

Standard of Care Regulation and the Implications on Pharmacy Law Education

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Conflict of Interest Disclosure

- We declare that neither of us, nor any immediate family member, have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

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Learning Objectives

At the completion of this activity, the participant will be able to:

- Define standard of care as it relates to healthcare provider regulation.
- Discuss the challenges in educating PharmD learners about standard of care regulation.
- Outline changes made to a pharmacy law curriculum to accommodate the concept of standard of care regulation.
- Describe one approach to teaching standard of care regulation in pharmacy law.

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Assessment Questions

True or False:

- A "standard of care approach" is rooted in specific, precise regulations.
- NABP has formed a task force to assist states with the transition to a standard of care approach.
- A "standard of care" approach uses a reasonable and prudent practitioner as its standard.

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Task Force to Develop Regulations Based on Standards of Care

May 18, 2018

THEREFORE BE IT RESOLVED that NABP convene an interdisciplinary task force to explore considerations for transitioning from strictly prescriptive rule-based regulations to a model that includes a standard of care process, and discuss the necessary tools (eg, peer review committees, enforcement approaches) for boards of pharmacy to make this transition.

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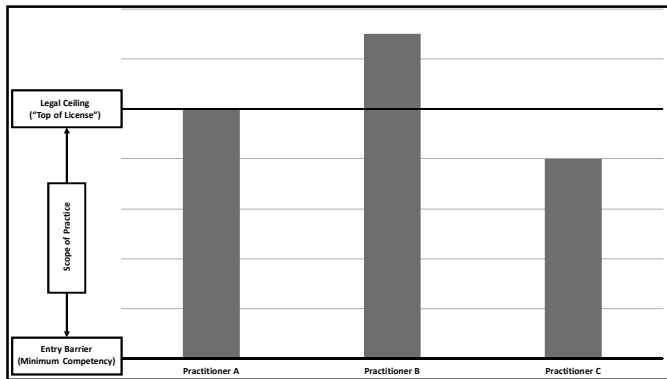
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• Scope of Practice

- 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.

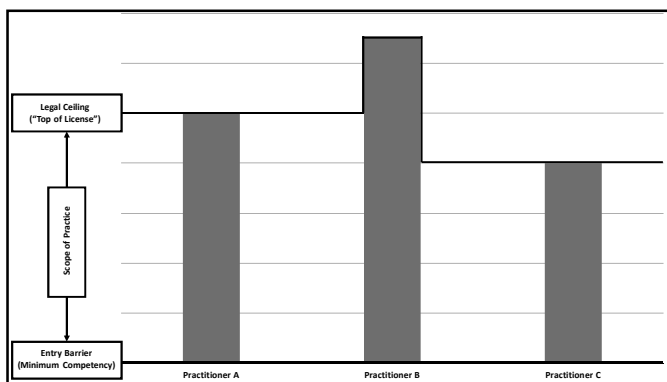


Medical Standard of Care

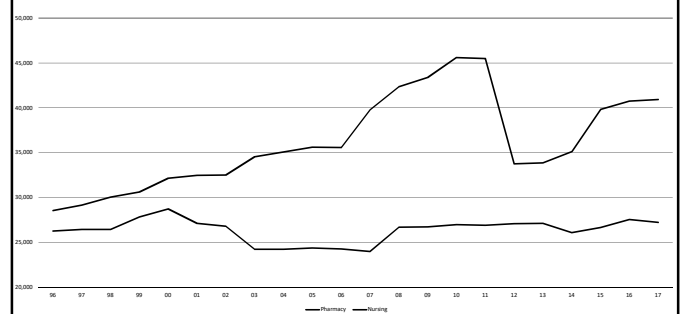
- The "medical standard of care" is typically defined as the level and type of care that a reasonably competent and skilled health care professional, with a similar background and in the same medical community, would have provided under the circumstances that led to the alleged malpractice.

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Total Word Count in Idaho Regulations from 1996 to 2017



400. Decision-Making Model (Nursing)

To evaluate whether a specific act is within the legal scope of nursing practice, a licensed nurse shall determine whether:

- The act is **expressly prohibited** by the Nursing Practice Act...
- The act was **taught** as a part of the nurse's education...
- The act is consistent with standards of practice **published** by a national specialty nursing organization or supported by recognized nursing literature or reputable published **research**...
- Performance of the act is **within the accepted standard of care** that would be provided in a similar situation by a reasonable and prudent nurse with similar education and experience...

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Two Different Approaches

• Nursing

- Stopped defining every individual task that each category of nurse could perform
- Transitioned to a "standard of care" approach
- Provided a decision-making model to identify if an act is within a nurse's scope

"Addition by Subtraction"

• Pharmacy

Added new rules for each task:

- 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 rules for each facility type:

- Telepharmacy (1,975 words)
- Automated dispensing systems (1,715)
- Centralized pharmacy services (682)

"Compensated Addition"



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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.

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Guidance to Pharmacists

- If someone asks why I made this decision, can I justify it as being consistent with good patient care?
- Would this decision withstand a test of reasonableness (e.g., would another prudent pharmacist make the same decision in this situation)?

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Professional Practice Standards



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Changes to Law Curriculum

- Additional time added to the Intro to Law component of the P1 year.
- Continuation of flipped classroom and a practical approach to learning the law in the P3 semester-long course
- No State MPJE to “teach to”
 - Exams re-designed
 - Practice question bank
- Case-based learning in P1 and P3 year specific to standard of care
 - Practice the ambiguity that standard of care involves

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Case-Based Learning

D.H. brings her daughter, S.H., who is in kindergarten (DOB 06/01/2013) to the pharmacy for her flu shot:

- Based on what is allowed by Alaska law, outline the next steps for DH and SH.
- Based on what is allowed by Idaho law, outline the next steps for DH and SH.

In your outlines, indicate the relevant ID and AK laws and the appropriate standard of care for SH.

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Case-Based Learning

Ryan Smith, DO, calls the pharmacy with a new verbal prescription for a schedule VI drug, and a pharmacy technician answers the phone:

- Based on what is allowed by Alaska law, outline the next steps of how this might be handled in the pharmacy.
- Based on what is allowed by Idaho law, outline the next steps of how this might be handled in the pharmacy.

In your outlines, indicate the relevant ID and AK laws and the appropriate standard of care.

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Case-Based Learning

M.C. a 48 year old woman presents to the pharmacy complaining of urinary urgency and frequency, dysuria, and lower abdominal discomfort. She has had a previous UTI and wants to know if there are any OTC options that can help until she can get in to see her physician.

- Based on what is allowed by Alaska law, outline the next steps of how this might be handled in the pharmacy.
- Based on what is allowed by Idaho law, outline the next steps of how this might be handled in the pharmacy.

In your outlines, indicate the relevant ID and AK laws and the appropriate standard of care.

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