

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take 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 not later than 5:00 p.m. on May 28, 2019.

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 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: Sections 4005 and 4132 of the Business and Professions Code authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4005, 4026.5, 4044.3, 4052, 4115, 4132 and 4202 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The California State Board of Pharmacy (board) proposes to add and adopt the minimum qualifications for a pharmacy technician to work at a remote dispensing site pharmacy.

Existing pharmacy law specifies that protection of the public is the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions, and it generally authorizes the board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. Additionally, existing law authorizes the board to issue a license to a pharmacy and a pharmacy technician.

Assembly Bill (AB) 401 (Aguiar-Curry, Chapter 548, Statutes of 2017) added, among other things, Business and Professions Code (B&P) Sections 4130, 4131 and 4132 to make the following changes:

- B&P section 4130 – Established the board’s authority to issue a remote dispensing site pharmacy (RDSP) license. Additionally, it established that the RDSP shall only be staffed by a pharmacist or a pharmacy technician.
- B&P section 4131 – Established that, if the RDSP is not staffed by a pharmacist, it shall be staffed by a pharmacy technician who meets the qualifications of B&P section 4132, with the direct supervision of a pharmacist, which can be done remotely.
- B&P section 4132 – Established that, in addition to B&P section 4202, a pharmacy technician working at a RDSP shall meet the qualifications promulgated by the board prior to working at a RDSP.

Previously, pharmacy law did not allow for the licensure of a remote dispensing site pharmacy. This proposal will adopt the regulation text at section 1793.9 based on the statutory changes made as a result of AB 401 and the requirement that the board establish minimum qualifications for pharmacy technicians working at a RDSP. Specifically, the proposal would:

- Specify that a pharmacy technician license be in good standing as defined by B&P section 4026.5.
- Specify that a pharmacy technician possess and maintain a certification issued by an approved certifying program.
- Specify that a pharmacy technician have a degree (associate’s in Pharmacy Technology or any bachelor’s degree) or complete a board approved training program.
- Require a minimum of 1,000 hours of work experience in the three years prior to working at a RDSP.

Anticipated Benefits of Proposal

This proposal is necessary to establish the specific minimum qualifications for pharmacy technicians working in a RDSP as part of the new statutory requirements enacted in AB 401, which increased access to prescription medication and pharmacist care for Californians living in rural areas by creating a RDSP. Additionally, consumers will be better protected by setting minimum qualifications for pharmacy technicians, which will guard against having unqualified technicians working with remote supervision in a RDSP.

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.

Fiscal Impact Estimates

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

The board may incur minor and absorbable costs associated with routine inspections. These costs would be absorbed by the board's existing resources and become part of its regularly scheduled site inspections.

The board does not anticipate any costs/savings to other state agencies or costs/savings in federal funding to the state.

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

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 and/or employees including the ability of California businesses to compete with businesses in other states. This determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over a few months. Additionally, the proposed regulation establishes the education and experience of a pharmacy technician working in a remote dispensing site pharmacy. This may impact available qualified potential employees; however, it should not have a significant fiscal impact on businesses.

Cost Impact on Representative Private Person or Business:

There are three options for an individual to obtain a pharmacy technician license to work in California. The first is through education; they can complete a training course accredited by the American Society of Health-System Pharmacists (ASHP), graduate from a school of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE), obtain an Associate Degree in Pharmacy Technology, or complete a training course that provides a minimum of 240 hours of instruction as required by CCR section 1793.6(c). The second is through certification and examination; they can successfully pass the Pharmacy Technician Certification Board (PTCB) or the Exam of the Certification of Pharmacy Technicians (ExCPT). The final option is through

military training pursuant to 16 CCR section 1793.6(b). Obtaining a pharmacy technician license through one of the approved routes would allow the licensee to work as a pharmacy technician in California; however, they would not be able to work in a remote dispensing site pharmacy until they have met the minimum qualifications specified in this regulatory proposal.

