

TITLE 16. BOARD OF PHARMACY

NOTICE CONCERNING PHARMACY TECHNICIANS

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) is proposing to take the rulemaking action described under the heading Informative Digest. 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 not later than December 6, 2021.

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 his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The Board may, after 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 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: Pursuant to the authority vested by sections 114.5, 115.4, 115.5, 4005, 4115, and 4202 of the Business and Professions Code, and to implement, interpret or make specific sections 144, 144.5, 163.5, 4007, 4038, 4005, 4115, 4115.5, 4202, 4207, 4400, and 4402 of the Business and Professions Code and section 11105 of the Penal Code, the Board is proposing to amend sections 1793.5 and 1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations and adopt section 1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST

A. Informative Digest

The Board proposes to amend sections 1793.5 and 1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations (CCR) and adopt section 1793.65 of Article 11 of Division 17 of Title 16 of the CCR to update the pharmacy technician application form incorporated by reference (Form 17A-5), update the requirements for schools providing training courses for pharmacy technicians, and add the Board-approved pharmacy technician certification programs in accordance with SB 952 (Anderson, Chapter 150, Statutes of 2016).

B. Policy Statement Overview

The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists and individuals who work within the pharmacy. The Board's mandate and its mission is to protect the public. Business and Professions Code (BPC) section 4005 authorizes the Board to adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. This rulemaking proposal clarifies and makes specific the requirements that apply to the Board's pharmacy technician application, pharmacy technician training courses and Board-approved certification programs.

The Board regulates individuals licensed as pharmacy technicians who work in pharmacies under the supervision of pharmacists. The Board has the authority and responsibility to specify the requirements for courses of training or certification programs for those seeking licensure as a pharmacy technician. The Board also has the authority and responsibility to specify pharmacy technician application requirements.

Existing law authorizes the Board to perform a thorough investigation of applications for licensure to determine whether the applicant is qualified for the license being sought and establishes the requirements necessary to qualify for a pharmacy technician license, including education and training requirements. Further, existing law authorizes the Board to approve courses of training and pharmacy technician certification programs as a means to qualify for licensure.

The regulations proposed in this rulemaking action would (1) update requirements for applying for licensure as a pharmacy technician, including modifying the application that is incorporated into the regulation by reference; (2) modify the requirements for qualifying courses of training for pharmacy technicians; and (3) specify which pharmacy technician certification programs are Board-approved pursuant to statute.

C. Anticipated Benefits of Proposal

This regulatory proposal ensures the pharmacy technician application is requesting current, relevant, and accurate information about pharmacy technician applicants. This information allows for the Board to make an appropriate licensing decision based on the applicant's fitness for duty as a licensed pharmacy technician. When licenses are appropriately issued to qualified applicants, California consumers' health and welfare are benefited in that the pharmacy technicians working throughout California are qualified to meet requirements to ensure safe preparation and handling of prescription medications for the pharmacist's review prior to dispensing to the consumer.

This rulemaking package ensures that Board regulations are revised to incorporate standards that better protect pharmacy technician students as well as the public. If students are given necessary information regarding their likely denial of licensure prior to committing to or completing the course, it may save them time and money. Requiring more stringent training courses for pharmacy technicians to become licensed will result in more qualified pharmacy technicians to better protect consumers' health and welfare.

When the Board updates the regulations regarding Board-approved pharmacy technician certification programs, the Board ensures that regulations specify and

memorialize the specific pharmacy technician certification programs that have Board approval. With the increase of an additional certification program accepted by the Board, pharmacy technician applicants can determine which of the two programs is best for them. Additionally, the applicants are not required to take one specific certification program. The benefit to the consumers of California is that their health and welfare may be better served by an increased number of pharmacy technicians available in the industry. When there is an increase in the number of licensed pharmacy technicians, each pharmacy can hire an adequate amount of staff to meet their consumers' needs.

D. Consistency and Compatibility with Existing State Regulations

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

E. Incorporation by Reference

This proposal would update CCR section 1793.5 to modify the version of the Board of Pharmacy's Technician Application (Form 17A-5) that is incorporated by reference (rev ~~4/2021~~ 2/2021).

FISCAL IMPACT ESTIMATES

The Board has made the following initial fiscal impact determinations:

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The regulations are anticipated to result in approximately 32 prospective students opting to not enroll in a pharmacy technician educational program and a corresponding reduction in initial license applications submitted to the Board each year.

Expenditure (savings): The regulations are anticipated to result in 32 fewer initial registration applications to be submitted to the Board per year.

The Board indicates a Program Technician III takes approximately 1 hour and a Staff Services Analyst 2 hours to complete the licensing workload at a cost of \$197 each application, which would result in workload and costs savings of approximately \$6,304 per year and up to \$63,040 over a ten-year period.

