

Empowering Pharmacy Personnel: Standard of Care Regulatory Model

Jennifer L. Adams, PharmD, EdD, FAPhA, FNAP
Associate Dean for Academic Programs, Professor
Idaho State University L.S. Skaggs College of Pharmacy



Disclosure

- The presenters do not have relevant financial relationships with ineligible companies and have no actual or potential conflict of interest in relation to this program/presentation.

Learning Objectives

- Define standard of care and bright line regulation as they relate to pharmacy practice regulation.
- Define scope of practice and pharmacist full practice authority and their relationship to standard of care.
- Discuss the continuum of pharmacist prescriptive authority and the influence of regulatory models on prescribing.

Bright Line Regulation

- An objective rule that resolves a legal issue in a straightforward, predictable manner. A bright-line rule is easy to administer and leaves little room for varying interpretation.
 - Example: *Miranda v. Arizona* (1966) establishing Miranda warning of rights to criminal suspects
 - Example: IDAPA 24.36.01.213 Each pharmacist must complete fifteen (15) CPE hours each calendar year between January 1 and December 31.

Standard of Care



The “medical standard of care” is typically defined as the level and type of care that a reasonably competent and skilled health care professional, with a similar background and in the same medical community, would have provided under the circumstances. This is often considered within the context of actions that led to alleged malpractice.



The regulatory model based on the “standard of care” is determined by the individual circumstances that present in practice rather than specific requirements codified in law, allowing for flexibility as practice guidelines change, technology changes, and new knowledge is identified. This model requires less regulatory modification to keep pace with change.

Example: Idaho Code 54-1726 **Standard of Care**. Acts or omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting.



**Idaho State
University**

What makes a SOC Regulatory Model?



Define standard of care:

Care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training and experience.



Include acts or omissions that fail to meet the standard of care in discipline standards.



Allow for delegation to those under supervision based on standard of care.



Idaho State
University

Scope of Practice

The services that a qualified health care professional is deemed competent to perform and permitted to undertake in keeping with the terms of their professional licensure.

Scope of Practice

- The activities that a health professional is permitted to engage in as defined by state laws and regulations
- Determined by the political process = geographical differences
- One-size-fits all: applies to all professionals in class
- Static (aside from law changes)

Clinical Ability

- The true competence and ability of the health professional
- Determined by education, training, career experience, and practice environment
- Individualistic: recognizes professional heterogeneity
- Dynamic; advances with new education, technology, etc.

MAY

CAN

Bright Line Model

Legal Ceiling
("Top of License")

