

# THE ROLE OF SCOPE OF PRACTICE, STANDARD OF CARE, AND PERMISSIONLESS INNOVATION IN THE REGULATION OF PHARMACY



In support of improving patient care, this activity has been planned and implemented by Idaho State Board of Pharmacy and Idaho State University. Idaho State University 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.

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## Disclosure

The planners and presenters of this presentation have no relevant financial relationships with a commercial interest pertaining to the content of this presentation.

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## Objectives

Discuss the risks and benefits of regulating pharmacy clinical services similarly to other healthcare professions

Describe the factors involved in determining a states' scope of pharmacy

Explain how the public health protection is retained under a standard of care model of regulation

**City of Sandpoint v. Independent Hwy Dist.**, 161 Idaho 121, 384 P.3d 368 (2016). "An administrative agency is limited to the power and authority granted it by the legislature. \* \* \* An agency must exercise any authority granted by the statute within the framework of that statutory grant. It may not exercise its sub-legislative powers [i.e. rulemaking powers] to modify, alter, enlarge or diminish the provisions of the legislative act which is being administered."

**Roberts v. Trans. Dep't.**, 121 Idaho 727, 827 P.2d 1178 (1991) (rules enacted in excess of an agency's "rule-making authority [are] invalid and unenforceable").

**Montana Soc. of Anesthesiologists v. Montana Board of Nursing**, 339 Mont. 472, 171 P.3d 704 (2007). "The scope of practice for CRNAs in Montana, as established by the Legislature, is the breath of the professional practice for which the CRNA is licensed. \* \* \* We agree with the District Court that the Legislature has not provided the BON with the authority to re-define or expand the scope of practice established by the CRNA's enabling legislation."

**Navo v. Bingham Memorial Hospital**, 160 Idaho 363, 373 P.3d 681 (2014).

"Standards of care are sensitive to evolving changes in the way health care services are delivered in the various communities in our state. Indeed, the Court has recognized that 'governmental regulation, development of regional and national provider organizations, and greater access to the flow of medical information' have provided 'various avenues by which a plaintiff may proceed to establish a standard of care.'"

## Idaho Pharmacy Board Rule 27.01.01.100

**"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 another individual under their supervision, a licensee or registrant of the Board must independently determine whether:

.01 Express Prohibition. The act is expressly prohibited by \* \* \* applicable state or federal laws, rules or regulations.

.02 Education, Training, and Experience. The act is consistent with licensee or registrant's education, training, and experience.

.03 Standard of Care. 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."

**Idaho Stat. § 6-1012. Proof of Community Standard of Health Care Practice in Malpractice Case**

"In any case, claim or action for damages due to injury to or death of any person brought against any physician and surgeon or other provider of health care . . . on account of the provision of or failure to provide health care . . . such claimant or plaintiff must, as an essential part of his or her case in chief, affirmatively prove by direct expert testimony and by a preponderance of all the competent evidence, that such defendant then and there negligently failed to meet the applicable standard of health care practice of the community in which such care was or should have been provided . . . ."

**Hall v. Rocky Mountain Emergency Physicians, LLC, 155 Idaho 322, 312 P.3d 313 (2013).**

Holding that the applicable standard of care is composed of three related components:

"First, it is the standard of care 'for the class of health care provider to which the defendant belonged and was functioning, taking into account the defendant's training, experience, and fields of medical specialization, if any.'"

"Second, it is the standard of care as it existed "at the time of the defendant's alleged negligence."

"Third, it is the standard of care 'in the same community.'"

**Krueger v. Bd. of Prof. Discipline of Idaho State Bd. of Med. Prac., 122 Idaho 577, 836 P.2d 523 (1992).**

The Idaho Supreme Court reaffirmed two prior decisions holding that "administrative boards [cannot] rely on their own expertise, experience and collective knowledge" in determining whether a licensee meets the standard of care.

**Peckham v. Idaho State Board of Dentistry, 154 Idaho 846, 303 P.3d 205 (2013).**

The Idaho Supreme Court reversed a Dental Board disciplinary decision because the board failed to provide evidence at the hearing as to the standard of care, i.e. "that a dentist in good standing under the circumstances Dr. Peckham encountered would have apprised his patient" as the board alleged was required.

**Permissionless Innovation, The Continuing Case for Comprehensive Technological Freedom, Thierer, A. (2016 rev. & expanded ed.)**

"The central fault line in innovation policy debates today can be thought of as the 'permission question.' The permission question asks, Must the creators of new technologies seek the blessing of public officials before they develop and deploy the innovations? How that question is answered depends on the disposition one adopts toward new inventions and risk taking more generally." p. 1 (emphasis added)

"[Permissionless innovation] refers to the notion that experimentation with new technologies and business models should generally be permitted by default. p. 1 (emphasis added)

In this book, I will show how precautionary principle thinking is increasingly creeping into modern technology policy discussions, and explain why that is dangerous and must be rejected, and argue that policy makers should instead unapologetically embrace and defend the permissionless innovation vision – not just for the internet but also for all new classes of networked technologies and platforms." p. 8 (emphasis added)

**Idaho Pharmacy Act**

Section 54-1702. **Legislative Declaration.**

"The practice of pharmacy in the state of Idaho is declared a professional practice affecting the health, safety, and welfare of the public and is subject to regulation and control in the public interest."

Section 54-1703. **Statement of Purpose.**

"It is the purpose of this act to promote, preserve and protect the health, safety and welfare of the public by and through the effective control and regulation of the practice of pharmacy . . . ."

**Mission of the Idaho Pharmacy Board**

"Promote, preserve and protect the health, safety and welfare of the public by and through the effective control and regulation of the practice of pharmacy."