Title 16. Board of Pharmacy DEPARTMENT OF CONSUMER AFFAIRS

Initial Statement of Reasons

Hearing Date: None unless requested, see Notice of Proposed Action

Subject Matter of Proposed Regulation: Continuing Education

Section Affected: Amend section 1732.5 and adopt section 1732.8 of Article 4 of

Division 17 of Title 16, California Code of Regulations (CCR)

Background

The California State Board of Pharmacy (Board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The Board's mandate and mission are to protect the public (Business and Professions Code (BPC) section 4001.1).

Existing law, codified in Business and Professions Code (BCP) section 4231, requires a pharmacist to complete thirty hours of continuing education (CE) every two years, and requires CE reporting as part of the license renewal process. Title 16, California Code of Regulations section 1732.5 sets forth the CE, and CE reporting, requirements for pharmacists. When applying for license renewal to the Board of Pharmacy, each pharmacist must submit satisfactory proof they have successfully completed thirty hours of approved CE courses in the twenty-four months preceding their renewal application. (16 CCR section 1732.5(a).) Two of those thirty hours "shall be completed by participati[ng] in a Board provided CE course in Law and Ethics." (16 CCR section 1732.5(b).)

Any pharmacist prescribing or furnishing certain specified pharmaceutical treatments, medications, or services is required to complete corresponding specialized CE as part of those thirty hours. Under BPC section 4052.3, any pharmacist furnishing emergency contraception medication is required to complete "at least one hour of approved [CE] on emergency contraception drug therapy." Under BPC section 4052.9, any pharmacist furnishing FDA-approved nicotine replacement products or administering smoking cessation services is required to complete one hour of CE "focused on smoking cessation therapy biennially." Finally, under BPC section 4232.5, any pharmacist prescribing a Schedule II controlled substance is required to have, within the previous four years, completed "an education course on the risks of addiction associated with the use of Schedule II drugs." CCR section 1746.4 implements the requirement that any pharmacist administering vaccines shall, once every two years, complete one hour of CE, from an approved provider, focused on immunizations and vaccines. CCR section 1746.5 implements the requirement that any pharmacist administering travel medications shall, once every two years, complete two hours of CE (separate from CE in immunizations and vaccines), from an approved provider, focused on travel medicine. Additionally, existing law, codified in BPC section 4202, establishes the licensure requirements for a pharmacy technician.

Problems Addressed

Assembly Bill 2194 (Ward, Chapter 958, Statutes of 2022) modified BPC sections 4231 and 4202, effective January 1, 2024, requiring pharmacists and pharmacy technicians, respectively, to complete at least one hour of continuing education in cultural competency during the two years preceding the renewal application. Further, the Board is prohibited from renewing a pharmacist or pharmacy technician license unless the individual has completed the course.

This regulatory proposal will amend 16 CCR section 1732.5. This regulatory proposal will combine the continuing education requirements for pharmacists, which are currently spread across numerous statutes and regulations, into one regulation section. This change will make it easier for pharmacist license renewal applicants to locate the requirements they must meet. This regulatory proposal will eliminate the sentence "Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision" from section 1732.5(b), ensuring all pharmacist license renewal applicants meet the requirements of the BPC, implemented in the regulations. This regulatory proposal will also define "Board approved CE course."

This regulatory proposal will adopt a new CCR section 1732.8 regarding license renewal requirements for pharmacy technicians. This regulatory proposal will implement the requirement that pharmacy technicians complete a one-hour cultural competency course, in compliance with BPC section 4202. This regulatory proposal will set forth the requirement to retain documentation demonstrating proof of completion of the cultural competency course. This regulatory proposal will also set forth the procedure for issuance of an inactive pharmacy technician license if the cultural competency course is not completed, or if the technician fails to provide proof of completion during an investigation or audit.

<u>Anticipated Benefits of this Regulatory Action</u>

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents.

Combining the continuing education requirements imposed on pharmacists into one regulation will reduce confusion, will help ensure compliance, and may reduce some of the administrative burden for pharmacists researching continuing education requirements within pharmacy law, which may in turn increase pharmacist availability to provide patient-centered care. Increasing pharmacist availability is a benefit to the health and welfare of California residents.

