



Idaho Pharmacy Law 2013

**Jurisprudence
Continuing Education**

Mark Johnston, RPh

Idaho State Board of Pharmacy

- Executive Director: Mark Johnston
- Public Member: Ed Speery
- RPh members:
 - Nicki Chopski: Chair
 - Holly Henggeler: vice Chair
 - Rich de Blaquiére
 - Kris Jonas

2013 Rule Changes

- Moves "equal protection" waiver parameter from criteria to content
- CPE: Corrects to 30 CPE hours for reinstatement, eliminates CPEU language, reiterates immunizing CE requirement.
- Harmonizes terms
- Refers to 2012 statutory exemptions
- Clarifies confusing language

2013 Rule Changes

- Adds "Green Book"
- License & Registration posting changed to immediately retrievable
- Student pharmacist & Tech-in-training registration clarified...cancelation included.
- Brand Only designation expanded
- Dispensing and admixture preparing RPh initials added to label requirements.

2013 Rule Changes

- Positive ID exceptions for correctional facility and delivery driver/mail added
- Annual CS inventory within 7 days of year prior inventory re-added & requirement with a change of Director added
- Drug product storage rules pertain to OTC
- Rx return rules mandating written protocols re-added

2013 Rule Changes

- Separate phone line & solid core or metal door grandfather clauses added
- 30 day allowance for PIC or director absence, clarified to not be upon opening
- Non-institutional RPh breaks, only if tech or student pharmacist on duty
- Public notified of holiday hours 7 days in advance

2013 Rule changes

- Delivery to correctional facility allowed
- Reporting of Director change: 10 days
- RN in ER dispensing parameters re-added
- Mail order required phone hours re-added

2013 Rule Changes

- ADS systems:
Prescriber, PIC or director may delegate ADS password (etc) oversight to designee
Nurse may stock ADS, if checked by RPh or utilizing bar coding or electronic technology
Temp sensitive drugs only in ADS if able to maintain required storage conditions

2013 Rule changes

- RPH review of institutional ADS usage not required if prescriber controls administration process in procedural areas
- Wasted drugs in institutional ADS clarified
- Drug return to institutional ADS by authorized personnel allowed, if scanning
- Self service system use in ER approved if no pharmacist is on duty in the community & pursuant to other restrictions

2013 Rule Changes

- Clarifies RPh can not practice medicine or conduct physical examinations
- Allows RPh to order lab tests
- Allows RPh substitution, upon a drug shortage, so long as directions are modified to equate to an equivalent amount of drug dispensed as is prescribed

2013 Rule Changes

- Non-resident drug outlets
- Central drug outlet (pharmacy, pharmacist)
- Mail service pharmacy
- Remote Office Location
- Strikes "telepharmacy across state lines"
- Centralized pharmacy services
- \$500 initial & \$250 renewal

2013 Rule Changes

- RPh License: Practice in ID or
Into ID from a central drug outlet that is not a pharmacy
- Pursuant to the independent practice of pharmacy
- RPh Registration:
PIC or Director of nonresident central drug outlet or mail service pharmacy
Into ID from a pharmacy or its COE

2013 Rule Changes

- RPh registration details moved to rules
- Nonresident central drug outlet & mail service pharmacy registration requirements such as an executive summary
- RPh Independent Practice clarified to not be centralized pharmacy services
- Centralized Pharmacy Services expanded pursuant to additional requirements, such as encrypted connection, secured area, etc

2013 Statute Changes

- Mainly non-resident changes, but cleaned up statutes addressing prescription drug order, student pharmacists, colleges or schools of pharmacy, CE, terms, etc
- "or into Idaho" and "or registration" added
- Requires all business entities and RPh that practice pharmacy into Idaho to license or register, but preserves Mail Order Pharmacy exemptions for employees
- Requires non-resident PIC & Fees

2013 Statute Changes

- Allows Board to inspect non-resident and charge expenses
- Non-resident drug outlets and RPh must follow Idaho law unless conflicts with home state law, except for tech practice limits, ratio, substitution and selection
- The Board may take any action against non-resident as it can against a resident
- Allows mirroring of other's orders
- Board may take action against non-resident drug outlets for the actions of their exempt employees

2013 Statute Changes

- Out of state mail service pharmacy act merged into Idaho Pharmacy Act
- ISHP's BOP diversity bill
- Update 'Spice' language
- Clarify that practitioners may share PMP data

Hot Topic: Compounding

- History of compounding law
- NECC and the MA BOP
- Congressional Bills
- Congressional inquiry
- FDA hearing
- NABP's plan
- ID law: requires patient specific prescription drug order to dispense
- Board direction: define compounding, office use exceptions, USP 797 lite, CE...

Draft Compounding Rules

- Compounding drug products
 - Application
 - USP
 - Manufacturing
 - General standards
 - COA
 - Prohibited compounding
 - Equipment
 - Disposing compromised drugs
 - Hazardous drugs

Draft Compounding Rules

- Scope of practice
 - Commercially available products
 - Anticipatory compounding
 - Office use
 - Research
 - Reconstitution
- Drug compounding controls
 - Policies and procedures
 - Accuracy
 - Non-patient specific records
 - Labeling

Draft Compounding Rules

- Sterile product preparation
 - Products requiring sterilization
 - Compounder responsibilities
 - Environmental controls
 - Equipment
 - Documentation
 - Policy and procedures

Proposed Rules

- Create harmony with statutes
- Clarify pharmacy security
- Clarify that CV max is 4oz
- CPE
- Secured delivery rooms

Proposed Statute Changes

- PMP
 - Allow peer assistance entity (Southworth Associates)
- CS Update
 - Recent DEA changes
- Wholesaler
 - CS only to valid DEA number and Idaho CS license

Hot Topic

- Last year:
- 17% of RPh audited are disciplined for CE violations
 - Diversion suspensions: 1
 - Diversion revocations: 10
 - Diversion restrictions: 15
 - Pharmacy Recovery Network
 - Administered by Southworth Associates

Idaho State Board of Pharmacy

- Thank you


