

TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Continuing Education (CE)

Section Affected: Amend §§ 1732.05, 1732.2, and 1732.5 of Article 4 of Division 17 of Title 16 California Code of Regulations.

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 adoption of the above section. The initial Statement of Reasons is updated as follows:

The 45-day public comment period began on November 13, 2015 and ended on December 28, 2015. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. The Board received one request for a hearing on the matter.

A regulatory hearing was scheduled and held on February 2, 2016 at 9:00am. During the regulatory hearing two commenters provided joint comments.

During the 45-day comment period, the Board received several comments. The Board considered the written comments and the oral testimony at its meeting held on February 24, 2016. In response to the comments received, the Board voted to further review the proposal.

At the July 27, 2016 Board meeting, the Board again discussed the proposed changes to 16 CCR section 1732.5 and voted to modify the language and release a modified text for public comment.

The modified text was noticed for a 15-day comment period that began on August 3, 2016 and ended on August 18, 2016. During that time, one comment was received. The Board considered the 15-day comment at its September 22, 2016 Board meeting. No additional modifications were made to the proposed text.

A summary of all comments received during all public comment periods and at the regulation hearing, as well as the Board's responses appears below.

The regulation was modified from the original proposed text as follows:

Section 1732.5 – Renewal Requirements for Pharmacists

Subdivision (b) was modified to remove “six (6)” and “in one or more of the following subject areas: (1) Emergency/Disaster Response, (2) Patient Consultation, (3) Maintaining Control of a Pharmacy’s Drug Inventory, (4) Ethics, (5) Substance Abuse, Including Indications of Red Flags and a Pharmacist’s Corresponding Responsibility, (6) Compounding” and replace with “two (2)” and “by participation in a Board provided CE course in Law and Ethics.” The last change was modifying the implementation date from July 1, 2018 to July 1, 2019. This modification was to ensure that California licensed pharmacists have the opportunity to stay current with California

laws and ethics. The Board determined that the Board should provide this CE free of charge in various formats, including in person and webinars to reach both in state and out of state pharmacists. Additionally, the Board determined that by providing the CE directly, the Board can ensure that pharmacists are getting the most current information that is directly impacting both the practice of pharmacy in California and California residents. Finally, the Board extended the pharmacist renewal effective date to July 1, 2019 to allow the Board time to develop the course and allow all pharmacists two years to complete the course.

Local Mandate

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

Small Business Impact

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the fact that the proposed regulation affects individual licensees and does affect businesses. Additionally, pharmacists are currently required to complete continuing education pursuant to Business and Professions Code (B&P) section 4231. The proposed regulation defines the content area for two of the required thirty hours of CE and those two hours will provided free of charge by the Board. Finally, the proposed regulation also permits pharmacists and pharmacy technicians to be awarded continuing education for attending Board and/or Committee meetings, which are free of charge to attend.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulation or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period / Regulation Hearing

During the 45-day public comment period from November 13, 2015 to December 28, 2015 and at the Regulation Hearing on February 2, 2016, the Board received numerous comments. The comments were provided to the Board in the Meeting Materials for the February 24-25, 2016 Board meeting, and were reviewed and considered by the Board at that meeting.

Written Comments from starship1980s@aol.com, submitted via email

Comment #1: Commenter expressed that pharmacists should be allowed to select the CE they wish to take to meet the renewal requirements. Commenter requested a hearing.

Response to Comment #1: The Board rejected the comment. The Board determined that it was necessary to have a subject specific training to ensure that all pharmacists are receiving

the necessary continuing education on the topics that have a substantial impact on the practice of pharmacy.

Written Comments from vercp@aol.com, submitted via email

Comment #2: Commenter offered support for the mandated specific subject area CE requirement. Commenter inquired if the Board could consider a way to help pharmacists identify the CE courses that fit into the six specific subject areas.

Response to Comment #2: The Board appreciates the comment. The Board determined that by having the Board provided the CE, the Pharmacists would immediately know that the continuing education is acceptable for the two hours required.

Written Comments from Douglas Barcon, PharmD.,

Comment #3: Dr. Barcon expressed concern that the six subject areas specified in the pending regulation were very narrow and contain “static material” that may not change frequently. Additionally, he indicated that pharmacists may not need continuing education in a specific areas (i.e. compounding) if they do not perform those types of duties. Further, Dr. Barcon indicated some pharmacists are certified in emergency response and would not need to complete continuing education in that area.

