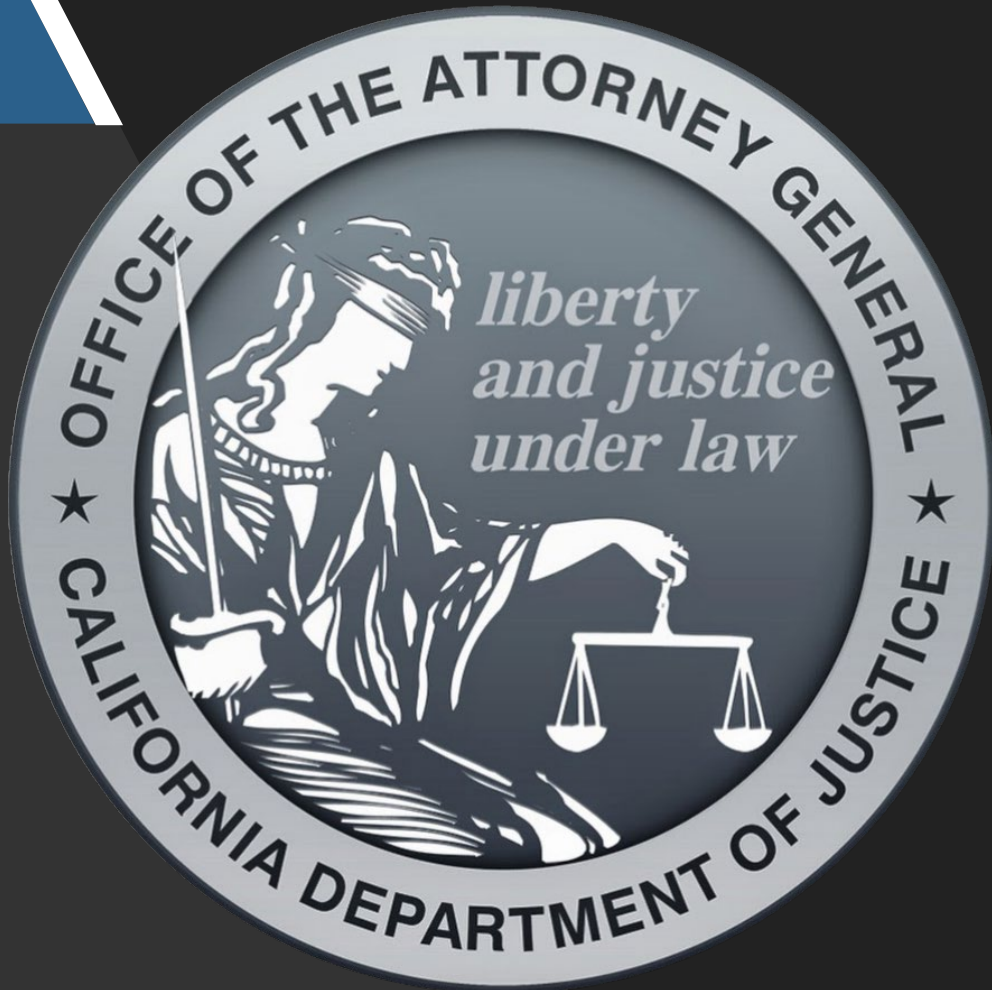




STANDARD OF CARE

FOR THE CALIFORNIA STATE  
BOARD OF PHARMACY

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The Office of the Attorney General represents state agencies and employees in judicial and other proceedings.

(Gov. Code, § 1040)

# 3 Department of Consumer Affairs

- ▶ The Department of Consumers Affairs (DCA) administers more than 3.4 million licenses in more than 280 license types including certificates, registrations and permits, from architects to accountants, dentists to veterinarians. DCA protects and serves consumers in the following ways:
  - ▶ DCA is a licensing entity.
  - ▶ DCA is a regulator.
  - ▶ DCA is an educator.

# Standard of Care Why do we care?

- ▶ The Board must prepare and transmit a report to the Legislature by July 2023 detailing whether moving to a standard of care model for pharmacy law is feasible and appropriate.
- ▶ It is helpful to understand what a standard of care model is and how it is used before the Board begins its discussions that will form the basis for drafting this required report.
- ▶ This presentation is for informational purposes only and does not provide a position about whether the Board can and/or should move to a standard of care model.
- ▶ The Board's report is essentially to assist the Legislature in deciding whether to revise pharmacy law in California to move to a standard of care model.

# Current Structure of CA Pharmacy Law

- Pharmacy law covers the following areas:
- Licensing requirements for pharmaceutical personnel and facilities.
- Authorized scope of practice for pharmacists (Section 4051 and 4052), pharmacy technicians (Section 4115) and intern pharmacists (Section 4114).
- Prescriptive rules that establish minimum operational standards for licensed facilities.
- Some statutes and rules detailed and some are governed by standard of care (*i.e.*, DUR is required prior to dispensing a drug but how it is to be done is governed by a standard of care).