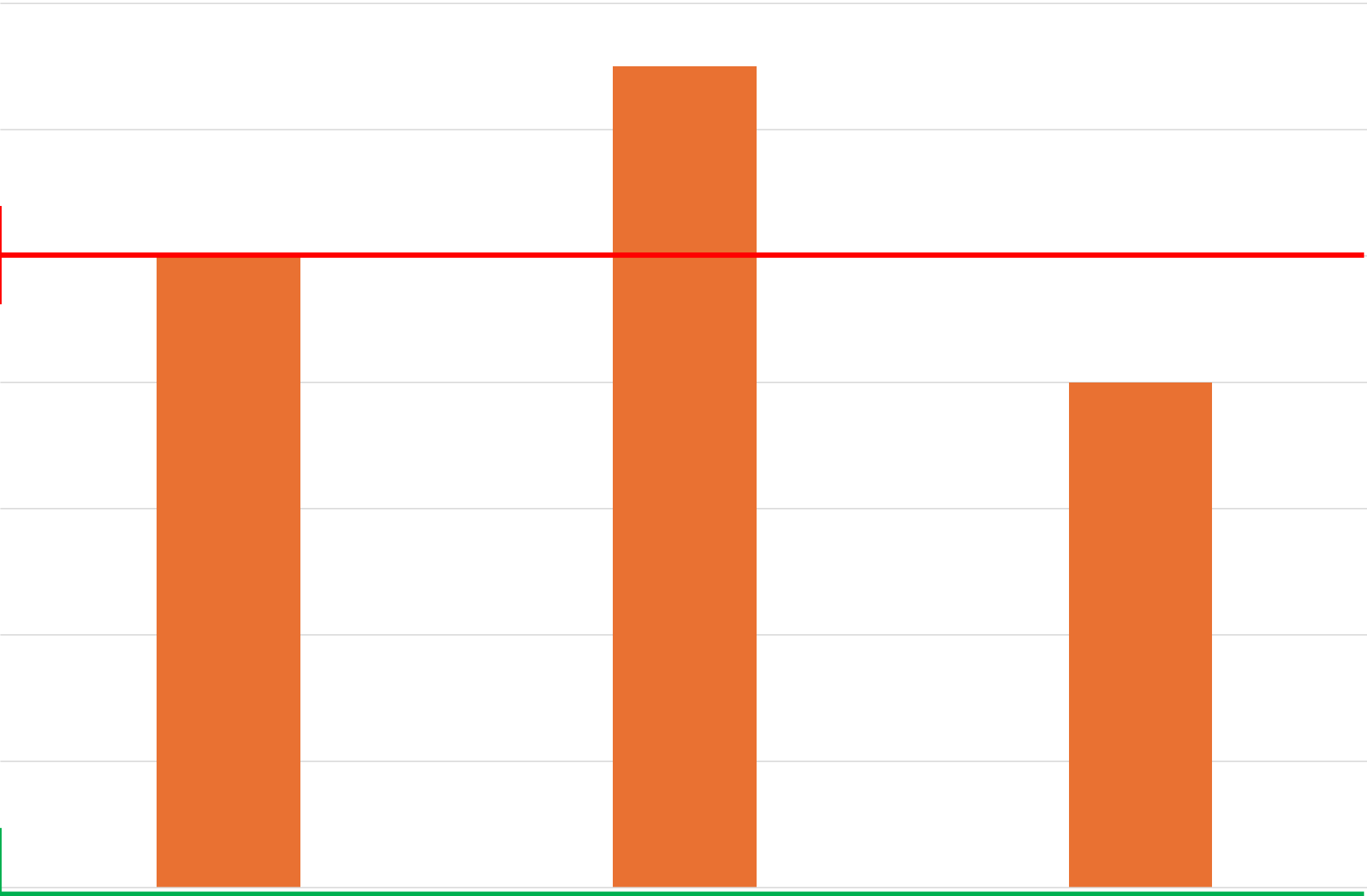
Scope of Practice

Entry Barrier
Minimum Competency

Practitioner A

Practitioner B

Practitioner C



Standard of Care Model without full implementation

Legal Ceiling
("Top of License")

