

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Remote Dispensing Pharmacy Technicians

Section Affected: Add Section 1793.9 of Article 11 of Division 17 of Title 16,
California Code Regulations

Problems Addressed

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians. (Business and Professions Code (B&P) section 4000, et seq.) The board's mandate and its mission is to protect the public. (B&P section 4001.1.) Additionally, existing law establishes that the board is authorized to issue a pharmacy license (B&P sections 4037 and 4110) and a pharmacy technician license (B&P sections 4038, 4115, and 4202).

Assembly Bill (AB) 401 (Aguiar-Curry, Chapter 548, Statutes of 2017) added, among other things, 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 by AB 401 and the necessity 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 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.

Benefits

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 as a licensing program under the board's jurisdiction. This statutory change increased access to prescription medication by creating a RDSP 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 would continue to protect the public by establishing the minimum qualifications for said pharmacy technician, which will protect against unqualified technicians working under remote supervision.

Specific Purpose of Proposed Changes and Rationale

The board's proposal makes the following changes:

Add Section 1793.9 of Article 11 of Division 17 of Title 16 of the CCR

The board is proposing to add the regulation title "Pharmacy Technician in a Remote Dispensing Site Pharmacy" to accurately identify the content of the regulation and clarify that the regulation only applies to pharmacy technicians working in a remote dispensing site pharmacy as required by B&P section 4132.

An introduction paragraph is added and reads, "A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:". This conforms to the statutory requirement that pharmacy technicians working at remote dispensing site pharmacies must meet board qualification requirements, and it explains that they must satisfy each of the specified regulatory requirements. Some of the regulatory requirements specified in this section are also statutory requirements that could, if individually met, qualify a person for an initial pharmacy technician license. (B&P section 4202.) The board determined that it is necessary for a pharmacy technician to meet the specified regulatory qualifications, even though they may exceed the minimum qualifications for initial licensure. Since pharmacy technicians working in a remote dispensing site pharmacy can work alone under the remote supervision of a pharmacist, they need additional education and training above the minimum to ensure that they are appropriately educated and trained to work under those conditions. The board determined that the combination of

regulatory requirements will ensure that qualified technicians are adequately prepared to work at remote sites.

Subdivision (a) adds “Possess a pharmacy technician license that is in good standing.” A pharmacy technician license is required by B&P section 4115 prior to working as a technician. B&P section 4026.5 defines “good standing” to mean that the license is not restricted by a disciplinary action. Since a pharmacy technician in a RDSP may work alone under the remote supervision of a pharmacist, the board determined that these technicians should not be on probation or have a restricted license. Such technicians already demonstrated a failure to comply with pharmacy law and require a greater degree of supervision.

Subdivision (b) adds “Possess and maintain a certification issued by an approved pharmacy technician certifying program.” Certification is one way pharmacy technicians may qualify for licensure. (B&P section 4002(a)(4).) The board determined that possessing and maintaining a certification is necessary to ensure that technicians working in an RDSP, who may operate without the physical supervision of a pharmacist, are sufficiently knowledgeable of industry changes and practice standards. To maintain the certification, the pharmacy technician must complete continuing education, as specified by the issuing agency. This helps to ensure that the pharmacy technician stays up-to-date on such changes and standards.

Subdivisions (c)(1) and (c)(2) add “Possess a minimum of an associate degree in pharmacy technology;”, and “Possess a minimum of a bachelor’s degree in any subject; or”. The board determined that a minimum of an associate’s degree in pharmacy technology or a bachelor’s degree in any subject is necessary to ensure that the pharmacy technician has the necessary communication skills (verbal and written) needed to run a RDSP without a pharmacist being physically present.

The proposed regulation would permit a technician holding a bachelor’s degree in any subject to qualify to work at an RDSP, even in subjects unrelated to the pharmacy technician practice. The board determined, however, that this was acceptable because a qualified technician would still need to possess and maintain the certification identified in subdivision (b) and have a minimum of 1,000 hours of on-the-job work experience under subdivision (d). Accordingly, qualified technicians with a bachelor’s degree in an unrelated subject will have the education, technical skills and knowledge needed to perform the duties of a technician being remotely supervised.

Subdivision (c)(3) adds “Complete a course of training specified by the board as provided in section 1793.6.” The subdivision provides an alternative for technicians that do not have an applicable associate’s or bachelor’s degree. But like the two-degree requirements, the board determined that it is necessary for RDSP technicians to have the educational background and communication skills needed to run an RDSP without a physically-present pharmacist, and that these skills may be acquired via a board-approved training course. These training courses offer specific training for pharmacy technicians and will provide the technician with the necessary knowledge. Board-approved training courses are defined in 16 CCR section 1793.6 and are also one of the ways to qualify for an initial pharmacy technician license, as specified in B&P section 4202(a)(2).