# Federal Laws Implicating Pharmacy Law

- ▶ Federal law also impose requirements on entities involved with distribution or dispensing of controlled substances (DEA licenses required as well as compliance with DEA rules regarding controlled substances).
- ▶ The federal Food, Drug and Cosmetic Act also has prescriptive rules that impact the practice of pharmacy in many areas. The FDA is the agency that administers and enforces this law and, among other things, regulates drug dispensing (*i.e.*, there are hierarchies for which drugs to dispense that require use of FDA-approved drugs (if any) except under designated exceptions).

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## Current California Disciplinary Process

- ▶ Under Bus. & Prof. Code section 4301, the Board can take disciplinary action against a licensee for unprofessional conduct.
- ▶ Unprofessional conduct includes, among other conduct, violations of any of the statutes of California or the United States regulating controlled substances or dangerous drugs. (Bus. & Prof. Code section 4301(j)).
- ▶ Unprofessional Conduct also includes causes for discipline for incompetence or gross negligence. This is a violation of standard of care (*i.e.*, in conducting a DUR a pharmacist misses an FDA warning of a risk). (Bus. & Prof. Code section 4301, subdivisions (b) and (c)).

# Current California Disciplinary Process

- ▶ The California model for discipline is a hybrid disciplinary model involving the potential for discipline for violating state and federal statutes and rules regulating controlled substances or dangerous drugs and violations of standard of care.
- ▶ Discipline can be imposed against a licensee for their own conduct in violating statutes or rules or standard of care (*i.e.*, a pharmacist does not provide a consultation when required or requested or misses a contraindication identified in FDA warnings on a drug).
- ▶ Discipline can also be imposed against a pharmacist for violations of law by pharmacy personnel under their supervision, such as pharmacy technicians or intern pharmacists.
- ▶ Finally, pharmacists-in charge are responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. PICs also can be disciplined for a pharmacy's violation of such laws even if unaware of the practices.



# Standard of Care Where did it come from?

- ▶ Historically, the concept of “standard of care” arose in context of lawsuits in which one party is harmed and suing another person or entity for their harm.
- ▶ The standard of care is that of the ordinary or reasonable person and the amount of care must be in proportion to the danger to be avoided based on reasonably foreseeable consequences.
- ▶ This standard is objective.
- ▶ Generally, what constitutes due care under the circumstances is a question of fact for the jury, however, the requisite standard of care can be established in judicial decisions or in statutes or regulations.
- ▶ If someone violates an applicable statute or rule and causes harm to another, the violation of the statute or rule is deemed to be a violation of the standard of care and the doctrine is referred to as negligence per se. This doctrine of negligence per se has been applied in the professional context in medical malpractice cases.
- ▶ Evidence Code section 669 also codified negligence per se as a presumption affecting burden of proof in applicable cases.

# Standard of Care Model vs. Regulatory Model

- ▶ California pharmacy law is a hybrid structure that incorporates both state and federal laws and regulations and standard of care provisions.
- ▶ Statutes are developed by the Legislature and can be motivated by patient safety or other societal interests (i.e. requirements related to controlled substance prescription forms and move to e-prescriptions are tied to reducing diversion of addictive drugs).
- ▶ The “standard of care” is the treatment that another reasonably prudent practitioner in a similar setting would give to a patient.
- ▶ From a practical standpoint, generally at hearing the standard of care is established by (dueling) expert testimony each hired by the Board and the Respondents.
- ▶ The Legislature and the Board are not typically engaged in the actual development of clinical standards of care.
- ▶ Can look to professional organizations, learned treatises for guidance.

# Examples of Standard of Care Model

## ▶ Board of Registered Nursing

- ▶ BPC section 2761 states: The board may take disciplinary action... for any of the following: (1) Incompetence, or gross negligence in carrying out usual certified or licensed nursing functions.
- ▶ Cal. Code of Regs., title 16, sections 1442 through 1443.5 define incompetence and gross negligence.
- ▶ Section 1442 states: "gross negligence" includes an extreme departure from the standard of care which, under similar circumstances, would have ordinarily been exercised by a competent registered nurse.
- ▶ Section 1443 states: "incompetence" means the lack of possession of or the failure to exercise that degree of learning, skill, care and experience ordinarily possessed and exercised by a competent registered nurse as described in Section 1443.5.

# Examples of Standard of Care Model (cont.)

## ▶ Medical Board of California

- ▶ BPC section 2234: The board shall take action against any licensee who is charged with unprofessional conduct which includes, but is not limited to, the following:
  - ▶ (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
  - ▶ (b) Gross negligence.
  - ▶ (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.
- ▶ Gross Negligence is defined as “the want of even scant care” or “an extreme departure from the standard of care.
- ▶ Negligence is the failure to use that level of skill, knowledge and care in diagnosis and treatment that other reasonably careful physicians would use in the same or similar circumstances. Sometimes called a “simple departure” from the standard of care.
- ▶ Note that after gross negligence, doctors can only be disciplined for repeated negligent acts.

