

## **California State Board of Pharmacy**

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## XVIV. <u>Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) sections</u> 1732.02, 1732.2, and 1732.5, Related to Board Accredited Continuing Education

At the October 2015 Board Meeting, the board approved proposed text to amend Sections 1732.02, 1732.2, and 1732.5 of Title 16 CCR, related to Board Accredited Continuing Education. The 45 day comment period began on November 13, 2015 and ended December 28, 2015. Additionally, a regulation hearing was held on February 2, 2016.

The Board received several comments during the comment period and at the regulation hearing.

## At this Meeting

The board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

- 1. Adopt the regulation as approved at the October 2015 Board meeting
- 2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

**The Attachment** immediately following this memo contains the proposed regulation text as noticed on November 13, 2015 and a compilation document of all the comments received during the 45 day comment period and at the regulation hearing.

# Board Accredited Continuing Education 1732.02, 1732.02, and 1732.5

## **Board Accredited Continuing Education -45-Day/Hearing Comments Comment Period Closed** December 28, 2015

Code Section	Commenter	Comment
1732.5	Starship1980s @aol.com	The California Board of Pharmacy should not impose the 6 credits of specific ce requirements in certain subject areas. Pharmacists should be allowed latitude in selecting whatever ce credits he or she wants to take in order to meet license renewal requirements. This proposed legislation should be lifted forthwith.  I want an administrative hearing on this issue.
1732.5	vercp@aol.com	It is good the board is considering to mandate certain subject areas for CE. If this is approved hopefully the board will consider some way to determine how pharmacists are supposed to monitor or know if a program falls within one of the six areas. For example, If a 60 minute CE is given on OTC review and there is approximately 20 minutes of OTC patient counseling, does this fraction apply (1/3 of 1 hour), the entire lecture apply (1 hour), or none of it (0 hour) can be counted because the board intention is foer the required consultation areas for a new Rx, change dose, etc? Perhaps a special ACPE course letter/number to designate if it qualifies as one of the 6 categories?  Thank you.  §1732.5 Renewal Requirements for Pharmacists (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months. (b) At least six (6) of the thirty (30) hours required for pharmacist license renewal shall be completed 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 Pharmacists renewing their licenses which expire on or after July 1, 2018, shall be subject to the requirements of this subdivision.
1732.5	Douglas Barcon	Current continuing education requirements allow pharmacists to select the areas of their continuing education based upon their practice settings and educational needs as specified in B&P Code Chapter 9, Division 2, Article 17 Continuing Education Sections 4232 (b) and (c), which may include pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy, but are not limited to these subjects.  Advanced practice pharmacists, once licensed, are required to comply with B&P Code Chapter 9, Division 2, Article 17 Continuing Education Sections 4233, which requires an additional 10 hours of practice relevant continuing education per renewal cycle in addition to the requirements of Section 4231.  The subject areas specified in the proposed 1732.5 are very narrow and have minimal change or are static material. Some of the subject material is included in other continuing education programs not directly related to subject areas (1)-(6). Requiring the pharmacist to duplicate education, specifically to comply with this regulation is not an effective use of time or resources, and in the case of an advanced practice pharmacist may reduce the actual practice-relevant continuing education total hours per year.

Code Section	Commenter	Comment
1732.5	Douglas Barcon	Depending on practice settings, such as health-system, pharmacists are trained on emergency/disaster response regardless of whether it is approved pharmacy continuing education. Some pharmacists are registered as Disaster Healthcare Volunteers with the State of California. Some pharmacists are members of CERT (Community Emergency Response Teams), which requires 20-hours of training. Some pharmacists have already completed the FEMA IS-100 and 200 programs, others have completed FEMA IS-700, and others furthered their education and completed FEMA IS-800 on National Response Framework for large scale disasters. Pharmacy continuing education on emergency/disaster response for these pharmacists offers little, and such pharmacists likely are more qualified than the instructor of the continuing education course. Is there a mechanism so that these pharmacists can opt out of the emergency/disaster response continuing education specified in 1732.5(b)(1)?  Pharmacists may be pulled away from more pertinent continuing education relevant to their practice in order to comply with the subject requirements specified in 1732.5(b)(1)-(6). For example, how many times must a pharmacist take continuing education on maintaining control of a pharmacy's drug inventory or on sterile compounding if they do not do sterile compounding? With one-hour programs, the six subjects are repeated every two years. Pharmacists will attend for the credit but the learning curve will go down after each repeat.
1732.5	Megan Maddox CPhA	The California Pharmacists Association (CPhA) and our members from the San Diego Pharmacists Association (SDPhA) would like to address some concerns with the Board of Pharmacy's proposed text specifically on §1732.5 Renewal Requirements for Pharmacists. Although we appreciate the intent of the proposed language as we support continuing education requirements for pharmacists, we are concerned with the specific mandate for 6 hours of the 30 total hours (not including the 10 additional hours for advanced practice pharmacists).  We are concerned that the mandate interferes with pharmacists obtaining continuing education to meet their educational needs in order to effectively and safely care for their patients. We believe that the proposed subject areas for mandated continuing education are inadequate as the subject areas are too narrow and do not apply to the many pharmacists whose functions do not include compounding and dispensing and will not help increase protection of the patient. This mandate would result in pharmacists obtaining continuing education that does not apply to their practice settings, patient population, or meet their professional educational needs.  Further, continuing education opportunities in the proposed categories are not readily available. We believe that the Board of Pharmacy should ensure availability of accessible, suitable programs or be able to provide programs directly to licensees. As a consequence, licensees may incur additional expenses for paid programs to meet these requirements, in addition to their time obtaining continuing education not relevant to them.  For these reasons, we ask that you consider our concerns and amend § 1732.5 (b) to eliminate the mandate that all pharmacists must complete at least six (6) of the thirty (30) hours required for pharmacist license renewal in the areas listed in 1-6.

