California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: **Board Members**

Subject: **Discussion of Proposed Issues to Raise as Part of Sunset Report**

Background

Article 1 of the Pharmacy Law (Business and Professions Code (BPC) sections 4000-4013) establishes January 1, 2026, as the sunset date for the Board.

For Board Discussion and Consideration

In preparation for the upcoming sunset review and submission of the legislative report, during the meeting, members and stakeholders will have the opportunity to identify issues for consideration in the legislative report. Staff notes that the Board has already identified several issues (including the pharmacist to pharmacy technician ratio and the proposed transition to a more robust standard of care enforcement model).

In advance of the meeting, the Board received potential items for consideration from Kaiser and the members of the California Pharmacy Council.[1] Additional details are provided below.

Kaiser requested the Board's consideration of the following statutory changes:

1. Amendment of BPC sections 4040 and 4051 to clarify that a prescription issued by a pharmacist is a valid prescription if it is issued pursuant to a policy, procedures, protocol, or collaborative practice agreement. Kaiser suggested that this change is necessary to clarify that a prescription that is issued by a pharmacist pursuant to a collaborative practice agreement authorized under BPC section 4052(a)(13) is a valid prescription.
2. Amendment of BPC section 4115 to clarify the specific pharmacy technician tasks that require the completion of practical training on injection technique and basic life support certification. Kaiser suggested that some pharmacies would choose to leverage some of the flexibilities in BPC section 4115(b), specifically, the ability to have pharmacy technicians receive prescription transfers and accept clarification on prescriptions; however, the requirement that technicians who perform those

[1] The California Pharmacy Council membership includes the deans from the schools of pharmacy and representatives of the California Pharmacists Association and the California Society of Health-System Pharmacists.

administrative tasks must complete a training course on injection technique and obtain basic life support certification is a barrier to do so.

3. Amendment of BPC section 4105 to clarify that a pharmacy may elect to maintain records of drug acquisition and disposition electronically regardless of the form in which the records were created. Kaiser suggested that this change would better align the Pharmacy Law with the provisions of California Evidence Code sections 1550 and 1552 and the Board's previously stated policy on electronic record retention in the January 2005 issue of *The Script* newsletter.

Members of the California Pharmacy Council support a change in the title of "Advanced Practice Pharmacist" to "Advanced Pharmacist Practitioner." In its request, the Council indicated that the criteria for the advanced license would remain the same. The rationale for the change include:

- To elevate the status of the pharmacist role in our state
- Increase the "brand" of pharmacist, enhance image, improve patient perception
- Signifies "provider" of patient care
- Signifies that pharmacist is in "practice" of the profession
- Easier acceptance in collaborative practice settings
- Adding "Practitioner" term places these professionals on par with other healthcare professionals, giving us equal status
- Signifies that we are an integral part of the healthcare team
- Veterans Affairs (VA) and some states have proactively adopted the "practitioner" terminology
    - VA (Clinical Pharmacist Practitioner, CPP)
    - North Carolina and Montana (CPP)
    - CA possibly would be the 3rd state to adopt the new title, other states may follow

In addition to these requests, below are some additional items that may be appropriate for consideration.

1. Establish self-assessment requirements in statute. (With the exception of the surgical clinic self-assessment, the self-assessment requirements are established in regulation.)
2. Consideration of increased citation and fine authority for mail order pharmacies for repeated violations of materially similar provisions within five years.
3. Consider what changes to pharmacy law are necessary to address incorporation of AI into pharmacy practice. Staff note that AI is only effective when a pharmacist is ultimately making the clinical decision.
4. Evaluate the issue of pharmacy deserts and actions the Board can take to expand pharmacy services to these areas.
5. The role of telehealth and other online platforms in directing patients to specific pharmacies.
6. Consideration of the proliferation of pharmacy delivery services including, for example, DoorDash, Uber, etc.
7. Consider business practices and impact on patient care.
8. Consider payor activities (including auditing practices) that negatively impact patient access.

Following discussion by members, staff will research items consistent with the Board's direction for consideration by the Board at a future meeting. In addition to raising new issues, the Board will be required to provide updates on the issues raised during its prior review.

Attachment 1 includes a copy of the Kaiser request.

Attachment 1

KAISER PERMANENTE®

December 20, 2023

California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

RE: California Board of Pharmacy Sunset Review

Dear President Oh and Executive Officer Sodergren:

Kaiser Permanente, at several 2023 California Board of Pharmacy meetings, has recommended a handful of changes to the Pharmacy Law that we believe the Board should pursue during its Sunset Review in 2025. To assist Board members and staff in the writing of the Board's Sunset Review report, we have consolidated our recommendations in this letter and accompanying attachments. We encourage the Board to review these recommended changes to the Pharmacy Law and to consider asking the legislature to include them in the Board's 2025 Sunset Review bill.

Attachment 1 includes recommended changes to California Business and Professions Code (BPC) sections 4040 and 4051 to clarify that a prescription issued by a pharmacist is a valid prescription if it is issued pursuant to a policy, procedure, protocol, or collaborative practice agreement as authorized by Chapter 9, Division 2 of BPC. We believe this change is necessary to clarify that a prescription that is issued by a pharmacist pursuant to a collaborative practice agreement authorized under BPC 4052(a)(13) is a valid prescription.

Attachment 2 outlines recommended changes to California BPC section 4115 to clarify the specific pharmacy technician tasks that require the completion of practical training on injection technique and basic life support certification. We believe that some pharmacies would choose to leverage some of the flexibilities in BPC 4115(b)—specifically, the ability to have pharmacy technicians receive prescription transfers and accept clarifications on prescriptions—however, the requirement that technicians who perform those administrative tasks must complete a training course on injection technique and obtain basic life support certification is a barrier to doing so.

Attachment 3 includes recommended changes to California BPC section 4105 to clarify that a pharmacy may elect to maintain records of drug acquisition and disposition electronically regardless of the form in which those records were created. This change would better align the Pharmacy Law with the provisions of California Evidence Code sections 1550 and 1552 and the Board's previously stated policy on electronic record retention in the January 2005 issue of *The Script* newsletter.

Kaiser Permanente appreciates the Board's consideration of these suggested changes to the Pharmacy Law, which we believe are commonsense and will benefit California consumers and the regulated public. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully submitted,

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

Attachment 1

4040.

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, the prescriber's license classification, and the prescriber's federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to ~~Section 4052.1, 4052.2, or 4052.6~~a policy, procedure, protocol, or collaborative practice agreement as authorized by this chapter.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or ~~pursuant to Section 4052.1, 4052.2, or 4052.6~~ by a pharmacist licensed in this state pursuant to a policy, procedure, protocol, or collaborative practice agreement as authorized by this chapter.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

4051.

(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 a policy, procedure, protocol, or collaborative practice agreement as authorized by this chapter~~Section 4052.1, 4052.2, 4052.3, or~~

~~4052.6~~, 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.

(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.

Attachment 2

4115.

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

(b) (1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

(A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

(B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision (a) of Section 4202 and maintains that certification.

(C) ~~The~~ A pharmacy technician who prepares and administers vaccines or prepares and administers epinephrine shall have~~as~~ successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(D) ~~The~~ A pharmacy technician who prepares and administers vaccines, prepares and administers epinephrine, or performs specimen collection for CLIA-waived tests shall be~~is~~ certified in basic life support.

(2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

Attachment 3

4105.

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) (1) ~~Any~~ The records required by this section may be ~~that are~~ maintained electronically, regardless of the form in which they were created. Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.