



July 12, 2024

Dear California State Board of Pharmacy,

We are writing to express our appreciation for the work that the Licensing Committee has done to advance the standard of care as a regulatory model for pharmacy. The modifications we suggest aim to improve the clarity and utility of the proposed amendments being considered by the State Board.

**Please find the details below:**

### **Section 4052**

(a) Notwithstanding any other law, a pharmacist may do all of the following:

(10) ~~Furnish an FDA approved or authorized medications that are as part of preventative health care services that do not require a new diagnosis, except for diagnoses related to self-care. The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice. This section shall not allow a pharmacist to furnish a medication for off-label use.~~

Justification: Grammatical clarification. The clause "Pharmacist shall notify..." has been moved to Section 4052 (d) below to cover all instances related to documentation and communication with other healthcare providers. The sentence prohibiting pharmacists from providing medication for off-label use is overly restrictive. Pharmacists must have the flexibility to provide medication based on best practices, emerging health threats, and patient welfare. Additionally, off-label use for package inserts are not routinely updated regarding guidelines, particularly when a brand becomes generic.

(11) Furnish an FDA approved or authorized noncontrolled medication for the treatment of conditions that

- (a) are minor, non-chronic health conditions
- (b) or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.

~~The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a primary care provider. This section shall not allow a pharmacist to furnish a medication for off-label use.~~

Justification: The clause "Pharmacist shall notify..." has been moved to Section 4052 (d) below for the same reason as stated above Section 4052 (a) (10).

(12) ~~Order and interpret drug therapy related tests. tests for the purpose, monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.~~



Justification: The clause “Pharmacist who orders and interprets...” has been replaced by Section 4052 (d) below to cover all instances related to documentation and communication with other healthcare providers.

(13) Initiate, adjust, or discontinue drug therapy for a patient under any of the following:

- (A) A collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.
- (B) Pursuant to an order or authorization made by the patient’s prescriber and in accordance with the policies, procedures, or protocols of the entity providing health care services. ~~unless a patient’s treating prescriber otherwise prohibits such action.~~

Justification: Strike “unless a patient’s treating prescriber otherwise prohibits such action.” Paragraph (13) (B) begins with “Pursuant to an order or authorization by the patient’s prescriber”, thereby obviating the need for the “unless” statement.

(17) Adjust ~~drug therapy regimens~~ prescription treatment drug regime consistent with ~~medication therapy management reviews~~ standard of care for chronic conditions.

Justification: Replace "regime" with "regimen." Remove reference to medication therapy management reviews. MTM reviews could be misinterpreted as published reviews or guidelines. Pharmacists must utilize contemporary knowledge in making drug therapy decisions based on the current standard of care.

## Section 4052

(d) A pharmacist who makes interventions as part of medication management shall document and communicate with other providers as appropriate.

Justification: Section 4052 (d) is new. It replaces “shall” communication statements in Section 4052 Subsections (10, 11, 12).

## Section 4050

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy ~~Pharmacist~~ practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of ~~patient care activities to optimize~~ appropriate drug use, drug-related therapy, disease management and prevention, and communication for clinical and consultative purposes. Pharmacy ~~Pharmacist~~ practice is continually evolving to include more sophisticated and comprehensive patient care activities.

Justification: “Pharmacy” practice is preferred over “Pharmacist” practice. Section 4050 (a) declares the practice of pharmacy to be a profession, not the practice of pharmacist. Pharmacy practice is consistent with defining language throughout the Business and Professions Code for other health professions, such as medical practice, nursing practice, dental practice, etc. Also, the added phrase “patient care activities to optimize” implies that pharmacists optimize by improving existing therapies, when in fact many pharmacists are charged with initiating, monitoring, and adjusting therapies. Preventative therapies such



as immunizations provide direct access to essential health care services. It is agreed that pharmacists do optimize drug use, etc., however, their contributions go well beyond optimization.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

(d) No state agency other than the board of pharmacy may define or interpret the practice of pharmacy for those licensed pursuant to the provisions of this chapter or develop standardized procedures or protocols pursuant to this chapter, unless so authorized by this chapter, or specifically required under state or federal statute. "State agency" includes every state office, officer, department, division, bureau, board, authority, and commission.