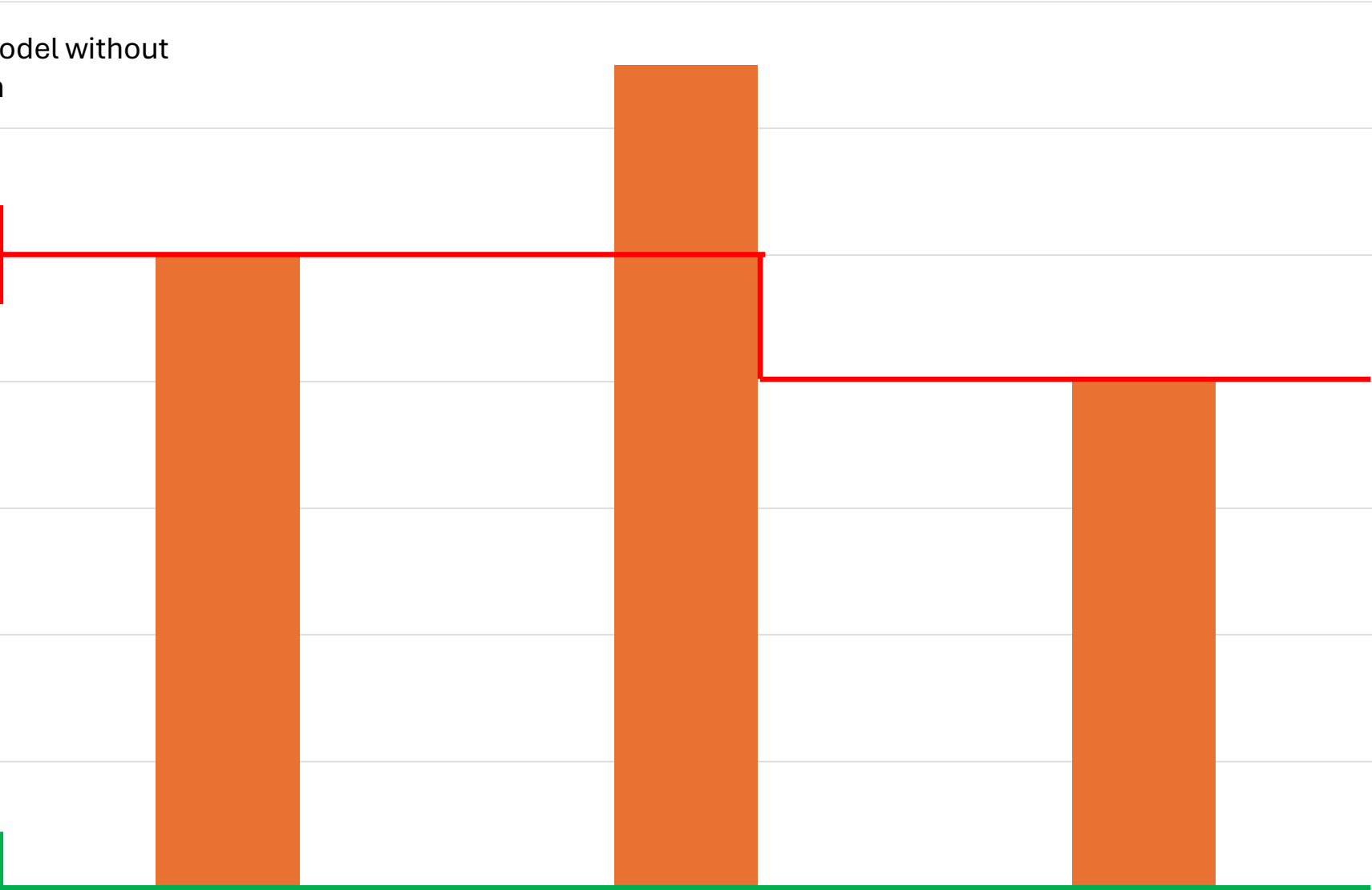
Scope of Practice

Entry Barrier
Minimum Competency

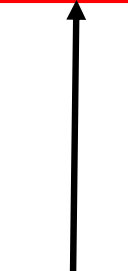