# Examples of Standard of Care Model (cont.)

- ▶ Board of Vocational Nursing and Psychiatric Technicians
  - ▶ Similar to Registered Nursing but:
    - ▶ Regulations section 2519 states: “gross negligence” means a substantial departure from the standard of care which, under similar circumstances, would have ordinarily been exercised by a competent licensed vocational nurse, and which has or could have resulted in harm to the consumer. An exercise of so slight a degree of care as to justify the belief that there was a conscious disregard or indifference for the health, safety, or welfare of the consumer shall be considered a substantial departure from the above standard of care.
    - ▶ Regulations section 2520 states: “incompetence” means the lack of possession of and the failure to exercise that degree of learning, skill, care and experience ordinarily possessed and exercised by responsible licensed vocational nurses.

# Example of Regulatory Model

- ▶ California Board of Accountancy
  - ▶ Complex profession, highly regulated for the protection of the public
  - ▶ Subject to both state and federal regulations as well as IRS, SEC, and other guidance
  - ▶ Not a healthcare profession, and therefore patient's lives are not at risk as in pharmacy or the other examples of healthcare professions.

# Benefits of Standard of Care Model

- ▶ The standard of care can shift over time as practice evolves, and may be more flexible to apply to unique factual situations
- ▶ The Legislature and the Board would not need to change/update laws and regulations as frequently
  - ▶ Fewer laws and regulations for licensees to learn and follow

# Drawbacks of Standard of Care Model

- ▶ Laws are less explicit causing practitioners to have doubt about what is or is not permissible and how they would be held accountable for standard of care violations.
- ▶ Board will have to rely on expert testimony to establish the standard of care, and cases can turn into a “battle of the experts” (*i.e.* a battle of finances).
- ▶ Standard of care may change based on location or practice setting, (*i.e.* practice in downtown Los Angeles may differ from practice in a small town in the mountains like Susanville, or from a chain store to an independent pharmacy). This could create differing standards in California.
- ▶ The standard of care model may not take into account different competing interests weighed by the Legislature in enacting specific requirements; (*i.e.* prescription forms, e-prescriptions, or inventory reconciliation processes designed to help prevent diversion of controlled substances).



# Benefits of Regulatory Model

- ▶ Statutes and regulations can be clear, explicit, and straightforward. Provides clear guidance about what is allowed or prohibited.
- ▶ Allows the public to engage in the rule-making process.
- ▶ Ensures that licensees are all following the same rules and can help promote consistency in standards across the State.
- ▶ Courts are deferential to agency interpretation of regulations. Courts may need guidance evaluating or weighing sources of expert testimony.

# Drawbacks of Regulatory Model

- ▶ Statutes and regulations that become out of date could possibly be a barrier to rapidly evolving pharmacy practice.
- ▶ Statutes and regulations can be time consuming and hard to change in time to address rapidly changing practice.
- ▶ Statutes and regulations require amendments to stay current.
- ▶ Simply more rules and regulations to remember and follow.

## Potential Uses of Standard of Care Model

- ▶ Before considering the feasibility or appropriateness of switching to a standard of care model, the Board may want to consider how stakeholders may wish to use a standard of care model.
- ▶ A Standard of Care model may be used to:
  - ▶ Replace minimum operating standards in pharmacies and other facilities.
  - ▶ Broaden a pharmacist's scope of practice based on self-determined education or skill, instead of the detailed protocols covering different areas of authorized practice (*i.e.*, PeP/PreP, contraceptives, vaccines, and naloxone).
  - ▶ Authorize discipline only in cases involving a pharmacist's breach of a standard of care to a patient similar to the Medical Board (Medical Board must prioritize investigations and discipline for cases involving gross negligence or repeated acts of negligence).

# Examples

- ▶ The Board of Pharmacy designated *In the Matter of the Accusation Against Pacifica Pharmacy* as a precedential decision.
- ▶ On pages 11-12 the administrative law judge discussed the standard of care.
- ▶ The standard of care includes a responsibility to comply with the laws and regulations governing pharmacy.
- ▶ In this case, the standard of care was to use professional judgment when dispensing controlled substances and comply with regulations.

# Final Considerations

- ▶ The Legislature has spent considerable time drafting a structure for pharmacy law balancing consumer protection and other competing interests.
- ▶ The Board has spent considerable time and effort developing regulations, educating licensees and the public, and enforcing them.
- ▶ The changes necessary to transition to a standard of care model will depend on the final determination of how to use a standard of care model in pharmacy law, and could include statutory and regulatory changes and education on the changes.
- ▶ Either way, pharmacy will continue to be a highly regulated industry – practitioners will have to comply with federal statutes and rules impacting pharmacy practice.

# Questions?