Response to Comment #3: The Board appreciates Dr. Barcon’s comment. The Board agreed with the comments and removed the six specific areas. The Board determined that by providing CE on Laws and Ethics, the Board can educate pharmacists on new laws being implemented and on laws that the Board is routinely issuing violation citations for.

Written Comments from Megan Maddox, California Pharmacist Association,

Comment #4: Ms. Maddox expressed concern that the proposed six subject areas are very narrow and could interfere with pharmacists obtaining continuing education that meets their educational needs. Ms. Maddox recommended that the subject specific requirement be removed.

Response to Comment #4: The Board appreciates this comment. The Board agreed with the comment and removed the six specific areas. The Board determined that by providing CE on Laws and Ethics, the Board can educate pharmacists on new laws being implemented and on laws that the Board sees arise as enforcement issues. Additionally, by limiting the requirement to 2 hours, pharmacists will still be able to select CE that meets their educational needs for the remaining required hours.

Written Comments from Phillip Drum, RPh.,

Comment #5: Mr. Drum objected that the required six subject specific CE. Mr. Drum indicated that pharmacists should have the discretion to take courses based on pharmacist need and not be forced to learn issues that a pharmacist may not face.

Response to Comment #5: See response to comment #4.

Written Comments from Paul Huntzinger, RPh.,

Comment #6: Mr. Huntzinger indicated he was against the required six subject specific CE.

Response to Comment #6: While this comment was received after the closure of the comment period, the Board did review the comment. See response to comment #4.

Written Comments from Kaiser Permanente,

Comment #7: Kaiser indicated section 1732.5(a) should be amended to include reference to Business and Professions Code (B&P) section 4231(b).

Response to Comment #7: The Board rejected this comment. While the Board does understand the section could be amended to add the reference, section 1732.5(a) is not being amended under this regulatory action. The exception that Kaiser is requesting is clear in B&P section 4231(b) and it is well known to the pharmacists in California.

Comment #8: Kaiser expressed concern that the subject specific areas would not ensure that pharmacists have the most update knowledge because they could take the required six hours in just one of the required subject areas. Additionally, Kaiser expressed concern that a large portion of licensed pharmacists are not current on pharmacy law. Kaiser recommended that the regulation be modified to require two or four hours of CE on changes in Pharmacy Law and Federal Pharmacy Law.

Response to Comment #8: See response to Comment #4.

Comment #9: Kaiser expressed concern that the regulation does not require “live and in person” continuing education. Kaiser cited information released by the Accreditation Council for Pharmacy Education (ACPE) that found remote/internet education to be less effective than “in person” education. Kaiser indicated that the current continuing education requirements are not meeting the needs for California Pharmacists and recommended that the Board require some “in person” continuing education.

Response to Comment #9: The Board rejects this comment. Requiring “in person” continuing education is outside the scope of this regulatory action. This Board determined that additional discussion and vetting of this requirement would need to be done. “In person” continuing education could have a substantial impact on pharmacists and additional review and stakeholder discussion would need to be completed before the Board moves in that direction.

First Modified Text – Response to Comments

During the 15-day public comment period from August 3, 2016 to August 18, 2016, the Board received one comment. The comment was provided to the Board in the Meeting Materials for the September 22, 2016 Board meeting, and was reviewed and considered by the Board at that meeting.

Written Comments from an Anonymous Commenter via Mail

Comment #10: Commenter indicated that the Board should not provide CE and that all CE should be ACPE accredited because pharmacists may be licensed in multiple states

Response to Comment #10: The Board rejected this comment. The Board provided CE will be available via multiple formats (Webinar, You Tube video, In Person) which will allow pharmacists in another states to complete the CE necessary for renewal. Additionally, the Board provided CE will ensure that pharmacists are current in the laws effecting California residents. While the Board does understand that pharmacists may be living and working in other states, a California licensed pharmacist can move to California and begin working at any time. It is important that those licensed pharmacist be aware of the pharmacy law changes that directly impact California residents.

At its September 22, 2016, meeting, the Board considered all of the comments and voted to adopt the continuing education regulation text as it was noticed on August 3, 2016.