



NABP

National Association of
Boards of Pharmacy

Regulating to Standard of Care in Pharmacy

California Board of Pharmacy

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NABP Mission Statement

NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

Vision Statement

Innovating and collaborating today for a safer public health tomorrow

NABP Purpose

Founded in 1904, the purpose of the Association is to provide for interstate and interjurisdictional transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation, and to improve the standards of pharmacist education, licensure, and practice by cooperating with state, national, and international government agencies and associations having similar objectives.



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Resolution from NABP Annual Meeting May 2018

- **RESOLUTION NO: 114-4-18**
TITLE: Task Force to Develop Regulations Based on Standards of Care
ACTION: PASS
- **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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NABP Task Force to Develop Regulations Based on Standards of Care

October 9-10, 2018

- **Recommendation 1:** NABP Should Encourage State Boards of Pharmacy to Review Their Practice Acts and Regulations, Consistent With Public Safety, to Determine What Regulations Are No Longer Applicable or May Need to Be Revised or Eliminated While Recognizing Evolving Pharmacy Practice.
- **Recommendation 2:** NABP Should Encourage State Boards of Pharmacy to Consider Regulatory Alternatives for Clinical Care Services That Require Pharmacy Professionals to Meet the Standard of Care.
- **Recommendation 3:** NABP Should Collaborate With States That May Adopt Standards of Care-Based Regulations to Identify, Monitor, and Disseminate Outcomes.



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NABP ask Force to Develop Regulations Based on Standards of Care

- **Recommendation 4:** NABP Should Develop a Definition of “Standards of Care” Based in Evidence to Be Included in the Model Act.
- **Recommendation 5:** NABP Should Monitor the Adoption of the Standards of Care-Based Regulation Model by the States and, if and When Appropriate, Consolidate and Share Information and Tools Obtained From Professional Regulatory Groups and Relevant Stakeholders for Regulating Standards of Care-Based Practice.



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NABP Model Act Changes Based on Recommendation #4

- Law Enforcement and Legislation Committee
- Meeting on January 23-24, 2019
- Amendments adopted August 2019

NABP Model Pharmacy Act/Rules

Standards of Care Definition

- “Standard of Care” means the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.



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States- Standard of care regulation

- Idaho
 - Washington
-
- Significant reduction in prescriptive regulation in practice sections
 - Broad language that does not require frequent review and updates
 - Enables innovative practice approaches that enhance patient care and safety



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Standard of Care Definition

- **Idaho**

- 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.
- ID Rule 27.01.01.100

- **Montana**

- establish standards of care for patients concerning health care services that a patient may expect with regard to pharmaceutical care.
- MT Rule 37-7-201



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Disciplinary tool for board review and determination of failure to meet standard

- **Idaho**

- *“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”*
- ID 24.36.01.104

- **Ohio**

- *“Failed to conform to prevailing standards of care”*
- 4729 1-4-01 subsection p
- 4729 1-3-02 subsection 2- Immunization administration

- **Wisconsin**


- *“practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist which harmed or could have harmed a patient”*
- PHAR 10.03

WAC 246-16-810 WA PQAC Sanction Schedule

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**Disciplinary tool for board review
and determination of failure to meet standard-
Continued**

- **Washington**
 - Practice below standard of Care
 - WAC 246-16-810

PRACTICE BELOW STANDARD OF CARE				
Severity	Tier / Conduct	Sanction Range In consideration of Aggravating & Mitigating Circumstances		Duration
		Minimum	Maximum	
least  greatest	A – Caused no or minimal patient harm or a risk of minimal patient harm	Conditions that may include reprimand, training, monitoring, supervision, probation, evaluation, etc.	Oversight for 3 years which may include reprimand, training, monitoring, supervision, evaluation, probation, suspension, etc.	0-3 years
	B – Caused moderate patient harm or risk of moderate to severe patient harm	Oversight for 2 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc.	Oversight for 5 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. OR revocation.	2 years - 5 years unless revocation
	C – Caused severe harm or death to a human patient	Oversight for 3 years which may include suspension, probation, practice restrictions, training, monitoring, supervision, probation, evaluation, etc. In addition - demonstration of knowledge or competency.	Permanent conditions, restrictions or revocation.	3 years - permanent



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Other State Approaches

- North Dakota
 - Pharmacy patient's bill of rights
 - *“To professional care provided in a competent and timely manner in accordance with accepted standards of pharmacy practice.”*
 - ND Admin Code 61-04-07-01
- Delaware
 - Pharmacist in Charge Responsibilities
 - *“Establish procedures within operation that maintain standard of practice as it relates to the dispensing of pharmaceuticals”*
 - DE Admin Code 3.12.4



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Additional factors impacting standard of care regulatory scheme

- **COVID-19 Pandemic**
 - Board and staff had to shift focus to supporting licensees during a PHE
 - Executive orders and federal PREP act gave wider practice authority
 - No current legislation on standard of care across the states to date



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Thank you