This proposal will ensure that pharmacy technicians are aware of the license renewal requirements, which will ensure that pharmacy technicians are appropriately licensed and trained, which benefits patient safety.

Educating pharmacists and pharmacy technicians on cultural competence improves communication between pharmacists/pharmacy technicians and patients, which will reduce medication errors and improve patient safety. Clear communication helps pharmacists and pharmacy technicians ask for and receive accurate medical information, and encourages active dialogue during consultations so that patients and pharmacists/pharmacy technicians can ask questions, correct misunderstandings, and build trust.

Specific Purpose of, and Rationale for, Proposed Changes

The Board's proposal makes the following changes:

Amend section 1732.5 – Renewal Requirements for Pharmacists

The Board proposes capitalizing "Board" throughout the section. This change is non-substantive because it is a grammatical change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency throughout the regulations. Inconsistent capitalization may result in misinterpretation and confusion.

The Board proposes lowercasing "section" throughout the section. This change is non-substantive because it is a grammatical change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency throughout the regulations. Inconsistent capitalization and lowercasing may result in misinterpretation and confusion.

The Board proposes amending subsection (a) to add "CE" after continuing education for the purpose of defining the term and providing its abbreviation. This is a nonsubstantive change that is part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This change is necessary for clarity with respect to cross-referencing the term continuing education in regulation text.

The Board proposes amending subsection (b). The first amendment will add "required CE hours" to the first sentence for the purpose of defining the term. This is a grammatical change necessary for clarity with respect to the thirty hours required for pharmacist license renewal in the regulation text. The second amendment will add "Further, beginning January 1, 2024, at least one (1) hour of the required CE hours shall be completed by participating in a cultural competency course from an accreditation agency approved by the Board pursuant to section 1732.05, covering the specified content areas as required by section 4231 of the Business and Professions Code." The purpose of this portion is to introduce the requirement that pharmacists take a cultural competency CE course. This portion is necessary to ensure pharmacists take the cultural competency CE course, and to implement the requirements of recently enacted legislation (Assembly Bill 2194 (Ward, Chapter 958, Statutes of 2022)) and the BPC.

The last amendment will remove the sentence "Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision." The purpose of this change is to ensure every pharmacist meets the BPC requirements implemented in subsection (b). The Board determined that it was necessary to remove this sentence to remove an old effective date from the regulation, which will eliminate confusion for pharmacists about which pharmacists must complete the law and ethics continuing education requirement, and to prevent confusion over which pharmacists must meet the cultural competency course requirement.

The Board proposes relocating prior subsection (c) to new subsection (e).

The Board proposes a new subsection (c) be added to read:

- (c) Pharmacists providing specialized patient-care services, as identified in subsections (c)(1)-(4) below, shall complete specialized CE (as part of the required CE hours) as follows:
 - (1) At least one (1) hour of approved CE specific to smoking cessation therapy, as required by section 4052.9 of the Business and Professions Code, if applicable.
 - (2) At least two (2) hours of approved CE specific to travel medicine, as set forth in section 1746.5 of this Article, if applicable.
 - (3) At least one (1) hour of approved CE specific to emergency contraception drug therapy, as required by Business and Professions section 4052.3, if applicable.
 - (4) At least one (1) hour of approved CE specific to immunizations and vaccinations, as set forth in section 1746.4 of this Article, if applicable.

These continuation requirements are already established within pharmacy law and are not being established by this regulatory action. The purpose of this proposal is to combine all the existing requirements into one regulation section for clarity. The Board determined that this duplication was necessity to ensure compliance with the multiple continuing education requirements and reduce the administrative burden on pharmacists when attempting to locate the continuing education requirements they must meet, as pharmacists will be able to refer to one regulatory section instead of searching across multiple statutes and regulations.

The Board proposes adding subsection (d) to read: "Pharmacists who prescribe any Schedule II controlled substances (as defined in Health and Safety Code section 11055) shall complete at least one (1) hour of the required CE hours by participating in a Board approved CE course once every four (4) years on the risks of addiction associated with the use of Schedule II drugs, as required by section 4232.5 of the Business and Professions Code." The purpose of this proposal is to implement a one-time continuing education requirement for pharmacists who prescribe Schedule II controlled substances. The Board determined adding this information to the regulation is necessary to ensure that all continuing education is listed within one regulation to reduce confusion for licensed pharmacists, and ensures that pharmacist have completed the appropriate continuing education based on their area of practice.