Practitioner A

Practitioner B

Practitioner C



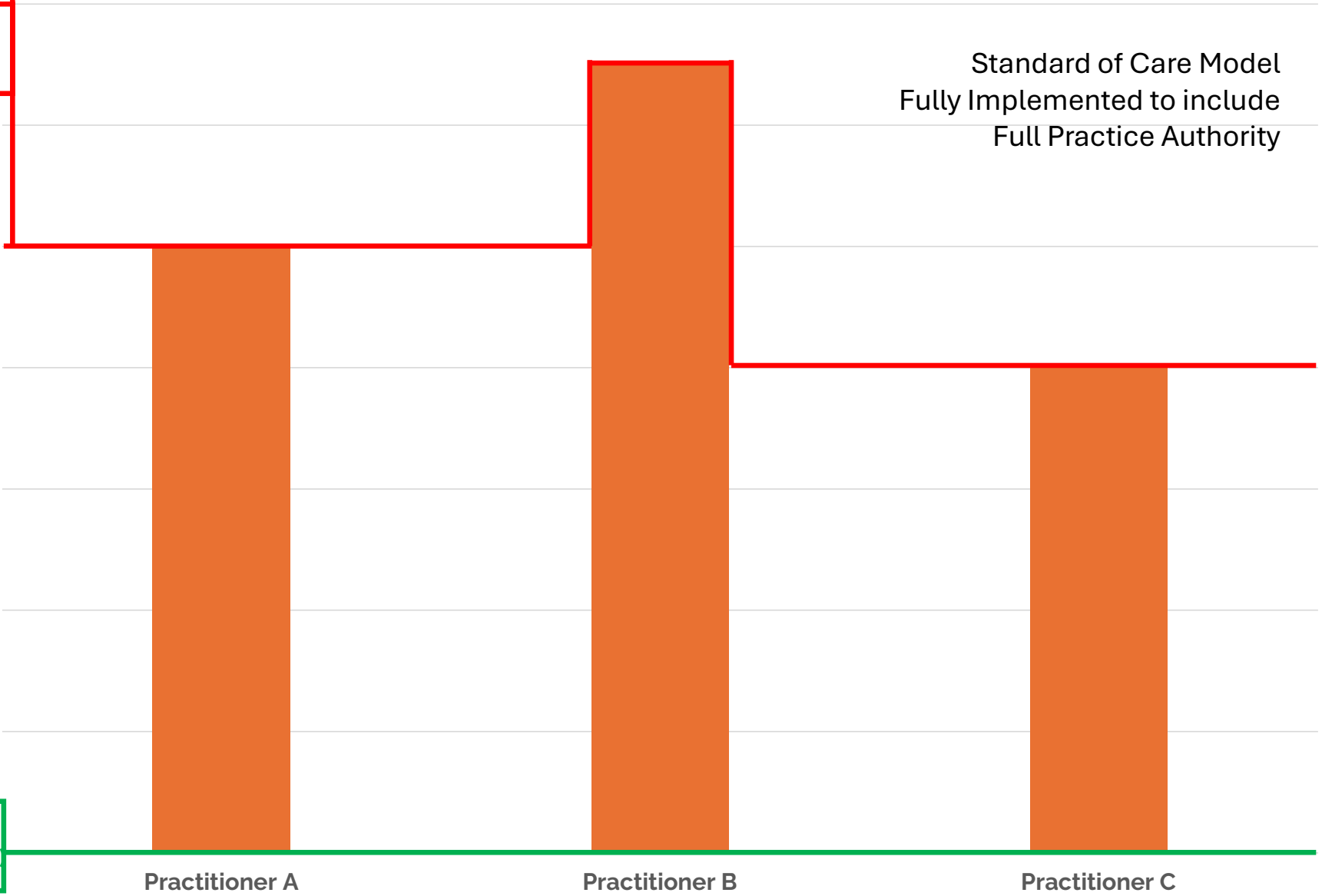
Legal Ceiling
("Top of License")