Additionally, the Board is anticipated to realize cost savings related to fewer denied applications being appealed. The Board estimates 40 percent (13) of the 32 initial registration applicants appeal the Board's decision to deny the application per year.

The Board currently incurs significant workload and costs to fully process and adjudicate an appeal. The average approximate cost per appeal is \$13,908 as follows:

- Office Technician – Administrative (50 minutes - \$48)
- Staff Services Analyst – Investigation & reporting (2 hours - \$132)
- Associate Governmental Program Analyst – Issuance of denial letter (10 minutes - \$13)
- Staff Services Manager I – Final review & decision (10 minutes - \$15)
- Attorney General and Office of Administrative Hearings – Approximate average \$13,700 per case

The Board estimates total annual cost savings (including licensing (32) - \$6,304 per year and appeals (13) - \$180,804 per year) of approximately \$187,108 per year and up to 1.8 million over a ten-year period.

Revenues (loss): The regulations will result in 32 fewer pharmacy technician applicants applying for registration and paying \$195 each to the Board, which results in decreased revenues of \$6,240 per year and up to \$62,400 over a ten-year period.

Additionally, the Department of Justice will complete 32 fewer fingerprint checks per year with lost revenues of \$1,568 per year and up to \$15,680 over a ten-year period.

The Board estimates total lost revenue to the state of approximately \$7,800 per year and up to \$78,000 over a ten-year period.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

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

Significant Statewide Adverse Economic Impact Directly Affecting Businesses (If Any):

The Board has made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees.

Business Impact:

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

The Board finds that updating the pharmacy technician license application, revising the pharmacy technician training course requirements, and specifying approved pharmacy technician certification programs, may have a minor statewide adverse economic impact on businesses.

The regulations are anticipated to result in approximately 32 prospective students opting to not enroll in a pharmacy technician educational program and paying tuition fees of \$20,000 per individual, which results in tuition revenue losses of \$640,000 per year and up to \$6.4 million over a ten-year period.

The Board indicates 110 to 125 educational programs will be impacted by the proposed regulations, which would result in an average revenue loss ranging from \$5,120 to \$5,818 per institution per year and up to \$51,200 to \$58,182 over a ten-year period.

Additionally, businesses in the state providing fingerprint services will have approximately 32 fewer fingerprint checks per year. These businesses typically charge \$75 per fingerprint check with \$49 being remitted to the Department of Justice. As a result, these businesses are estimated to incur revenue losses of \$832 per year and up to \$8,320 over a ten-year period.

Cost Impact on Representative Private Person or Business:

The regulations are anticipated to result in approximately 32 prospective students opting to not enroll in a pharmacy technician educational program each year.

Expenditures (savings): These (32) individuals will save approximately \$20,000 each in tuition and training costs, as well as Board registration fees (\$195), fingerprint check fees (\$75), and National License Database fees (\$8).

The Board estimates total annual savings for these individuals of approximately \$649,000 per year and up to \$6.49 million over a ten-year period.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

While the Board does not have nor does it maintain data to define if any of its licensees are a “small business” as defined in Government Code section 11342.610, the Board made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. The Board has determined that the proposed regulation would have little effect on small businesses. Existing law allows a training course as one of the pathways to licensure for pharmacy technicians. The Board is not aware of any small businesses that provide pharmacy technician training programs.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/New Businesses:

The Board concludes that it is:

- (1) Unlikely that the proposal will create or eliminate any jobs within California;
- (2) Unlikely that the proposal will create new, or eliminate existing, businesses in California; and
- (3) Unlikely that the proposal will expand businesses currently doing business within the state.

The Board has determined that the regulatory proposals herein are unlikely to have any impact on the creation or elimination of jobs, the creation of new businesses, the elimination of existing businesses, or the expansion of businesses in the State of California.

This rulemaking proposal clarifies and makes specific the requirements that apply to pharmacy technician application requirements, training courses and qualifications. The Board notes this regulatory proposal allows for the acceptance of an additional pharmacy technician certification.

Benefits of Regulation:

This regulatory proposal will benefit the health and welfare of California consumers by ensuring that the Board updates the requirements for the pharmacy technician application, training course, and certification programs and will better protect patients by providing for a better screened, trained, and educated pharmacy technician licensed and working in California.

The benefits to the public include consumer protection for future pharmacy technician training course students, and for the health and welfare of California residents. When a pharmacy technician is properly trained as a result of the training course, the consumers of California may experience fewer compromises in safe handling of prescription medication and medication errors prior to a pharmacist's review.

The regulatory proposal will not affect worker safety and the state's environment.

CONSIDERATION OF ALTERNATIVES

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 either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations during the written comment period at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed actions and has available all the information upon which the proposals are based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the person designated below as contact person, or by accessing the Board's Web site at <http://www.pharmacy.ca.gov>.

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 Board's Web site www.pharmacy.ca.gov.

CONTACT PERSON

Materials regarding this proposal can be found at www.pharmacy.ca.gov. Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

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