The Board proposes amending subsection (e), prior subsection (c), to add the phrase: "demonstrating compliance with the provisions of this section". The purpose of this

addition is to inform pharmacist licensees of the reason they are maintaining their certificates of completion for their continuing education credits. Adding this phrase is necessary so licensed pharmacists know "why" they are required to maintain their certificates. Since compliance with continuing education is verified via continuing education audits (BPC section 4231), retaining the certificates demonstrating compliance will aid in expediting the audit process, as the auditors will have clear records available to them.

The Board proposes adding subsection (f) to read "Board approved CE course' shall mean coursework from a provider meeting the requirements of section 1732.1." The purpose of this addition is to provide a definition and reference location. This is necessary to provide clarity to the regulated public, as well as to entities offering continuing education courses, that the continuing education courses must meet the requirements of CCR 1732.1, which specifies the requirements for accredited providers of continuing education.

The reference section is updated to add sections 4052.3, 4052.8, 4052.9, and 4232.5, which are the specific BCP sections that require specific continuing education courses based on practice area.

Adopt section 1732.8 – Renewal Requirements for Pharmacy Technicians

The Board proposes adopting section 1732.8 to provide clarity to the regulated public and clearly define the renewal requirements for Pharmacy Technicians. These requirements are effective January 1, 2024.

The Board proposes adding subsection (a) to read as follows:

(a) Beginning January 1, 2024, as a condition of renewal, a pharmacy technician licensee shall submit proof satisfactory to the Board that the applicant has completed at least one (1) hour of continuing education (CE) in a cultural competency course covering the specified content areas, from an accreditation agency approved by the Board pursuant to section 1732.05, during the two years preceding the application for renewal, as required by section 4202 of the Business and Professions Code. All pharmacy technicians shall retain their certificate of completion for four (4) years from the date of completion of the cultural competency course demonstrating compliance with the provisions of this section.

This continuing education requirement is already established within pharmacy law (in the BPC) following the recent enactment of Assembly Bill 2194 (Ward, Chapter 958, Statutes of 2022). The purpose of this inclusion is to implement the BPC requirement and inform pharmacy technicians of the specifications of the requirement. The Board determined that this duplication (of the language in BPC section 4202 for pharmacy technicians, and in CCR sections 1732.5(a), (b), and (e), which provide the CE requirements for pharmacists) is necessary to inform pharmacy technicians of this additional requirement and ensure their compliance, as continuing education was not previously required, and the language in this proposed new section is consistent with

and mirrors the existing language in CCR section 1732.5 for pharmacists. Additionally, the Board determined it is necessary for certificates of completion to be retained for four years to mirror the requirements for pharmacists and assist the Board in verifying compliance during continuing education audits.

The Board proposes adding subsection (b) to read as follows:

(b) If an applicant for renewal of a pharmacy technician license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the Board that the licensee has completed the cultural competency course as required, the Board shall not renew the license and shall issue the applicant an inactive pharmacy technician license.

The purpose of this addition is to provide clarity and implement the requirement that the Board not license any pharmacy technicians that fail to meet the cultural competency course requirement. It is already established within pharmacy law (in the BPC) following the recent enactment of Assembly Bill 2194 (Chapter 958, Statutes of 2022). The purpose of this inclusion is to implement the BPC requirement and inform pharmacy technicians of the specifications of the requirement, and the consequences of failure to meet the requirement. The Board determined that this duplication is necessary to inform pharmacy technicians of this additional requirement and ensure their compliance, as continuing education was not previously required. Including the information within this regulation will ensure pharmacy technicians are aware of the consequences (non-renewal) should they not complete the course or they fail to provide satisfactory proof of completion to the Board. The Board determined that satisfactory proof will be verified during continuing education audits and through disclosure of course completion on the renewal application, which will be available on the Board's website.

The Board proposes adding subsection (c) to read as follows:

(c) If, as part of an investigation or audit conducted by the Board, a pharmacy technician fails to provide documentation substantiating the completion of CE as required in subsection (a), the Board shall cancel the active pharmacy technician license and issue an inactive pharmacy technician license in its place. A licensee with an inactive pharmacy technician license issued pursuant to this section may obtain an active pharmacy technician license by submitting renewal fees due and submitting proof to the Board that the pharmacy technician has completed the required CE.