Scope of Practice



Entry Barrier
Minimum Competency



Standard of Care Model
Fully Implemented to include
Full Practice Authority

Practitioner A

Practitioner B

Practitioner C

Implementation of SOC

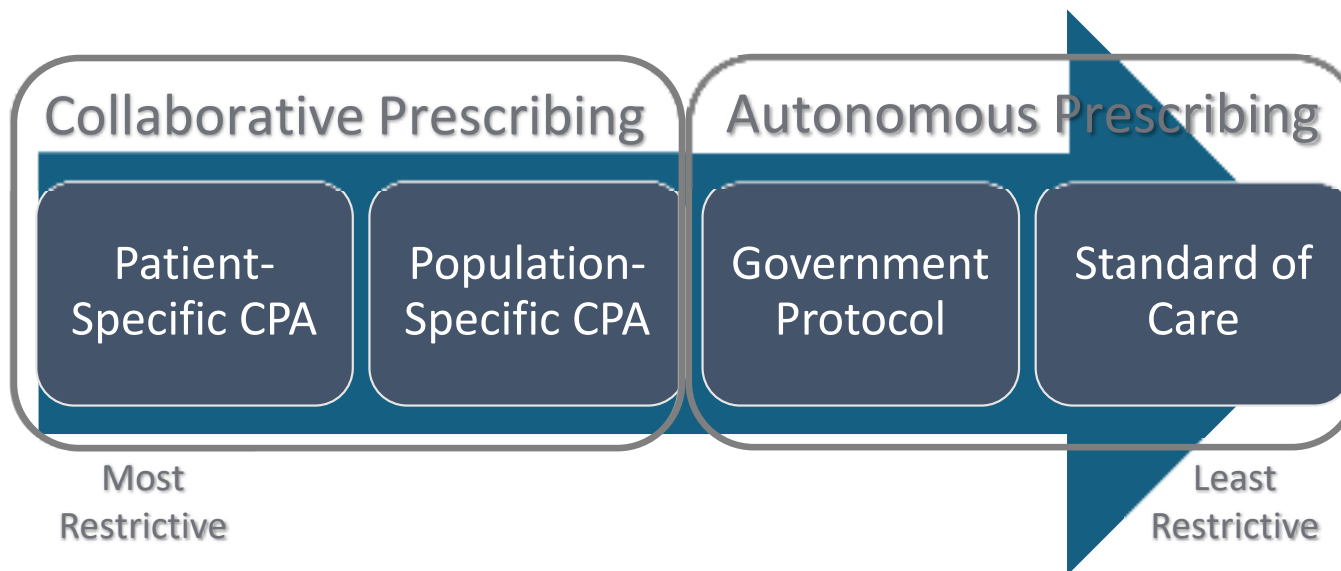
- Adopt a Broad Definition of "Practice of Pharmacy"
- Allow Elasticity for Scope of Practice Advancement Over Time
- Decide Which Limited Instances Still Necessitate Prescriptive Regulation
- Eliminate All Remaining Unnecessary Regulations
- Strengthen Accountability Mechanisms and Oversight



Idaho General Approach to the Practice of Pharmacy

- PRACTICE OF PHARMACY: GENERAL APPROACH. To evaluate whether a specific act is within the scope of pharmacy practice in or into Idaho, or whether an act can be delegated to other individuals under their supervision, a licensee or registrant of the Board must independently determine whether:
 - Is it expressly prohibited?
 - Is it appropriate for the licensee or registrant's education, training, and experience?
 - Does the act fall within the accepted standard of care?

Continuum of Pharmacist Prescriptive Authority



New York - Limited Pharmacist Prescribing/Dispensing/Administration Authority

Population-based collaborative practice agreements

- Must be with a physician only
- Restricted to specific settings
- Experience/training requirements

Non-patient specific order of:

- Immunizations with CPA (18 and older, specific immunizations listed in law)
- HIV PEP (7 day supply)
- Self-administered hormonal contraceptives

Administration of:

- Long acting injectables
- Anaphylaxis medications

“Full-scope pharmacist services include all proactive and comprehensive interventions that prevent or manage illness and are within an individual’s competency to perform independently.”

—Dr. Ross Tsyuki

Chair of the Department of Pharmacology, University of Alberta⁵⁴



What is Pharmacist Full Practice Authority?

Unrestricted ability to:

