Toward Permissionless Innovation: Transitioning Pharmacy to “Standard of Care” Regulation

Alex J. Adams, PharmD, MPH
Executive Director
Idaho State Board of Pharmacy
Alex.Adams@bop.idaho.gov

Nicole L. Chopski, PharmD
Chairman
Idaho State Board of Pharmacy
Nicole.Chopski@bop.idaho.gov
Learning Objectives

• Differentiate the regulatory approaches taken by the nursing and pharmacy professions

• Describe Idaho’s approach to updating the following law categories:
  • Professional Practice Standards
  • Facility Standards

• Discuss how Utah compares
Pharmacy

- General Provisions
- Board Governance
- Licensing
  - Professional Practice Standards
  - Facility Standards
  - Educational Institution Standards

Nursing
Total Word Count in Regulations from 1996 to 2017
Total Word Count in Regulations from 1996 to 2017
Total Word Count in Regulations from 1996 to 2017
Total Word Count in Regulations from 1996 to 2017
Total Word Count in Regulations from 1996 to 2017
Total Word Count in Regulations from 1996 to 2017
Change in Word Count (By %) from 1996 to 2017
## Two Different Approaches

<table>
<thead>
<tr>
<th>Nursing</th>
<th>Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Stopped defining every individual task that each category of nursing could perform</td>
<td>• Added new tasks:</td>
</tr>
<tr>
<td>• Transitioned to a “standard of care” approach</td>
<td>• CPAs (388 words), vaccines (725), independent practice (130)</td>
</tr>
<tr>
<td>• Provided a decision-making model to identify if something is within a nurse’s scope</td>
<td>• Naloxone (312), epinephrine (896), tobacco cessation (267), TB skin testing (247)</td>
</tr>
<tr>
<td></td>
<td>• Technician delegation (1,184)</td>
</tr>
<tr>
<td></td>
<td>• Added new facility types</td>
</tr>
<tr>
<td></td>
<td>• Telepharmacy (1,975 words)</td>
</tr>
<tr>
<td></td>
<td>• ADS (1,715)</td>
</tr>
<tr>
<td></td>
<td>• Centralized pharmacy services (682)</td>
</tr>
</tbody>
</table>
# Two Different Approaches

**Nursing**
- Stopped defining every individual task that each category of nursing could perform
- Transitioned to a “standard of care” approach
- Provided a decision-making model to identify if something is within a nurse’s scope

**Pharmacy**
- Added new tasks:
  - CPAs (388 words), vaccines (725), independent practice (130)
  - Naloxone (312), epinephrine (896), tobacco cessation (267), TB skin testing (247)
  - Technician delegation (1,184)
- Added new facility types
  - Telepharmacy (1,975 words)
  - ADS (1,715)
  - Centralized pharmacy services (682)

**“Addition by Subtraction”**

**“Compensated Addition”**
Learning Objectives

• Differentiate the regulatory approaches taken by the nursing and pharmacy professions

• Describe Idaho’s approach to updating the following law categories:
  • Professional Practice Standards
  • Facility Standards

• Discuss how Utah compares
Professional Practice Standards

General Approach (Rule 020)

• **Express Prohibition** – is the act expressly prohibited by state or federal law?

• **Education and Training** – is the act consistent with the licensee’s education, training, experience?

• **Standard of Care** – is the act within an accepted standard of care that would be provided by a reasonable and prudent licensee with similar education, training, experience.
Professional Practice Standards
Professional Practice Standards

Order & Interpret Tests
Physical Assessment
Administer Medications
Prescription Adaptation Services (Finite)
Independent Prescribing Authority (Finite)

Collaborative Practice Authority
Prescription Adaptation Services

• Renewals
  • Continuation of Therapy: 30 day supply 1 time in 6 month period

• Changes
  • Therapeutic Substitution
  • Dispensing Quantity
  • Medication Synchronization
  • Formulation / Route
  • Complete Missing Information
Independent Prescriptive Authority

- All non-prescription drugs
- Minor Ailments
  - Flu, strep throat, uncomplicated UTIs, lice, cold sores
- Prevention
  - Motion sickness, Lyme disease, travel medications, immunizations, fluoride supplements
- Gaps in Care
  - Statins for patients with diabetes, SABA for patients with controller
- Miscellaneous
  - Tobacco cessation, TB skin tests, opioid antagonists, supplements to an infusion order
- Devices
  - Spacers, nebulizers, diabetes testing supplies, pen needles, syringes
- Emergency Medications
  - Epinephrine auto-injectors, diphenhydramine, SABA
Professional Practice Standards

- Order & Interpret Tests
- Physical Assessment
- Administer Medications
- Prescription Adaptation Services (Finite)
- Independent Prescribing Authority (Finite)

Advanced Delegation to Support Staff

Collaborative Practice Authority
Advanced Delegation

• Supervision
  • The function is performed under a pharmacist’s supervision

• Education, Skill and Experience
  • The function is commensurate with the education, skill, and experience of the technician or pharmacist intern

• Professional Judgment Restriction
  • Any function that requires the use of a pharmacist’s professional judgment may be performed by a pharmacist intern
Facility Standards

• Leverage existing accountability mechanisms: theft/loss, errors, adulteration, misbranding, etc.

• Minimum Filling Requirements
  • Valid Prescription Drug Order
  • Prospective Drug Review
  • Labeling
  • Verification of Dispensing Accuracy
  • Patient Counseling

• Select exclusions (e.g., institutional setting) and augmenters (e.g., no pharmacist on site)

• Ability to move any step “off site”
Unprofessional Conduct

• The following acts or practices are declared to be unprofessional conduct and conduct contrary to the public interest:

• “Standard of Care. Providing health care services which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting.”
Learning Objectives

• Differentiate the regulatory approaches taken by the nursing and pharmacy professions

• Describe Idaho’s approach to updating the following law categories:
  • Professional Practice Standards
  • Facility Standards

• Discuss how Utah compares
Total Word Count Comparison

- **2017 Idaho**: 20,003 words
  - Statute: 19,426
  - Rule: 577
- **2018 Idaho**: 22,295 words
  - Statute: 21,396
  - Rule: 899
- **Utah**: 25,849 words
  - Statute: 25,281
  - Rule: 568
Word Count Comparison By Category

- **General Provisions**: Utah 7,595, Idaho 8,531
- **Board Governance**: Utah 9,079, Idaho 5,414
- **Licensing**: Utah 5,756, Idaho 6,396
- **Professional Practice Standards**: Utah 17,243, Idaho 16,450
- **Facility Standards**: Utah 11,457, Idaho 4,930