

**TITLE 16: BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS**

**FINAL STATEMENT OF REASONS**

**Subject Matter of Proposed Regulations:** Continuing Education

**Section Affected:** California Code of Regulations (CCR), Title 16, Division 17, Article 4, Amend section 1732.5 and adopt section 1732.8

**Updated Information**

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment and adoption, respectively, of the above sections. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on December 15, 2023, and ended on January 29, 2024. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

During the 45-day comment period no comments were received. At its February 8, 2024 Board meeting, the Board adopted the regulation text as noticed on December 15, 2023 and delegated to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Additionally, the Board notes that "proof satisfactory to the Board" means the Board evaluates the facts presented by the licensee on a case-by-case basis, taking into account individual licensees' situations and proof of completion of the licensees' continuing education. Ideally, licensees provide their certificates of completion as "proof satisfactory"; however, if a licensee cannot present the certificates (for example, as has previously been the case, when a natural disaster occurred and many licensees' certificates of completion were destroyed), this case-by-case evaluation taking into account a licensee's specific circumstances provides the Board with the ability to accept other types of proof of completion, which benefits licensees.

**Non-Substantive Changes**

The Board amended "Article 5" to "Article 4" in the heading of the proposed regulation text to reflect the Article of the CCR in which the amended and newly-adopted regulation sections will be located.

**Section 1732.5**

Subdivision (b) is amended to remove "Further, beginning January 1, 2024," and to capitalize "At". These changes are non-substantive changes without regulatory effect.

The regulations were originally proposed by the Board prior to January 1, 2024, and as the effective date of the regulation will be after January 1, 2024, including that date within the regulation text is no longer necessary.

Subdivision (e) is amended to change the term “demonstrating” to “to demonstrate” for grammatical clarity, a non-substantive change without regulatory effect.

The “Reference” portion at the end of the section is amended to underline the “and” before “4232.5”. This is a non-substantive change without regulatory effect that indicates that the “and” is being added to the text.

### Section 1732.8

Subdivision (a) is amended to remove “Further, beginning January 1, 2024,” and to capitalize “As”. These changes are non-substantive changes without regulatory effect. The regulations were originally proposed by the Board prior to January 1, 2024, and as the effective date of the regulation will be after January 1, 2024, including the date within the regulation text is no longer necessary. Additionally, the first sentence is amended to add “license” prior to “renewal” as a non-substantive change without regulatory effect. As drafted, the language implies the term “license”; however, specifically stating the term provides clarity, indicating at the beginning of the sentence what renewal is being referenced. Finally, the last sentence is amended to change the term “demonstrating” to “to demonstrate” for grammatical clarity, a non-substantive change without regulatory effect.

Subdivision (c) is amended to add the term “satisfactory” to the last sentence so that the language reads “...and submitting proof satisfactory to the Board...” to mirror the language within Business and Professions Code section 4202(d) and use the same phrase consistently throughout the regulation sections that are the subject of this rulemaking.

### Initial Statement of Reasons

The paragraph on page 4 that begins with “The Board proposes adding subsection (d) to read” is amended to read:

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 continuing education requirement, which will be completed one time every four years by pharmacists who prescribe Schedule II controlled substances.

Completing this continuing education requirement one time every four years will ensure pharmacists who prescribe Schedule II controlled substances are staying current with the latest industry developments, changes in prescription medications, and changes in technology to provide California residents with the best possible care. Additionally, the proposed language reads that the pharmacist “shall complete at least one (1) hour of the required CE hours” as pharmacists have extensive education related to controlled substances, the Board determined that at least a one hour course was appropriate to understand the risks of addiction. Additionally, this mirrors the one hour requirement for other specialized continuing education courses for consistency. 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 pharmacists have completed the appropriate continuing education based on their area of practice.

### **Local Mandate**

A mandate is not imposed on local agencies or school districts.

### **Small Business Impact**

While the Board does not have nor does it maintain data to determine if any of its licensees (pharmacies and clinics) are a “small business”, as defined in Government Code section 11342.610, the Board determined that the proposed regulatory action will not have a significant adverse economic impact on small businesses. 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.

### **Consideration of Alternatives**

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, as effective and less burdensome to affected private persons than the adopted regulation, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

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.

## **Objections or Recommendations/Responses to Comments**

During the public comment period from December 15, 2023 to January 29, 2024, the Board received no comments.