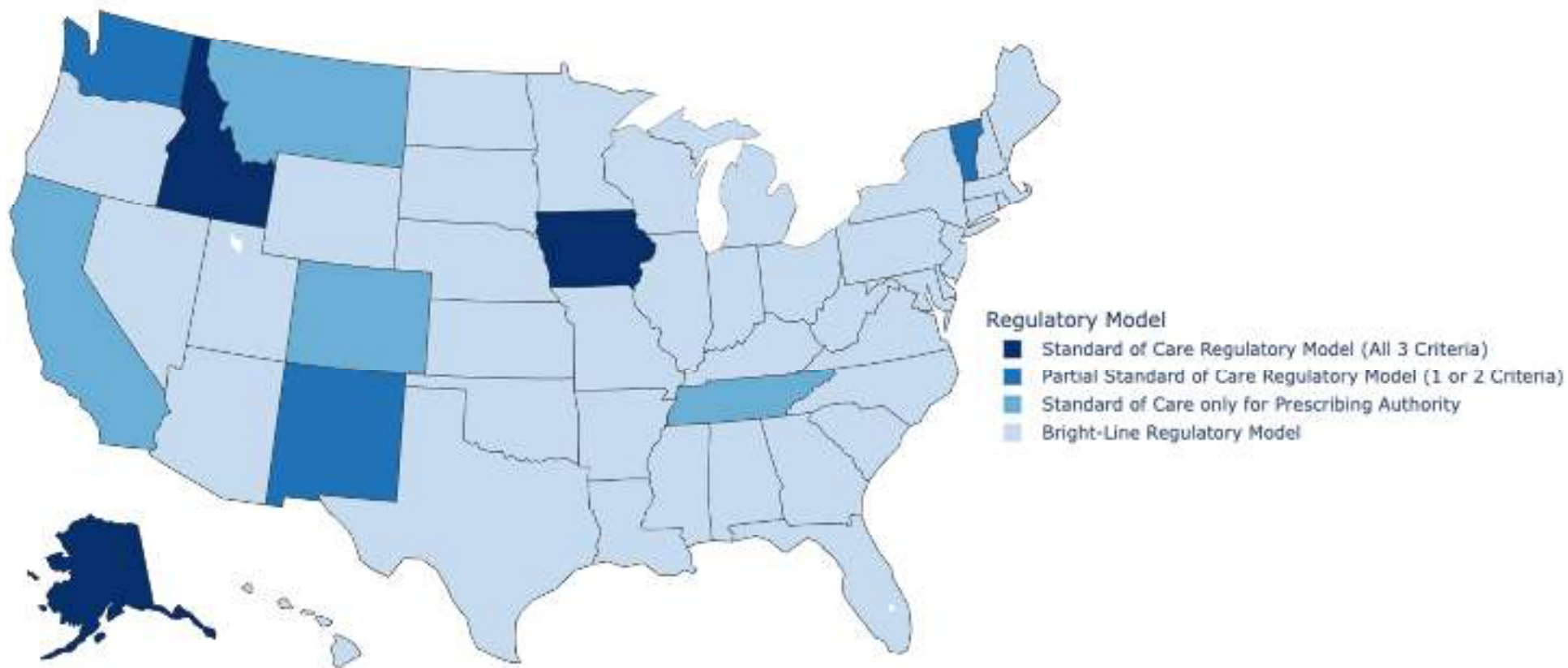
- Diagnose conditions
- Prescribe independently
- Order, interpret, and administer laboratory tests and imaging
- Administer drugs and devices
- Prescription adaptation
- Continuation of therapy