Code Section	Commenter	Comment
1732.5	Phillip Drum, RPh	As a 30 yr licensed pharmacist in California, I STRONGLY object to the changes proposed in section 1732.5 (b) (b) At least six (6) of the thirty (30) hours required for pharmacist license renewal shall be completed 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  This is the beginning of a slippery slope towards dictating which type of CE pharmacist MUST perform in order to gain licensure. As pharmacists, there are wide areas of responsibilities that we may possess that do not include direct patient care (patient consultation, substance abuse - red flags), dispensing of medication (drug inventory, emergency disaster), use of IV drugs (compounding) and someone else's determination of what constitutes ethical behavior (which IS sorely lacking in today's world - with the consideration of legalizing marijuana).  We should NOT be pandering to special interests - as other states have done - with poor outcomes.  Leave it to our discretion where our weaknesses may lie for our jobs and our profession - NOT force us to learn about issues we will NOT use in our role as a pharmacist.  I strongly object to this entire concept and recommend removal of any changes to section 1732.5.
1732.5		I'm against the revised CE proposal. Pharmacist should be allowed to take CE appropriate to their practice. Ethics? Couldn't locate one pharmacist CE on the topic Compounding? Wow - really? Cool area, but how many pharmacist do it? The same for the other areas. Just more noise to clutter our practice.
1732.5(a)	Kaiser	Section 1732.5 (a) is vague and unclear because it does not reference Business & Professions Code (B&P Code) Section 4231(b) as an exception to the requirement for Continuing Education specified in in the proposed regulation provision of 1732.5(b). However, for reasons stated below the Board should consider sponsoring a change in B&P Code to provide a more beneficial and efficient way to accomplish the purpose of the regulation change as discussed by the Board of Pharmacy over the past four to eight years.

Code Section	Commenter	Comment
1732.5(b)	Kaiser	Proposed NEW sub-section 1732.5(b), as proposed, would not accomplish the intent of the Board to help assure that all pharmacists renewing their licenses are up-to-date on pharmacy law changes (federal and State statutes and regulations) that have been adopted to further the Board's mission to protect the public. The proposed language lists six subject areas in which pharmacists must have at least six (6) hours of continuing education for renewal every two (2) years. However, the language says "in one or more" of the subject areas. By using that phrase it is possible, indeed probable, that pharmacists will choose only one or two of the subject areas in which to obtain all six (6) hours and thus the pharmacists' license could be renewed for decades, perhaps their entire careers, without being familiar with the subject areas the Board felt were important enough to public safety to be specifically included a regulation.  Over the past four to eight years or more, the Board has recognized and discussed a continuing problem with a substantial number of California licensed pharmacists not being familiar with current pharmacy law, especially recently enacted law changes meant to address urgent or chronic practice. issues that have put the public at risk or that could have been resolved in ways that increase public benefit. For example, when the law change required each pharmacy to have a Quality Assurance Program to prevent errors in dispensing, compounding, etc., the Board's inspectors continued to find pharmacists and pharmacists-in-charge for many years that were unaware of the requirement. Other similar problems occurred like changes in reporting requirements or impaired pharmacists, taking appropriate actions per a pharmacist's Corresponding Responsibility for controlled substance dispensing, meeting revised requirements for compounding-especially Sterile Compounding, preventing diversion of controlled substances from inventory, changes in prescription label standards, etc. And, perhaps most of all, it inhi

