

Written Comments Received

#1 CSHP



August 21, 2024

California State Board of Pharmacy,

The California Society of Health System Pharmacists' leadership and members wish to express our gratitude to the Board for their comprehensive, inclusive, and progressive efforts in evaluating if a transition to a standard of care enforcement model would be both feasible and appropriate for the regulation of pharmacy.

We have reviewed the proposed standard of care statutory language presented at the full Board of Pharmacy Committee meeting on August 1, 2024. Overall, we agree with most of the statutory language presented as aligning with the overall objective to benefit patients by providing expanded and timely access to patient care from suitably educated, trained and experienced pharmacists.

We wish to especially note the proposal at BPC 4050 wherein "pharmacy" is substituted with "pharmacist" in defining the services provided as dynamic patient-orient service that applies a body of knowledge to improve patient health. This change memorializes the fundamental difference between a pharmacist being a health care provider and the responsibilities of medication stewardship associated with the business of pharmacy. CSHP strongly supports the use of "pharmacist" rather than "pharmacy."

We request the Board's consideration of our recommendations (noted in red underlined font) to the following sections of the proposed standard of care statutory language.

1. BPC 4052 (a)(1)

Proposed:

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

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for the office use by the prescriber

Recommendation:

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

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for administration to a patient in the setting of the prescriber

Rationale:

Compounded medications provided to a prescriber should be explicitly intended for use in the office of the prescriber and not distributed to the patient for use outside of the prescriber's office

2. BPC 4052(a)(4)

Proposed:

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

~~(4) Perform procedures or functions in a licensed health care facility as authorized by~~

~~Section 4052.1. Initiate and perform routine patient assessment procedures including skin puncture and~~

~~clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement~~

Amendments of 1988 (42 U.S.C. Sec.263a) and the regulations adopted thereunder by the federal Health Care Financing Administration as authorized by section 12 06.5 or section 12 06. 6

Recommendation:

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

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1. Order, initiate and perform routine patient health screenings, assessment procedures including but not limited to skin puncture and clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec.263a) and the regulations adopted thereunder by the federal Health Care Financing Administration as authorized by section 12 06.5 or section 12 06. 6c

Rationale:

Pharmacists should have the ability to “order” assessments and health screenings given they frequently work as a member of clinical team whereby they may be directing the care of a patient through others as the lead such as with other pharmacists and/or pharmacy technicians.

Pharmacists should be able to order, initiate and perform and initiate health screenings as well as patient assessments. Health screenings are preventive measures that involve conducting specific tests or examinations to detect potential health problems before symptoms appear (e.g., blood pressure checks, cholesterol tests, depression scales, dementia tests). Patient assessments are evaluations of an individual's health status and used to ensure safe and effective therapy outcomes such as HgA1C levels for diabetics, HIV testing for PrEP therapy, or weight loss with medication treatment. Both terms should be used to ensure a holistic approach to the pharmacist's evaluation and care of patients.

3. BPC 4052(a)(9)

Proposed:

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

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to patients and other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate

Recommendation:

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

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to patients, or their designee, and other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate.

Rationale:

Adding in “their designee” allows for surrogate health decision makers to receive the information necessary to properly advocate for the patient.

4. BPC 4052(a)(10)

Proposed:

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

(10) Furnish an FDA approved or authorized medications that is preventative or does not require a diagnosis. 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.

Recommendation:

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

(10) Furnish an FDA approved or authorized medications, or devices, as part of ~~that is~~ preventative healthcare services or does not require a diagnosis. 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.~~

Rationale:

Devices should be included given that medications are at times dependent on devices for administration or monitoring of the medication therapy. The addition of "healthcare services" provides context to what is meant by "preventative."

Pharmacists should be allowed to furnish medications for off label use. Frequently medications are commonly used for off label use and recognized as appropriate. The FDA estimates between 10 to 50% of medications are used for off label use. In many cases an "off label" use is considered "standard of care". So much so California law requires coverage of "off label" uses in certain situations.

5. BPC 4052(a)(11)(b)

Proposed:

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

(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.

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Rationale:

Pharmacists should be allowed to furnish medications for off label use. Frequently medications are commonly used for off label use and recognized as appropriate. The FDA estimates between 10 to 50% of medications are used for off label use. In many cases an "off label" use is considered "standard of care". So much so California law requires coverage of "off label" uses in certain situations.

6. BPC 4052(a)(12)

Proposed:

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

(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.

Recommendation:

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

(12) Order and interpret drug therapy related tests and **health screening and assessments for drug selection, initiation, monitoring, and managing the efficacy, and toxicity of drug therapies.** ~~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.

Rationale:

The language should clarify what the drug related tests are intended for - selection, initiation, monitoring, and managing. The why for the tests should also be clear; to manage efficacy and toxicity.

7. BPC 4052(a)(13)(B)

Proposed:

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

(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.

Recommendation:

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

(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 or** 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.

Rationale:

Pharmacists are currently able to initiate, adjust, and discontinue drug therapy in accordance with policies, procedures, or protocols in health care entities without specific prescriber authority. Section (B) requires both the patient's prescriber authority and policies, procedures, or protocols. As such the word should be "or" not "and".

8. BPC 4052(a)(15)

Proposed:

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

(15) Complete missing information on a prescription for a noncontrolled medication if there is evidence to support the change.

Recommendation:

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

(15) Complete missing information on a prescription for a controlled substance, as authorized by federal law, noncontrolled medication if there is evidence to support the change.

Rationale:

Amendment of the language to include controlled substance is in alignment with current federal law.

9. BPC 4052(a)(17)

Proposed:

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

(17) Adjust prescription treatment drug regime consistent with medication therapy management reviews for chronic conditions.