**Standard
of Care:**
Balancing
Scope Expansion
and
Patient Safety



Adapted from materials from Cicero Institute

Pharmacy Regulatory Models Across the United States



References

1. Adams JL, O'Connor S, Seignemartin B, Shipman AJ, McConnell W, Dudman A, Akers J, Vernon V. Battling professional self-sabotage: Embracing standard of care as the future of pharmacy regulation. *J Am Pharm Assoc.* 2023. DOI: <https://doi.org/10.1016/j.japh.2023.08.015>.
2. Frost T, Wolfson J 2024 Toward Pharmacist Full Practice Authority <https://ciceroinstitute.org/research/toward-pharmacist-full-practice-authority/>
3. Adams, AJ. 2019. Transitioning pharmacy to “standard of care” regulation: Analyzing how pharmacy regulates relative to medicine and nursing. *Res Social Adm Pharm.* <https://www.sciencedirect.com/science/article/abs/pii/S155174111830562X?via%3Dihub>
4. Adams AJ, Chopski NL, Adams JL. How to implement a standard of care regulatory model for pharmacists. *J Am Pharm Assoc.* 2024. DOI: <https://doi.org/10.1016/j.japh.2024.02.007>.
5. Vernon V, O'Connor S, Seignemartin B, Shipman AJ, Akers J Adams J. Development of a Rubric to Assess Pharmacy Regulatory Models. *Journal of the American College of Clinical Pharmacy.* 2025. <https://doi-org.libpublic3.library.isu.edu/10.1002/jac5.70011>
6. Adams AJ, Weaver KK. 2019. Pharmacists' Patient Care Process: A State “Scope of Practice” Perspective. *Innovations in pharmacy*, Vol. 10, No. 2. <https://pubs.lib.umn.edu/index.php/innovations/article/view/1389/1485>
7. Adams AJ, Weaver KK, Adams JL. 2023. Revisiting the Continuum of Pharmacist Prescriptive Authority. *JAPhA.* 63(2023) 1508-1514 [https://www.japha.org/article/S1544-3191\(23\)00238-8/fulltext](https://www.japha.org/article/S1544-3191(23)00238-8/fulltext)
8. Shakya, Shishir and Plemmons, Alicia and Bae, Kihwan and Timmons, Edward, The Pharmacist Will See You Now: Pharmacist Prescriptive Authority and Access to Care in Idaho (December 6, 2022). Available at SSRN: <https://ssrn.com/abstract=4294905> or <http://dx.doi.org/10.2139/ssrn.4294905>
9. Professional Standards Authority for Health and Social Care, United Kingdom. Right Touch Regulation. 2025 <https://www.professionalstandards.org.uk/publications/right-touch-regulation-2025#>
10. Cornell Law School Legal Information Institute https://www.law.cornell.edu/wex/bright-line_rule
11. Carmichael JM, et al. Collaborative Drug Therapy Management by Pharmacists. *Pharmacotherapy.* 1997;17(5):1050-1061.

Assessment Questions

- 1. Which statement best distinguishes *standard of care* regulation from *bright line* regulation in pharmacy practice?**
 - A. Standard of care provides detailed, task-specific rules, while bright line regulation allows broad professional judgment with few explicit requirements.
 - B. Standard of care relies on professional judgment guided by expected clinical behaviors, while bright line regulation specifies explicit, prescriptive rules that must be followed.
 - C. Both standard of care and bright line regulation emphasize detailed checklists for compliance.
 - D. Bright line regulation focuses on outcomes, whereas standard of care focuses on procedural steps.

Assessment Questions

1. Which statement best distinguishes *standard of care* regulation from *bright line* regulation in pharmacy practice?
 - A. Standard of care provides detailed, task-specific rules, while bright line regulation allows broad professional judgment with few explicit requirements.
 - B. Standard of care relies on professional judgment guided by expected clinical behaviors, while bright line regulation specifies explicit, prescriptive rules that must be followed.
 - C. Both standard of care and bright line regulation emphasize detailed checklists for compliance.
 - D. Bright line regulation focuses on outcomes, whereas standard of care focuses on procedural steps.

Assessment Questions

2. Which option best describes the relationship between a pharmacist's *scope of practice* and the *standard of care*?

- A. Scope of practice defines the minimum acceptable quality of care, while standard of care determines the legal boundaries of what a pharmacist may do.
- B. Scope of practice and standard of care are interchangeable terms describing state-level statutes.
- C. Scope of practice outlines what activities a pharmacist is legally permitted to perform, while the standard of care defines how those activities must be carried out to meet professional expectations.
- D. Standard of care expands a pharmacist's scope of practice beyond what is defined in law.

Assessment Questions

2. Which option best describes the relationship between a pharmacist's *scope of practice* and the *standard of care*?

- A. Scope of practice defines the minimum acceptable quality of care, while standard of care determines the legal boundaries of what a pharmacist may do.
- B. Scope of practice and standard of care are interchangeable terms describing state-level statutes.
- C. **Scope of practice outlines what activities a pharmacist is legally permitted to perform, while the standard of care defines how those activities must be carried out to meet professional expectations.**
- D. Standard of care expands a pharmacist's scope of practice beyond what is defined in law.



Questions?
jenadams@isu.edu