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1732.5(b)	Kaiser	Pharmacists who graduated from California pharmacy schools do receive pharmacy law instruction that includes specific California requirements but for a variety of reasons recent changes in pharmacy law are not the subject of the California Practice Standards and Jurisprudence exam the Board administers. Thus, the emphasis on study for that licensing exam may overlook recent changes. The next reason for a lack of sufficient familiarity to changes in California pharmacy law, is that the Board of Pharmacy's newsletter, "The Script", is no longer distributed to all pharmacists. It is only available on the Board's web site, which means that pharmacists must proactively seek the "new law" information. Also, it has been noted that the updates on pharmacy law courses are the most popular sessions at California's two major pharmacist conventions. However, less that 9% of California's licensed pharmacists belong to those two associations, combined, and even less attend the conventions.  Further, the proposed new sub-section of the Regulation lists specific subject areas that are all areas of California Pharmacy Law changes in relatively recent years, especially at the time they were proposed for the regulation. Undoubtedly, there will be important law changes each year adopted by the Legislature, the Board of Pharmacy or the federal government in response to important current problems or opportunities. By the particular manner in which the particular proposed subject areas are listed, the regulation actually takes away from the intent of the Board to have all pharmacists promptly aware of the current pressing pharmacist regulatory issues. In other words, by listing them specifically instead of something like a "Current Pharmacy Law Update", pharmacists are likely to see courses that are advertised as those specific subjects.  A better, more effective and efficient alternative would be to adopt regulatory language that requires perhaps two to four hours every two years of accredited courses in "Recent Changes in Californi

Code Section	Commenter	Comment
1732.5(b)	Kaiser	The Board should change the proposed language to state the requirement in this more general way, which would not only be more amenable to accommodate ongoing and current priorities during each two-year renewal period but it would address the resistance to the regulation from pharmacists that do not intend to have a listed specialty practice, such as compounding. For example, one of the proposed subjects is "Compounding". A continuing education course that is advertised as "Compounding" will be marketed to those pharmacists that have compounding as the only or a substantial portion of their daily practice. It is likely to be lengthy and highly technical. It will cover current law but the majority of its content will not be relevant to the vast majority of California pharmacists. Conversely, a course that is promoted as "Recent developments in Pharmacy Law", for example, will include law changes and expectations for pharmacist compounding and be much more applicable and satisfactory to that majority of pharmacists not involved in compounding. But it will keep them abreast of what they need to know if they do become involved in compounding. Likewise for the subject area of "Emergency/Disaster Response and the other listed subject areas.  Finally, the proposed regulation does not adequately address recent information publicized by the Accreditation Council for Pharmacy Education (ACPE), which not only is the accreditation organization for all California Board of Pharmacy recognized pharmacy schools, but is also one of the two accreditation organizations for California pharmacy continuing education. ACPE reported show that continuing education that is not taken "live and in person" in an interactive process, is not very effective. ACPE also reported that about 80% of the pharmacist continuing education process results in much lower average comprehension and retention of subject area information. It also does not allow pharmacists to discuss content with instructors or peers, thus not making it "real". Continuing to
1732.5(b)	Kaiser	Continuing Education requirements are not meeting the needs or expectations for pharmacists in California.

## Board Accredited Continuing Education Initial Proposed Text

### **BOARD OF PHARMACY**

**Proposal to amend** § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

## §1732.05. Accreditation Agencies for Continuing Education

- (a) The following organizations are approved accreditation agencies:
  - (1) The Accreditation Council for Pharmacy Education.
  - (2) The Pharmacy Foundation of California California Pharmacists Association.
- (b) Accreditation agencies shall:
  - (1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.
  - (2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.
  - (3) Provide the board with the names, addresses and responsible party of each provider, upon request.
  - (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.
  - (5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.
  - (6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.
  - (7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.
- (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

**Proposal to amend** § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

## § 1732.2. Board Accredited Continuing Education

- (a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.
- (b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.
- (c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

  (d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.
- (e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.
- (f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

**Proposal to amend** § 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

## §1732.5 Renewal Requirements for Pharmacists

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six (6) of the thirty (30) hours required for pharmacist license renewal shall be completed 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) <u>Substance Abuse</u>, <u>Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility</u>
- (6) Compounding

<u>Pharmacists renewing their licenses which expire on or after July 1, 2018, shall be subject to the requirements of this subdivision.</u>

(b) (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.