Justification: Section 4050 (d) is new. With recognition that the Licensing Committee has recommended removal of statutory language referring to other boards or agencies, this section codifies the importance of the board of pharmacy in defining and interpreting the practice of pharmacy. See Chapter 6 Nursing, Section 2725 (e) – effective 1/1/2004.

### **Amend BPC 4051 as follows:**

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient or patient's agent.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) The pharmacist provides the service or activity in accordance with the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience.

Justification: Section 4051 (b) (4) is new. It is important to explicitly state that a pharmacist must provide services or activities authorized in Section 4052 in accordance with the accepted standard of care. This concept applies to all health professions and it is incumbent on health care providers to only provide services for which they are qualified.

### **Section 4000**

This chapter constitutes, and may be cited as, the ~~Pharmacy Law~~ Pharmacy Practice Act.

Justification: The California Business and Professions Code Division 2 Healing Arts provides Chapters and Articles related to the various health professions. The chapters pertaining to the following are cited as the: Medical Practice Act, Nursing Practice Act, Dental Practice Act, Respiratory Care Practice Act, Optometry Practice Act, etc. While all contain the laws applicable to their profession, only Chapter 9 Pharmacy is cited as "Pharmacy Law". The National Association of Boards of Pharmacy has developed



and maintains the Model State Pharmacy Act to provide State Boards of Pharmacy with model language for developing state laws. Section 101 Title of Act recommended language: This Act shall be known as the Pharmacy Practice Act.

## Division 2 Healing Arts, Chapter 1 General Provisions, Article 11 Professional Reporting

**Section 800** [Establishes requirement for reporting, to appropriate licensing board, of complaints alleging acts of misconduct in connection of performance of professional services by licensee. It further requires that any judgment or settlement paid by licensee or licensee's insurer in excess of \$3,000 be reported to the licensing board]

**Section 805** [Defines Peer Review]

Section 805 (a) (2) "Licentiate" means a physician and surgeon, doctor of podiatric medicine, clinical psychologist, marriage and family therapist, clinical social worker, professional clinical counselor, dentist, licensed midwife, physician assistant, pharmacist, or nurse practitioner practicing pursuant to Section 2837.103 or 2837.104. "Licentiate" also includes a person authorized to practice medicine pursuant to Section 2113 or 2168.

**Justification:** Pharmacists are included in professional reporting requirements under Section 800. Peer review as defined in 805 should also apply to pharmacists as part of a process to review medical outcomes or quality of professional care provided by licentiate.

We greatly appreciate the Board of Pharmacy's diligent efforts and commitment to advancing the standard of care as a regulatory model for pharmacy practice. The proposed amendments reflect a comprehensive understanding of the evolving role of pharmacists in healthcare. As a work group dedicated to enhancing pharmacy practice, we are enthusiastic about the potential positive impacts of these changes. We look forward to continued collaboration and remain deeply interested in supporting the Board's initiatives to ensure that pharmacists can deliver the highest standard of care to their patients.

Thank you,

### California Pharmacy Standard of Care Work Group members:

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- Steve Chen, PharmD, FASHP, FCSHP, FNAP, Professor of Clinical Pharmacy and Associate Dean for Clinical Affairs, USC School of Pharmacy
- Richard Dang, PharmD, BCACP, Assistant Professor of Clinical Pharmacy, USC School of Pharmacy
- Amy Hohmann, PharmD, Pharmacy Resident, Loma Linda University Medical Center
- Kevin Komoto, PharmD, MBA, Chief Operating Officer, Komoto Healthcare
- Lisa Kroon, PharmD, CDE, Professor of Clinical Pharmacy and Chair, Department of Clinical Pharmacy, UCSF School of Pharmacy
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- Nathan Painter, PharmD, CDE Clinical Professor of Pharmacy, UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences
- Daniel Robinson, PharmD, FASHP, Dean and Professor Emeritus (retired), Western University of Health Sciences.
- Rita Shane, PharmD, FASHP, FCSHP, Vice President and Chief Pharmacy Officer, Cedars-Sinai Medical Center; Assistant Dean, UCSF School of Pharmacy



