Idaho Pharmacy Law: Developments and Practical Applications for 2020

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Disclosures
The planners and presenter of this presentation have disclosed no conflict of interest, including no relevant financial relationships with any commercial interests.

Learning Objectives
• Discuss the 2020 statutory changes impacting the profession of pharmacy in Idaho
• Discuss the 2020 rule changes impacting pharmacy practice in Idaho
• Describe potential law changes for 2020 and beyond

Activity
Mark the words/concepts that you know well enough to explain to others with (+)
Mark the terms you think you know what they mean with (?)
Mark the terms you would like to learn more about with (-)

___Statute
___Rule
___Sine Die
___Executive order
___Omnibus rulemaking
___Independent prescriptive authority
___House Bill 182
___Zero Based Regulation
___Retrospective analysis
___‘Verify a License’

Idaho Board of Pharmacy

Statute vs Rule
• Statute – Idaho Code - Law
  • Acts with title (37 and 54), chapter (27 & 17)
  • Set forth by the legislature
  • Grants authority for the Board and their ability to promulgate rules

• Idaho Administrative Code or IDAPA or Rules (27.01.01)
  • Derive authority from law
  • Carry the force and effect of law
  • Fills in details beyond the statute
  • Approved by the legislature

Follow different paths through the legislature
Effective Dates of Change

- Rule changes from Omnibus rulemaking took effect July 1, 2019
- Rule edits made after 7/1/19, will take effect at sine die (the end of the 2020 legislative session)
- Statute changes will take effect July 1, 2020

Reauthorization of the Rules

- Administrative rules are traditionally reauthorized annually by the legislature at the conclusion of the session
- 2019 Legislative session ended without the traditional reauthorization
- The Governor reprinted rules as both temporary and proposed to ensure existing administrative rules remained in effect. (Rules were set to expire 7/1/19)
- Omnibus rule making

Omnibus Rule Making

- Re-organization of rule book (again)
  Combined five chapters of rules into one chapter
- Aligned with the Red Tape Reduction Act
- Changes considered at two negotiated rulemaking sessions wrapped into Omnibus rule docket
- Edits were made to simplify current rules and remove unnecessary barriers and restrictions

Highlights of Rule Changes

- Eliminated unused and self-apparent definitions
- Removed the administrative burden of policy and procedures as a matter of law, except for compounding (Use of policy and procedures remains a best practice)
- Added flexible staffing and eased administrative burden for remote dispensing sites

Highlights of Rule Changes (cont’d)

- Permitted expiration of controlled substance prescriptions to match DEA
- Standardized labeling requirements for all prescription types
- Removed outdated temporary scheduling language related to Epidiolex
- Removed unnecessary language due to the passage of House Bill 182 from the 2019 session (“the list”)

Governor Little News Release 7/19/2019

*Effective as of 7/1/19
Additional Rule Changes

• Open public meetings held in July and August

• Two additional rules of significance emerged
  1. Collapsed to 2 categories of technicians
  2. Continuing education requirement alternative

Collapsed to 2 Categories of Technicians

Rule 221 Technician Registration:

• Currently registered Grandfathered Technicians, Technicians-in-Training and Student Technicians will be converted to Technician registration
  
• Eliminated requirement to become certified after two years (or be out) as a matter of law
  
• No change to Certified Technician language

CPE Requirement Alternative

Rule 213.03 Alternative to CPE:

• A pharmacist may substitute a current certification by a nationally accredited pharmacy practice-specific specialty certification program

• Submit upon audit

Governor News Release 12/4/19

Learning Objectives

• Describe the rule changes that will go into effect in 2020

• Describe the statute changes that will go into effect 7/1/2020

• Discuss potential changes for 2021

• Review rules for key topics

Agency Legislation for 2020

• Statute Change  HB 315
  
• Mirrored federal law with respect to the scheduling of synthetics: opioids, cannabinoids, and cathinones

• Made no change as it relates to the 2018 Farm Bill
Agency Legislation for 2020

• Statute Change  HB 316

• Removed statutorily listed drugs and drug classes that pharmacists could prescribe except immunizations (due to the passage of House Bill 182 from the 2019 session)

