definitions, including compounding and wholesale distribution
  - Housekeeping, including 54-1734 that explains who can possess CS
  - Requires processes to identify suspicious orders and limit grey wholesaling

# 2015 Rule Change

- Distributing Pharmacies to follow the same laws as wholesalers, legal distributions:
  - Emergency medical reasons
  - Intra-company
  - Sale of a closing pharmacy
  - Nuclear pharmacy
  - Office use

# 2015 Rule Change

- Office Use distribution
  - Minimal quantities
  - For administration
  - Not further distributed
  - New: non-sterile compounded drug product, limited to 5%

# 2015 Rule Changes

- Distributing Pharmacies to follow the same laws as wholesalers:
  - Deliver only to properly licensed/registered persons
  - Deliver only to address on license/registration
  - Suspicious order monitoring
  - Invoice, not prescription drug order
  - Monthly reporting, except intra-company
  - Federally required transaction documentation

# 2015 Rule Changes

- Outsourcing facility registration and practice standards
  - Federal law: 503B of FDCA
  - PIC & inspection required
  - Can be coincidentally registered as a mail service pharmacy
  - Policy and procedures
  - Reporting

# 2015 Rule Change

- Biosimilar substitution of interchangeable products
  - Substitution Vs Selection
  - Purple Book
  - No notification requirements

# 2015 Rule Changes

- Foreign Graduates
- Technician-in-training
- Labeling
- Controlled Substance Inventory
- Immunization emergency kits
- Nonresident pharmacist practice

# 2015 Rule Changes

- Pharmacy Security
  - Housekeeping and tamper proof hinges
- Pharmacist Authorized Entry,  
Combines four sub rules into one:
  - Pharmacist absence (retail)
  - Pharmacist absence (institutional)
  - Closed Pharmacy
  - Temporary visitors for legitimate business purposes

# 2015 Rule Changes

- Repackaging previously dispensed drugs by another pharmacy
  - Into unit dose within 3 days
  - Pharmacist verification: drugs, original order, not adulterated
  - Labeling
  - Record keeping
  - Policy and Procedures

# 2015 Rule Changes

- Retail telepharmacy with remote dispensing sites:
  - Tech: 2,000 hours
  - Supervise from pharmacy only
  - Enhanced video surveillance
  - Enhanced security requirements
  - Continuous Quality Improvement Program

# 2015 Rule Changes

- Compounding:
  - Labeling
  - Compounding exceptions
  - Bulk drug substances must be obtained from a FDA registered manufacturer and arrive with a Certificate of Analysis
  - Prohibited compounding: demonstrable difficulty in compounding & withdrawn drugs

# 2015 Rule Changes

- Compounding (continued)
  - Triad relationship required
  - Can't compound commercially available drugs, unless not regular or in inordinate amounts and medically warranted or unavailable
  - Anticipatory compounding
  - Policy and Procedures required

# 2015 Rule Changes

- Compounding (Continued)
  - Accuracy
  - Non-patient specific records
  - New hazardous drug section pursuant to proposed USP Chapter 800
  - Updated sterile compounding rule (no changes from last year's proposal)

# Hot Topics

- Other 2015 bills (not run by the Board)
  - Naloxone
  - Medication synchronization
  - Pharmacy Audits
  - Tele-health
  - Naturopath prescriptive authority
  - Psychologist prescriptive authority
  - CBD oil
  - Epi Pens
  - Biosimilar substitution: notification

# Potential 2016 Rule Changes

- Own Use Doctrine
- Statewide Protocol Agreements
- Controlled Substance Storage
- Non-Pharmacy Registration
- Technician Registration Cancellation
- Student Pharmacist Hours
- Phone number on Prescription Pad
- Compounding

# Potential 2015 Statute Changes

- Uniform Controlled Substances Act
- Coroner Access to PMP
- Contraceptives and prophylactics

# Hot Topic

Past 3 years:

- 26% of RPh audited in 2014 have CE violations: CPE monitor
- Diversion suspensions: 9
- Diversion revocations: 31
- Diversion restrictions: 33
- Pharmacy Recovery Network
  - Administered by Southworth Associates

# Idaho State Board of Pharmacy

- Thank you

