



Idaho Pharmacy Law 2014

Jurisprudence

Continuing Education

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Idaho State Board of Pharmacy

- Executive Director: Mark Johnston
- Public Member: Ed Sperry

- Pharmacist members:
- Holly Henggeler: Chair
- Rich de Blaquiere: Vice Chair
- Nicki Chopski
- Kris Jonas

2014 Rule Changes

- Several create harmony with statutes
- Clarify pharmacy security rules pertain to all pharmacies
- Clarify that CV max is 4oz

2014 Rule Changes

- Positive ID requirement satisfied with WHTI documents:
 - Enhanced Driver's License
 - Nexus Air Card

2014 Rule Changes

- Continuing Pharmacy Education:
 - Max of 3 hours non-ACPE or CME
 - Sterile compounding requirement
 - More structure for Board approved CPE
 - *21 day advanced notice
 - *Sponsor applies, not attendee
 - * Application includes learning objectives, resume of presenter, the presentation, etc

2014 Rule Changes

- Secured Delivery Room:
 - Attached or adjacent to pharmacy
 - Alarm & structural requirements
 - Security system that records entrance
 - Two token entry
 - Common Carrier conducts employee back ground checks
 - Policy and Procedures

2014 Statute Changes

- PMP
 - Patient may assign delegate to access their PMP Data (Southworth Associates)
- CS Update: Recent DEA changes
- Wholesaler
 - CS distributed only to valid DEA and Idaho CS registrant

2014 Statute Changes

- Epi-pens in schools
- Mandatory prescriber registration for on-line access to PMP
- CI scheduling: designer ecstasy

Proposed 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.

Proposed 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.

Proposed 2015 Statute Change

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

Other non-substantive housekeeping

Proposed 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

Proposed 2015 Statute Changes

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

2015 Pending Rule Change

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

Pending 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

Pending 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 Pending Rule Change

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

Pending 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

Pending 2015 Rule Changes

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

Pending 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

Pending 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

Pending 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

Pending 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

Pending 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

Pending 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 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