• Changes the requirement for prospective drug utilization review to be limited to “New” prescriptions

*Effective as of July 1, 2020

Review of 2019 House Bill 182

• Brought forth by Rep. Zollinger

• Eliminated the need for the BOP to specifically authorize in rules a list of drugs, drug categories and devices

• That are specifically authorized in rules adopted by the board

Activity – Each item listed on the left fits within a category on the right. Match them

- Group A Strep
- Cold Sores
- Hormonal Contraception
- Uncomplicated UTI
- Influenza
- Mild Cough
- Immunizations
- Nitroglycerin - acute chest pain
- HIV PrEP and PEP

A. No New Diagnosis
B. Minor and Generally Self-Limiting
C. Have a test, like CLIA, to guide diagnosis
D. Emergency – In professional judgement of RPh threaten health & safety of the patient

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Zero Based Regulation- EO 2020-01

• Replaces Red Tape Reduction Act

• Requires all rule chapters to be reviewed by 2026

• Staggers schedule across and within agencies

• Repeals the rule chapter

• New chapter shall reduce burden or be neutral
Zero Based Regulation- EO 2020-01

- Agency to use retrospective analysis to justify adding rules back in
  - Were the benefits realized and did the rule meet the legislative intent?
  - Is there existing federal law in place?
  - How does the rule compare to other states?
  - If Idaho is more stringent, is there a reason?
  - What is the impact on stakeholders?
  - What cumulative regulatory volume does it add?

- Requires public notice and publication of the retrospective analysis
- Requires 2 public meetings minimum
- Moratorium on new rules this year (exception, but rigorous criteria)
- Future amendments to align with chapter renewal

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Pop Quiz and Not-So-Trivial Trivia

Review of key topics

- CPE
- License verification
- Updates to licensing system and e-Gov
- Individual license renewal
- Controlled substances
- Individual Information Reporting
- PDMP reporting accuracy
- Reliable Information Resources for law related topics

Pop Quiz and Not-So-Trivial Trivia

Topic: CPE

True or False:

For Continuing Pharmacy Education in 2020, a pharmacist needs 15 ACPE credits between January 1 and December 31?

TRUE – See Rule 213
Pop Quiz and Not-So-Trivial Trivia

Topic: License Verification

Multiple Choice:

Which of the following is the best way to verify the license or registration for a new hire?

A. Ask the person if they have an active license or registration
B. Have them bring you a printed copy
C. Use “Verify a License” on the Board’s website
D. Call the Board of Pharmacy and ask

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Pop Quiz and Not-So-Trivial Trivia

Topic: Updates to Licensing System and e-Gov

Multiple Choice:

Recent upgrades to the licensing system provided a number of improvements. Which of the following does the system allow:

A. Print your license/registration cards online
B. “Business Hours” can be updated online
C. “Licenses in Other States” can be updated online
D. Employment changes
E. All of the above

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Topic: License Renewal for Individuals

Multiple Choice:

In 2020, individual licenses/registrations should be renewed when?:

A. June 30, 2020
B. December 31, 2020
C. By the last day of your birth month
D. Idaho eliminated license renewal

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Pop Quiz and Not-So-Trivial Trivia
Topic: Controlled Substances

Multiple Choice:
When selling small quantities of controlled substances to a prescriber for office use, what information needs to be verified?:

A. The prescriber has an active DEA (not expired)
B. The prescriber has an active Idaho Controlled Substance Registration (not expired)
C. The address to which the product is going matches the registered address on the DEA/ID CSR
D. All of the above

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Pop Quiz and Not-So-Trivial Trivia
Topic: Controlled Substances

True or False
It’s okay for a pharmacy to partial fill a C2 prescription in Idaho.

A. True
B. False

Pop Quiz and Not-So-Trivial Trivia
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B. False

Pop Quiz and Not-So-Trivial Trivia
Topic: Controlled Substances - Partial fill of a C2 prescription

(1) Partial fills
A prescription for a controlled substance in schedule II may be partially filled if—
(A) it is not prohibited by State law;
(B) the prescription is written and filled in accordance with the subchapter, regulations prescribed by the Attorney General, and State law;
(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and
(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2) Remaining portions
(A) In general
Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—
(i) may be filled; and
(ii) shall be filled not later than 30 days after the date on which the prescription is written.