## Frequently Asked Questions

References: California Business and Professions Code, Division 2 Healing Arts.

### **Why are changes related to standard of care needed in pharmacy law?**

Section 4050 (d), enacted in Jan 2014, declared pharmacists as health care providers. This change was not accompanied by conforming language to create a regulatory environment that supported the provider status of pharmacists.

### **What is the standard of care?**

A practice and regulatory model used by other health professions that allows providers to practice at a level consistent with their individual education, training, experience, and practice setting. A pharmacist must provide the service or activity in accordance with the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience.

### **Is standard of care an attempt by the pharmacy profession to expand scope of practice?**

No. The purpose of standard of care is ultimately about leveraging pharmacists' skills and knowledge to improve patient care, enhance access to healthcare, and create a more efficient healthcare system.

### **What are the advantages of a standard of care model?**

- Addresses healthcare challenges such as healthcare professional shortages and high costs
- Improves health outcomes California
- Increases access to healthcare, especially in rural and underserved areas
- Fully utilizes the competence and ability of healthcare professionals
- Evolves with advancements in education, technology, science, and practice standards
- Recognizes professional heterogeneity
- Avoids tying fixed regulations to an entire class of health professional
- Avoids lengthy statutory and regulatory changes as practice and health care evolve
- Facilitates adaptive collaboration between health professionals for optimal patient care and healthcare team

### **How would the Board of Pharmacy discipline violations of standard of care?**

Under **Section 4306.6**, the board may initiate disciplinary proceedings for unprofessional conduct that includes acts or omissions that involve the inappropriate exercise of a pharmacist's education, training, or experience. The board may utilize **Section 800** for required reporting of complaints alleging acts of misconduct in connection of performance of professional services by a licensee and **Section 805** for existing peer review processes.

### **What support exists for standard of care as a regulatory model for pharmacy?**

Prepared by:

#### **California Pharmacy Standard of Care Work Group members**

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# california pharmacists association

In October 2018, the National Association of Boards of Pharmacy (NABP) convened a task force to explore the feasibility of transitioning from prescriptive rule-based regulations to a model that defines regulations through a standard of care process. As a result, NABP recommended that state boards of pharmacy consider regulatory alternatives for clinical care services that require pharmacy professionals to meet the standard of care. NABP has defined the “Standard of care” as the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances. (Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, August 2023)<sup>1</sup>

The 2021-2022 House of Delegates of APhA approved the policy statement: APhA requests that state boards of pharmacy and legislative bodies regulate pharmacy practice using a standard of care regulatory model similar to other health professions’ regulatory models, thereby allowing pharmacists to practice at a level consistent with their individual education, training, experience, and practice setting. (JAPhA. 62(4):941, July 2022)<sup>2</sup>

An excellent and detailed commentary: Adams AJ, Chopski NI, Adams JA. "How to implement a ‘standard of care’ regulatory model for pharmacists." JAPhA 64 (2024) 102034.<sup>3</sup>

<https://doi.org/10.1016/j.japh.2024.02.007>

## References:

1. National Association of Boards of Pharmacy. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. August 2023.
2. American Pharmacists Association. Policy Statement. JAPhA. 2022;62(4):941.
3. Adams AJ, Chopski NI, Adams JA. How to implement a “standard of care” regulatory model for pharmacists. JAPhA. 2024;64:102034. doi:10.1016/j.japh.2024.02.007.

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