Idaho Pharmacy Law: Developments and Practical Applications for 2020

Nicole Chopski, PharmD, BCGP, ANP
Executive Director
Idaho State Board of Pharmacy

In support of improving patient care, Idaho State University Kasiska Division of Health Sciences is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.
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

Holly Henggeler
Kristina Jonas
Richard de Blaquiere
Justin Messenger
Ed Sperry
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

*Effective as of 7/1/19
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”)

*Effective as of 7/1/19
Idaho pursues further cuts to state regulations

Boise, Idaho – Governor Brad Little and legislative leaders today announced the state will pursue further cuts to Idaho’s administrative rules.

The Legislature to **cut and simplify 40 percent of Idaho’s administrative rules.**

“Conservative principles work, and they’re what the people of Idaho expect from our government,” Governor Little said. “We can fulfill government’s role without overburdening citizens and businesses. Those at the top must test, try and eliminate all unnecessary government programs. Idaho’s high standard of living and quality of life come from a commitment to limited government.”

Ultimately, the state may achieve

In a joint press conference today to announce the state will pursue further cuts to Idaho’s administrative rules, Governor Little and legislative leaders called on the Legislature to cut and simplify 40 percent of Idaho’s administrative rules.

“Other states are paying attention to what’s happening in Idaho,” Senate Pro Tem Brent Hill said. “Idaho is leading the rest of the country yet again. We are showing other states and the federal government that meaningful regulatory reform can happen when elected leaders in the executive and legislative branches work together in an open, transparent process and drive change.”

“The rule reauthorization process that started in the spring expedited the good work Governor Little started in January, when more than 20 legislators joined him at the signing of two executive orders aimed at scaling back Idaho’s Administrative Code,” House Speaker Scott Bedke said. “Our efforts to closely examine our laws started collaboratively and will continue collaboratively. Together we created a good process, and the Legislature is committed to continuing to work with Governor Little and his administration to make it a cyclical practice.”

Hearings will be held on proposed changes, and the public will have the opportunity to provide written and oral comments on any potential licensing changes.
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

*Effective as of Sine Die
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

*Effective as of Sine Die*
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

*Effective as of Sine Die
Idaho cuts and simplifies 75 percent of rules in one year, becomes least-regulated state in country

Trump Administration looks to Idaho on achieving regulatory reform
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

*Effective as of July 1, 2020
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
Activity – Each item listed on the left fits within a category on the right. Match them

C. Group A Strep
B. Cold Sores
A. Hormonal Contraception
B. Uncomplicated UTI
C. Influenza
B. Mild Cough
A. Immunizations
D. Nitroglycerin - acute chest pain
A. 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
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
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?
Zero Based Regulation- EO 2020-01

• 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
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
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
For Continuing Pharmacy Education in 2020, a pharmacist needs 15 ACPE credits between January 1 and December 31?
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
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
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
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
Pop Quiz and Not-So-Trivial Trivia

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
Pop Quiz and Not-So-Trivial Trivia

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
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
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
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

Topic: Controlled Substances

True or False

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

A. True
B. False
(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 this 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?
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?

The information that occurs on an application or renewal
Contact information (including email)
Employment changes
Pop Quiz and Not-So-Trivial Trivia

Topic: PDMP Reporting Accuracy

Think – Pair – Share

Accurate PDMP submission is critical and required by law.

What can front line pharmacists and technicians do to ensure the submitted information is accurate?
Pop Quiz and Not-So-Trivial Trivia

Topic: PDMP Reporting Accuracy

Think – Pair – Share

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
X- DEA is on the prescription and appropriately selected
Error report corrections are made timely
Reversals and revisions are made timely (See Rule 400 & 401)
Pop Quiz and Not-So-Trivial Trivia

Topic: Reliable Sources of Board Information

Multiple choice

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

A. Board newsletter  
B. Social media posts  
C. Attending a law CPE  
D. Board website
Pop Quiz and Not-So-Trivial Trivia

Topic: Reliable Sources of Board Information

Multiple choice

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

A. Board newsletter
B. Social media posts
C. Attending a law CPE
D. 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 technician-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
Assessment Question #1

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 technician-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
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)
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
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??

Nicole Chopski, PharmD, BCGP, ANP
Executive Director
Idaho State Board of Pharmacy
Nicki.Chopski@bop.Idaho.gov
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 threaten 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
  - Flushes, device supplies, local anesthesia
  - Catheter occlusion agents, ekit drugs
- Emergency Situations
  - Diphenhydramine, epinephrine, SABA
- Lyme Disease Prophylaxis