Pop Quiz and Not-So-Trivial Trivia
Topic: Individual Information Reporting

Think – Pair – Share
Rule 501.02 requires licensees/registrants to update the board within 10 days with what information?
**Rule 501.02** requires licensees/registrants to update the board within 10 days with what information?

- The information that occurs on an application or renewal
- Contact information (including email)
- Employment changes

**Accuracy of PDMP Submission**

Accurate PDMP submission is critical and required by law. What can front line pharmacists and technicians do to ensure the submitted information is accurate?

- Verify DEA numbers are not expired
- DEA is on the prescription and appropriately selected
- Error report corrections are made timely
- Reversals and revisions are made timely

**Reliable Sources of Board Information**

Which of the following is not a reliable source of Board information?

- Board newsletter
- Social media posts
- Attending a law CPE
- Board website

**Assessment Question #1**

A pharmacy tech-in-training registration is set to expire Aug 15, 2020. If the legislature approves the pending rules, which of the following statements are correct?

- A. The technician will submit a renewal for a tech-in-training registration by Aug 15, 2020
- B. The technician must become a certified technician prior to the expiration date of the tech-in-training registration
- C. The technician-in-training will be designated a technician, will renew prior to the last day of their birth month and they can maintain that status if desired
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Assessment Question #2
A group of pharmacists are reviewing pending statute changes to the Pharmacy Practice Act (54-1704.05) that are before the 2020 legislature. It’s noted that fluoride, tuberculin skin testing, opioid antagonists and tobacco cessation products are no longer specifically listed as items pharmacists can prescribe independently.
What implication does this have on independent prescriptive authority?
A. Pharmacists can no longer prescribe these drugs or drug categories
B. A collaborative practice agreement is required for pharmacists to prescribe these products
C. All of these can continue to be prescribed by pharmacists independently in accordance with the rules as they fit within the parameters of 54-1704.05(g)

Assessment Question #3
As required by statute, pharmacies are required to submit accurate data to the PDMP database. When choosing an information system (or in review of a current system) to meet this requirement, the software should be able to do which of the following?
A. Transmit data by the end of the next business day
B. Differentiate when a prescriber has an X – DEA number and a standard DEA number and appropriately assign the prescriptions accordingly.
C. Ensure the DEA number submitted has not expired
D. All of the above

Hot Topics in 2020
CBD Oil
Marijuana
Telehealth Act
Idaho Injectable Cosmetic Safety Act
PBM legislation
Chiropractic physician's prescribing
Naturopathic Doctors
Rules:
Medicaid omnibus rules
Board of Medicine rules - Naturopathic Medical Doctors, Naturopathic Physicians
2020 Idaho Law Update and Review

What questions do you have for me??

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HB 191 Parameters
- In accordance with FDA labeling
- Limited to conditions
  - No New Diagnosis
  - Minor and Generally Self-Limiting
  - Have a test, like CLIA, to guide diagnosis
  - Emergency – In professional judgement of RPh threatens health & safety of the patient
- No CS, Compounded drugs or biologicals

Minor Conditions
- Lice
- Cold Sores
- Motion Sickness
- Uncomplicated UTI
- Allergic Rhinitis
- Mild Acne
- Mild Cough

Devices
- Inhalation Spacers
- Nebulizers
- Blood Sugar Testing Supplies
- Pen Needles
- Syringes for Diabetics

CLIA waived tests
- Influenza
- Group A Strep

Clinical Gaps in Care
- Statins for Diabetics
- Short Acting Beta Agonists for those Dx with Asthma that have a long acting therapy in place
Others

• Travel Drugs
• Supplements to an Infusion order
  • Flushing, device supplies, local anesthesia
  • Catheter occlusion agents,skill drugs
• Emergency Situations
  • Diphenhydramine, epinephrine, SABA
• Lyme Disease Prophylaxis