

Lessons Learned in “Standard of Care” Regulation

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Financial Disclosures

Our speaker Alex Adams declares that he does not have a relevant affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.

Additionally, the individuals involved in the planning of this activity have not had an affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this CPE program within the past 24 months.

All relevant financial relationships have been mitigated.

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OBJECTIVES

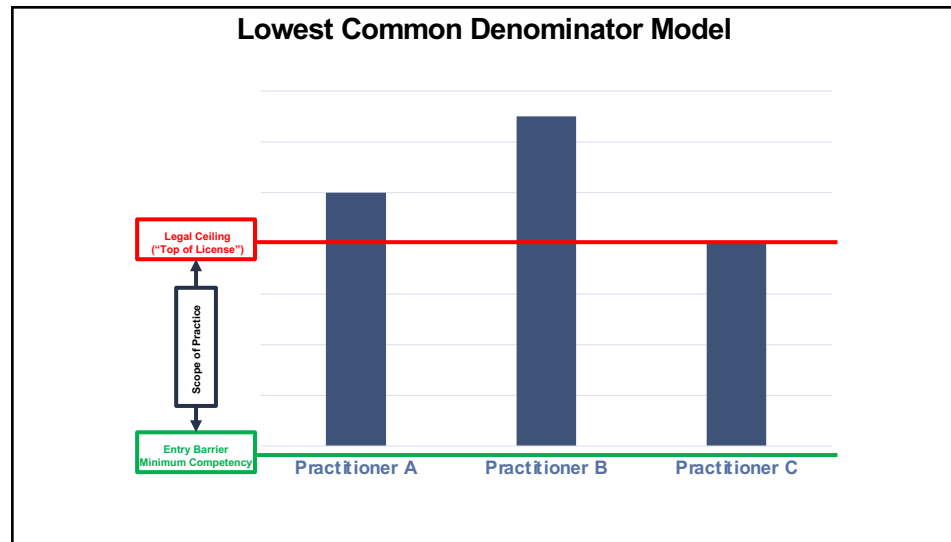
- Define "standard of care" regulation
- Describe differences between "standard of care" from traditional "prescriptive regulation"
- Discuss how pharmacy regulates professional services relative to other health professions

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STANDARD OF CARE REGULATION

- 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.

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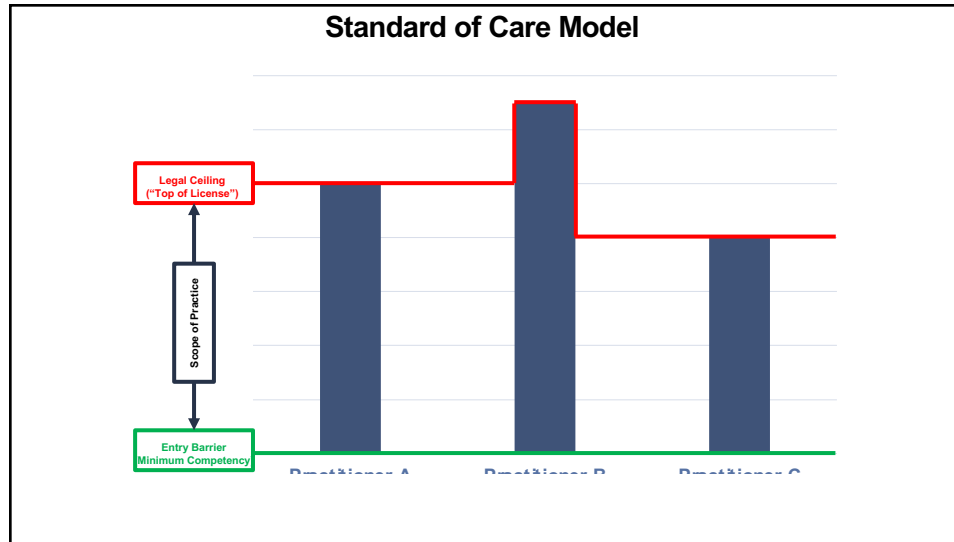
Standard of Care

- Regulation is determined by education, training, career experience, and practice environment
- Individualistic: recognizes professional heterogeneity
- Elastic; advances with new education, technology, etc.

Prescriptive Regulation

- Regulation is determined by the political process
- One-size-fits all: applies to all professionals in class
- Static (aside from law changes)

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HOW TO ADOPT A STANDARD OF CARE MODEL

1. Adopt a broad definition of the "practice of pharmacy"
2. Allow elasticity for innovations that are heretofore un contemplated
3. Decide which limited instances still necessitate prescriptive regulation
4. Eliminate unnecessary prescriptive regulations
5. Strengthen accountability mechanisms and oversight

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1. Broad Definition of "Practice of Pharmacy"

- "Practice of pharmacy" means the safe interpretation, evaluation, compounding, **administration**, and dispensing of prescription drug orders, patient counseling, **collaborative pharmacy practice**, provision of **pharmaceutical care** services, proper storage of drugs and devices, **and prescribing of drugs and devices**, as may be further defined in this chapter."

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2. Allow Elasticity for Innovation

- 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:
 - The act is **expressly prohibited** by [law].
 - The act is consistent with licensee or registrant's **education, training, and experience**.
 - Performance of the act is within the accepted **standard of care** that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training and experience.

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3. Decide When Prescriptive Regulation is Still Needed

Idaho retained prescriptive regulations for the following:

- Controlled substances
- Compounding
- Prescription adaptation (e.g., extensions, therapeutic substitution, quantity/formulation change, etc.)

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4. Eliminate Unnecessary Regulation

- “Prior to prescribing tobacco cessation products, the pharmacist must successfully complete a course on tobacco cessation therapy taught by a provider accredited by ACPE.”
- “The pharmacist shall recommend that the patient seek additional assistance for behavior change including, but not limited to, the Idaho QuitLine.”

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5. Strengthen Accountability

- The following acts or practices by any licensee or registrant are declared to be specifically, but not by way of limitation, **unprofessional conduct** and conduct contrary to the public interest:
- 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.

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CLOSING THOUGHTS

- Don't wrestle with theoreticals. Always ask:
 - ▷ How have other states approached this?
 - ▷ How have other health professions approached this?
 - ▷ What has their actual experience been?
- Be comfortable in the grey area...focus on probabilities, not remote possibilities
- Recognize the difference between law and practice
- Each regulation matters as each one sets a precedent
- Eventually you will be the old-timer. What do you want your story to be?

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Learning Assessment Question 1

Which of the following best defines “standard of care”

- a) The level and type of care that a competent health care professional would have provided under certain circumstances.
- b) The expectation of services that a patient should determine.
- c) The ability to use a check list to ensure pharmacies are in compliance with regulations.
- d) The competence of a physician who performs surgery at a well known health care facility.

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Learning Assessment Question 2

Which of the following differentiates “standard of care” from “prescriptive regulations”?

- a) Standard of care is a one-size-fits all approach.
- b) Prescriptive regulations are individualistic.
- c) Standard of care is elastic and advances with new education.
- d) Prescriptive regulations are determined by education and practice environments.

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Learning Assessment Question 3

Which of the following is part of the steps towards how to adopt a standard of care model?

- a) Adopt a prescriptive definition of the "practice of pharmacy".
- b) Allow for strict rules that are prescriptive in nature.
- c) Loosen accountability mechanisms and oversight.
- d) Eliminate unneeded prescriptive regulations.

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