

DEPARTMENT OF CONSUMER AFFAIRS

TITLE 16. BOARD OF PHARMACY

Division 17

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
CONTINUING EDUCATION**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments, relevant to the action proposed, in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board at its office by January 29, 2024.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. The Board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period.

The Board may, after holding a hearing if requested and considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Authority: Sections 462 and 4005, Business and Professions Code (BPC). Reference: Sections 462, 4052.3, 4052.8, 4052.9, 4202, 4231, 4232, and 4232.5, Business and Professions Code.

Informative Digest/Policy Statement Overview

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 (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 (CCR) 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 participat[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.

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 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.

Anticipated Benefits of the Proposed Regulations

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.

This regulatory proposal will not affect worker safety or the state's environment.

Consistency and Compatibility with Existing State Regulations

While developing these regulations and amendments, the Board conducted a search of any similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT AND ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State:

The proposed regulations do not result in a fiscal impact to the state. The Board currently ensures compliance with its regulation of the pharmacy industry 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 for pharmacy technicians to 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.

Nondiscretionary Costs/Savings to Local Agencies: None

Mandate Imposed on Local Agencies or School Districts: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact:

The Board has made the initial determination that the proposed regulatory action will not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other States. This proposal provides pharmacists and pharmacy technicians with clarifying information regarding 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 with the statutes.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

Effect on Small Business:

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 has determined that the proposed regulatory action will not affect small businesses. The proposed regulations directly impact pharmacists and pharmacy technicians only and do not impact businesses.

Business Reporting Requirements

This regulatory proposal does not require businesses to file a report with the Board.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/Businesses:

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. Thus, the Board concludes 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; and,
- (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 the continuing education provisions for pharmacists. Additionally, this regulatory proposal provides clarity to pharmacy technicians regarding the one-hour cultural competency course they must complete pursuant to BPC section 4202. This regulatory 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.

Benefits of Regulation:

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.

The Board has 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.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board must determine that no reasonable alternative it considered to the regulation, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposal described in this Notice, or more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments—relevant to the above determinations—in writing, at the address listed below for the Contact Person, during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, the Initial Statement of Reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the person named below.

You may obtain a copy of the Final Statement of Reasons once it has been prepared, by making a written request to the Contact Person named below or by accessing the website listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Lori Martinez
Address: Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel
Address: Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text ,if any, can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.