The purpose of this inclusion is to implement the BPC requirement and inform pharmacy technicians of the requirement, the consequences of failure to meet the requirement, and how they can regain active licensure if they fail to meet the requirement and are subsequently issued an inactive license. This addition is necessary to ensure pharmacy technicians comply with the investigation and audit requirement (providing documentation substantiating the completion of CE), and know the procedure to follow if they do not comply, are issued an inactive license, and want to regain active licensure. The Board has determined that compliance will be verified through continuing

education audits. Additionally, as the Board shall not renew a pharmacy technician license unless the course is completed (pursuant to BPC section 4202), the Board determined that an "inactive" pharmacy technician license must be issued, pursuant to BPC 462. The issuance of an inactive license will prevent the license from being permanently cancelled, pursuant to BPC 4402(e). This allows pharmacy technicians to pay a separate renewal fee and change the license back to an active status upon successful completion of the cultural competency course.

The authority and reference sections are added to include sections 462, 4005, and 4202, which are the specific BPC sections that require continuing education, provide the Board's authority, and require the cultural competency course.

Underlying Data

- 1. Assembly Bill 2194 (Ward, Chapter 958, Statutes of 2022).
- 2. Relevant Meeting Materials and Minutes from Board Meeting held February 6-7, 2023.
- 3. Relevant Meeting Materials and Minutes from Licensing Committee Meeting held January 24, 2023.
- 4. Relevant Meeting Materials and Minutes from Licensing Committee Meeting held January 27-28, 2022.

Business Impact

The Board has made the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other States. This proposal provides pharmacists and pharmacy technicians with clarifying information with respect to continuing education and cultural competency course completion. Pharmacists and pharmacy technicians may have an initial expense to complete the cultural competency course required by BPC sections 4202 and 4231, and they may have a minimal continuing education fee every two years to maintain compliance.

Economic Impact Assessment:

Aside from the creation of a new course in cultural competency, which may nominally be considered "new business", such business will likely be provided by existing course providers and existing staff. As such, the Board has determined that this proposal will not:

- (1) create jobs within California;
- (2) eliminate jobs within California;
- (3) create new businesses within California;
- (4) eliminate existing businesses within California;
- (5) expand businesses currently doing business in the State of California.

This proposal will not create or eliminate jobs or businesses, or expand businesses, within California. This proposal combines several pre-existing statutes and regulations

and strikes a confusing sentence from a current regulatory continuing education provision. Additionally, this proposal provides clarity to pharmacy technicians with respect to the one-hour cultural competency course they must complete pursuant to BPC section 4202. This proposal sets forth the requirement to retain documentation demonstrating proof of completion of the cultural competency course. And this regulatory proposal sets forth the procedure for issuance of an inactive pharmacy technician license if the cultural competency course is not completed, or if the technician fails to provide proof of completion, especially during an investigation or audit

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents by eliminating some administrative burdens for pharmacists, increasing the availability of the pharmacists to provide patient-centered care, and ensuring that pharmacy technicians and pharmacists are appropriately licensed and trained, all of which benefits patient safety.

Additionally, the Board determined that this regulatory proposal will not impact worker safety, or the state's environment, as these changes do not involve worker safety or the environment.

Fiscal Impact Assessment:

The proposed regulation does not result in a fiscal impact to the state. The Board currently ensures compliance with its regulation through its continuing education audit program.

The proposed amendments specify CE coursework and fulfillment requirements for licensees as part of license renewal. The regulations do not increase the total number of CE hours required. As a result, the Board does not anticipate an increase in workload or costs.

There will be an increase in the number of continuing education audits completed as a result of the requirement that pharmacy technicians complete a cultural competency course; however, this fiscal impact is a result of the underlying statute and not this regulatory proposal.

The regulations do not result in costs or savings in federal funding to the state.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or as effective or less burdensome to affected private persons and equally effective in achieving the purposes

of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

The Board considered not combining the statutes and regulations (in the proposed amended regulation section); however, the Board determined that easing the administrative burden on pharmacists was a benefit to patient safety, and therefore necessitated this change.