Recommendation:

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

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

Rationale:

Removal of the word “prescription” acknowledges that not all medication therapy for chronic disease requires a prescription thereby including prescription, over the counter medications, and dietary supplements. Addition of “standard of care” for management of chronic conditions acknowledges such management is dynamic and evolving.

10. BPC 4052(d)

Proposed:

(d) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide a service or function authorized by subdivision (a) where the pharmacist has made a professional determination that (1) they lack sufficient education, training, or expertise, or access to sufficient patient medical information, to perform such service or function properly or safely; or (2) performing or providing such service or function would place a patient at risk.

Recommendation:

(d) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide a service or function authorized by subdivision (a) where the pharmacist has made a professional determination that (1) they lack sufficient education, training, or expertise, or access to sufficient patient medical information, or appropriate setting, to perform such service or function properly or safely; or (2) performing or providing such service or function would place a patient at risk.

Rationale

An appropriate setting is important to ensure provision of quality care whether it be issue of privacy, adequate space to perform assessments, or access to necessary equipment.

11. BPC 4040(a)(2)

Proposed:

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:
(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, 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, pharmacist, 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.

Recommendation:

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:
(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, 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, pharmacist, 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~~

Rationale:

Deletion of reference to the codes is to make the section consistent with the listings for nurse midwives, physician assistants, and nurse practitioners where code sections have been eliminated

12. BPC 4052.7

Proposed:

(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.
(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:
(1) All the information required by Section 4076.
(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.
(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.

Recommendation:

(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.
(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:
(1) All the information required by Section 4076.
(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.
(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.

Rationale:

This section should not be deleted as it allows for patients to have their medications repackaged in a manner that facilitates medication adherence which is a leading cause for medication therapy failure. Additionally, long term care facilities (LTCF) require the use of unit dose packaging (e.g., blister packs) and they also must allow for freedom of choice on the resident's preferred pharmacy. As such, a resident of a LTCF may need to have their medication repackaged after being dispensed.

On behalf of CSHP's Board of Directors and our members we are grateful for the Board of Pharmacy's collaborative approach to advance a standard of care regulatory model that will serve the profession of pharmacy to accomplish our ultimate objective of providing accessible pharmaceutical care to the citizens of California. We stand ready to continue our collaboration with the Board of Pharmacy and further our mutual objectives as "leaders in patient safety, wellness and optimal use of medications."

Sincerely,

Loriann De Martini, PharmD, MPH, BCGP
Chief Executive Officer
California Society of Health System Pharmacists

Written Comments Received

#2 CPhA



california pharmacists association

To: Members of the California State Board of Pharmacy Licensing Committee

Dear Members of the Licensing Committee,

We are writing to provide additional input and justification to recommendations that were provided to the Licensing Committee on July 12, 2024 (see 24_jul_bd_mat_xiii pg 114-119). Once again, we thank the Licensing Committee for their important work in advancing standard of care as a regulatory model for pharmacy. If the committee has any questions or concerns that we could address, we are at your service.

Section 4052(d)

Recommendation for Removal:

~~(d) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide a service or function authorized by subdivision (a) where the pharmacist has made a professional determination that (1) they lack sufficient education, training, or expertise, or access to sufficient patient medical information, to perform such service or function properly or safely; or (2) performing or providing such service or function would place a patient at risk.~~

Justification

Subsection (d) was added and not available to CPhA when we made our initial recommendations. Section 4052 (a) begins with the statement “Notwithstanding any other law, a pharmacy may do all of the following. The “may” statement is a clear indication that a pharmacist is not obligated to provide activities 1-17. A central premise of standard of care is that pharmacists shall only engage in activities that are supported by setting, education, training, and experience. Section 4051 (b) refers to activities described in Section 4052 (1-17) being performed if all of the following conditions are met: new item 4051 (b)(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.

In addition, 4052 (d)(2) above introduces unnecessary exposure to the pharmacist. With nearly any medical, pharmaceutical or health care intervention, patients are exposed to risk. Every decision made by a health care provider is based on a risk-benefit analysis. We therefore recommend removal of subsection (d).

We have previously recommended the addition of 4052 (d) as such: A pharmacist who makes interventions as part of medication management shall document and communicate with other providers as appropriate.



california **pharmacists** association

Section 4050

We have previously commented on this section and strongly believe that the original language in which the Legislature declared the practice of pharmacy to be a profession should be unchanged. This was landmark legislation that was enacted in January 2014 recognizing pharmacists as health care providers. To our knowledge Section 4050 has served the public and the profession well. There are those who believe that “pharmacy” practice should be replaced by “pharmacist practice.” For those who have dedicated their professional careers to the advancement of pharmacy practice such a change would make little sense. Pharmacy, medical, nursing, dental, optometry, etc. are all adverbs that describe a type of practice. Pharmacist (a noun) does not serve that function.

General comment about “standard of care” vs. “standard of practice”

Please see Frequently Asked Questions as provided in our July 12, 2024 recommendations to your committee. In summary, standard of care has been defined by the National Association of Boards of Pharmacy and appears in the Model State Pharmacy Act and Model Rules (2023). The American Pharmacist Association issued a policy statement requesting state boards and legislative bodies to regulate pharmacy practice using a standard of care regulatory model. The California Business and Professions Code, under Healing Arts (Division 2) has used standard of care in its General Provisions and it appears in the practice acts for medicine (repeatedly), optometry, and advanced nursing. Finally, there is an ever-growing body of literature based on standard of care. We believe that consistency is extremely important as our profession evolves to better serve California.

We appreciate your consideration of these points and remain committed to working collaboratively to enhance pharmacy practice in California.

Sincerely,

Sean Kim, PharmD

Senior Manager, Practice & Professional Development on behalf of

California Pharmacists Association & California Pharmacy Standard of Care Work Group