The board issued approximately 5,991 pharmacy technician licenses in FY 2016/2017. Of that, approximately 12 (0.2%) qualified by graduating from a school of Pharmacy, approximately 121 (2.0%) qualified by having an Associate Degree in Pharmacy Technology, approximately 1,873 (31.3%) qualified by passing an exam (being certified by a pharmacy technician certifying program), and approximately 3,985 (66.5%) qualified by completing a board approved training program.

In some cases, when an applicant is qualifying by passing an exam, they also completed a training program to prepare them for the exam. In these cases, the board qualifies the applicant based on the exam and not the training program. The board does not track when applicants have met both qualifications. The board is unable to determine how many of the 1,873 licensees that qualified by passing an exam also completed a training program; however, the board estimates that approximately 25% (468) of those exam qualifiers also completed the training program.

There are two exams that applicants and licensees can take to become certified by a pharmacy technician certifying program (PTCB or ExCPT). The one-time cost for these exams is \$115 and \$129, respectively. This proposed regulation requires that the certification be maintained, which requires the licensee to renew the certification with either PTCB or ExCPT every two years. The certification bi-annual renewal fee costs are \$40 and \$169, respectively. The exam providers also require 20 hours of CE bi-annually. CE programs are available in 2-hour sessions and cost from zero to \$10.

Currently, there are approximately 130 pharmacy technician training/degree programs available. The cost of these programs ranges from free (Job Corp), to \$19,500 at post-secondary schools. Pharmacy technicians that are PTCB or ExCPT certified and have not completed a training course and do not have a Bachelor's degree would need to complete one of these programs.

The board estimates that, at most, approximately 460 jobs at a remote site dispensing pharmacy will be available. Additionally, the board estimates that approximately 2% (1,430) of pharmacy technician licensees may seek employment within a remote dispensing site pharmacy. If the percentages from FY 16/17 remain true, approximately 982 licenses may need to take one of the certifying exams. Of the remaining 448, 336 (75%) pharmacy technicians may need to complete a training program. This would result in a cost ranging from zero to \$6,552,000 to the pharmacy technicians depending on the training course the licensee selected to complete.

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 (pharmacies) are a “small business” as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over a few months. Additionally, the proposed regulation only establishes the education and experience of a pharmacy technician working in a remote dispensing site pharmacy. This may impact available qualified potential employees; however, it should not have a significant fiscal impact on small businesses.

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;
- (3) Unlikely that the proposal will expand businesses currently doing businesses within the state

While it is unlikely that this proposal will impact jobs or businesses, the authority to issue a remote dispensing site pharmacy license, as granted by AB 401, may increase the number of licensed pharmacies within California. As a result of AB 401, there could be an increase in available pharmacy technician jobs for individuals who meet the minimum qualifications as specified in this proposal.

Benefits of Regulation:

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation implements AB 401, which established a remote dispensing site pharmacy. This statutory change increased access to prescription medication by creating a remote dispensing pharmacy in rural areas, where pharmacies are not readily available. As a result of the statutory change, additional entities may apply to become licensed by the board to establish new remote dispensing site pharmacies in California. These new remote dispensing pharmacies can be staffed by a qualified pharmacy technician and remotely monitored by a pharmacist, which would result in the availability of additional jobs for qualified pharmacy technicians and allow for better access to prescription medication and remote

pharmacist care. This proposal establishes the minimum qualifications for said pharmacy technician. These minimum qualifications may impact qualified potential employees for remote dispensing pharmacies, but do not benefit worker safety in California or the 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 of Pharmacy has prepared an initial statement of the reasons for the proposed action and has made available all the information upon which the proposal is 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 Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <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 website listed below.

Contact Person

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

Name: Lori Martinez
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
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The backup contact person is:

Name: Debbie Damoth
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Sacramento, CA 95834
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Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website: www.pharmacy.ca.gov.