

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Pharmacy Technician Certification Programs**

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 Persons in this Notice, must be received by the Board at its office by October 7, 2024.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will 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. A hearing may be requested by making such request in writing addressed to the individuals listed under "Contact Persons" in this notice.

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 persons designated in this Notice as the Contact Persons 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: Pursuant to the authority vested by Business and Professions Code (BPC) sections 4005 and 4202, the Board proposes amending section 1793.65 of Division 17 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (BPC section 4000, et seq.). The Board's mandate and mission are to protect the public (BPC section 4001.1).

Existing law at BPC section 4202 establishes the requirements for obtaining a pharmacy technician license and includes four pathways to licensure. One of these pathways is certification by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the Board.

Existing regulation at CCR section 1793.65 specifies that the pharmacy technician certification programs approved by the Board are the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association, and establishes a December 31, 2024 sunset date for these program approvals.

BPC section 139 requires the Department of Consumer Affairs (DCA) to develop a policy regarding examination development and validation, and occupational analysis. The section further requires that every board within DCA have a method for ensuring that every licensing examination administered by or pursuant to contract with the board is subject to periodic evaluation, which must include:

1. A description of the occupational analysis serving as the basis for the examination;
2. Sufficient item analysis data to permit a psychometric evaluation of the items;
3. An assessment of the appropriateness of prerequisites for admittance to the examination; and
4. An estimate of the costs and personnel required to perform these functions.

The DCA Licensure Examination Validation Policy (which has been established to meet the mandate of BPC section 139) provides in part that, generally, an occupational analysis and examination outline should be updated every five years to be considered current.

Statutory changes, effective January 1, 2017, updated the provisions for authorized pharmacy technician certification programs by expanding authorization to programs accredited by the National Commission for Certifying Agencies. (Prior provisions of the law limited the provisions to certification by the Pharmacy Technician Certification Board.) In response to the change, the Board promulgated regulations to identify the Board-approved programs. Although the Board initiated the rulemaking in 2017, for a variety of reasons, the regulation did not become effective until January 1, 2023.

The Board has contracted with the DCA Office of Professional Examination Services (OPES) to conduct evaluation of the two pharmacy technician certification programs to ensure compliance with the provisions of BPC section 139. While the work to conduct the evaluations is underway, it is anticipated that the evaluation results will not be available until Fall 2024. Given this anticipated timing, the Board determined that it was appropriate to extend the current sunset date of the program approvals to ensure this pathway to licensure remains in place.

This proposal will amend section 1793.65 of Article 11 of Division 17 of Title 16 of the CCR to extend the current program sunset date from December 31, 2024 to June 30, 2026 (18 months) to allow sufficient time for the OPES evaluations to be conducted, consideration of the results by the Board, and completion of a subsequent rulemaking. This will ensure that the current approved pharmacy technician certification programs remain a valid pathway for licensure for pharmacy technician applicants during that process.

Anticipated Benefits of Proposal

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents.

This proposal extends the current December 31, 2024 sunset date by 18 months (to June 30, 2026) to allow sufficient time for the OPES evaluations to be conducted, consideration of the results by the Board, and completion of subsequent rulemaking. Extending the current sunset date will ensure that the two certification programs continue to be pathways to licensure for pharmacy technicians. Maintaining this licensure pathway allows pharmacy technician applicants the flexibility to determine which of the two programs is best for them. The benefit to the consumers of California is that their health and welfare may be better served by an increased number of pharmacy technicians in the industry. When there is an increase in the number of licensed pharmacy technicians, each pharmacy can hire the staff necessary to meet their consumers' needs.

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

Evaluation of Consistency and Compatibility with Existing State Regulations

During the process of developing this regulatory proposal, 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.

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The regulations do not result in a fiscal impact to the state. The Board already accepts these two certification programs, and this proposal allows the Board to continue to do so while the program evaluation is completed.

The regulations do not result in a fiscal impact to the state in the form of federal funding or any cost or savings to any state agency.

Nondiscretionary Costs/Savings to Local Agencies: None

Cost to any Local Agency or School District for which Government Code Sections 17500 - 17630 Require Reimbursement: None

Mandate Imposed on Local Agencies or School Districts: None

Significant Effect on Housing Costs: None

Business Impact Estimates:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The proposed amendment extends the current December 31, 2024 sunset date by 18 months (to June 30, 2026). This extension may result in continued revenue for the certification programs, as pharmacy technician applicants will be able to continue completing the programs. This is a benefit to the programs and not an adverse effect.

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.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The Board has determined that this regulatory 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.

The Board determined that this proposal will not create or eliminate jobs or businesses. The proposed amendment extends the current December 31, 2024 sunset date by 18 months (to June 30, 2026). The benefit to the consumers of California is that their health and welfare may be better served by an increased number of pharmacy technicians in the industry. When there is an increase in the number of licensed pharmacy technicians, each pharmacy can hire the staff necessary to meet their consumers' needs.

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

Business Reporting Requirements

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

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 two certification programs approved by the Board are not small businesses.

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 Persons, 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 persons designated in this Notice as the Contact Persons 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 Persons

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.