Subdivision (d) adds “Complete 1,000 hours of experience working as a pharmacy technician within the three years prior to first working in the remote dispensing site pharmacy.” Based on the board’s experience and expertise, the board determined that 1,000 hours of pharmacy technician work experience is appropriate to ensure that the pharmacy technician has sufficient on-the-job training to run a RDSP with only the remote supervision of a pharmacist. This time equates to six months of full time work, which is sufficient for a pharmacy technician to develop the knowledge needed. Additionally, 1,000 hours is not too restrictive for the license type and duties associated with the license type, but ensures enough experience in a pharmacy setting to protect the public.

Additionally, the board determined that three years is an appropriate time-frame to ensure that the pharmacy technician’s experience is sufficiently recent to be useful and applicable, and that the technician is current with respect to pharmacy law and the practice of pharmacy. The board also selected three years to maintain consistency with other provisions of pharmacy law, such as the requirement that designated representatives have one year of paid work experience in the past three years. (B&P sections 4053, 4053.1, and 4053.2.) This requirement is necessary to establish that the pharmacy technician has the appropriate level of job training and experience to perform the duties of a pharmacy technician while being remotely supervised.

The authority and reference statutes have been added as appropriate in compliance with the section 11346.2(a)(2) of the Government Code. Sections 4005 and 4132 of the Business and Professions Code were added as the authority sections and sections 4005, 4026.5, 4044.3, 4052, 4115, 4132 and 4202 of the Business and Professions Code were added as the reference sections.

B&P section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

B&P section 4026.5 defines “good standing” as it relates to the status of a license issued by the board.

B&P section 4044.3 defines “remote dispensing site pharmacy” and specifies the administration and qualified pharmacy technician staffing requirements.

B&P section 4052 specifies the procedures a pharmacist may perform.

B&P section 4115 specifies the requirement that a person be licensed prior to working as a pharmacy technician and the activities a pharmacy technician may perform under the supervision of a pharmacist.

B&P section 4132 specifies the activities that a pharmacy technician may not perform while working at a remote dispensing site pharmacy. Additionally, this section specifies the requirement that the board promulgate regulations as to the minimum qualifications of a pharmacy technician working at a remote dispensing site pharmacy.

B&P section 4202 specifies the education and training requirements to obtain a pharmacy technician license.

Previously, while pharmacy law did allow for the licensure of a pharmacy technician, it did not allow for the licensure of a RDSP. As a result of a statutory change (AB 401), the board now has the authority to issue a license to a remote dispensing site pharmacy. As part of the statutory change, the board is required to establish the minimum qualifications for a pharmacy technician working at a RDSP.

The board determined that pharmacy technicians working in a RDSP must have additional education and training because, even though they are being monitored from an offsite location by a pharmacist, they are responsible for the daily operation of the RDSP. As discussed, several of the qualifications identified in the proposed regulation are minimum qualifications for a pharmacy technician license. The proposal would establish enhanced education and experience requirements to ensure that technicians working at remote sites have adequate knowledge and experience for the job.

Underlying Data

1. Assembly Bill 401 (Aguiar-Curry, Chapter 548, Statutes of 2017)
2. Bill Analysis of the Assembly Committee on Business and Professions dated April 4, 2017
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Licensing Committee Meeting held January 16, 2018 (Meeting Materials Pages 1-3 and Attachment 2, Minutes Pages 1, 7-9).
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held February 6-7, 2018 (Meeting Materials Pages 1-4 and Attachment 2, Minutes Pages 1, 18-21).

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 qualified potential employees; however, it should not have a fiscal impact on businesses.

Economic Impact Assessment

The board concludes that this regulatory proposal will have the following effects:

- (1) It is unlikely that the proposal will create or eliminate any jobs within California;
- (2) It is unlikely that the proposal will create new, or eliminate existing, businesses in California; and

- (3) It is unlikely that the proposal will expand businesses currently doing business within the state.

The board concludes that the economic impact of this proposal will not be significant. The authority to issue a remote dispensing site pharmacy license, as granted by AB 401, may increase the number of licensed pharmacies within California; however, this possible creation and/or expansion of businesses was a result of the statutory change and not a result of this proposal. There may be an increase in available pharmacy technician jobs and supervising pharmacist jobs for remote dispensing pharmacies. This potential creation of jobs was also the result of AB 401, not this proposal. It is not likely that this proposal will eliminate any jobs in California as the statutory change was intended to add additional pharmacies to communities that did not already have access to a pharmacy. Thus, it is unlikely that the qualifications set by this proposal would eliminate jobs that did not exist prior to the statutory change.

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 RDSP 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. Additionally, the statutory change established the requirement that the board promulgate regulations to enact the qualifications for a pharmacy technician working in a RDSP. This proposal establishes the minimum qualifications for said pharmacy technician.

This regulatory proposal does not affect worker safety or the state's environment. The proposed regulation implements part of AB 401, which gave the board authority to issue licenses to remote site dispensing pharmacies. This proposed regulation establishes the minimum qualifications for pharmacy technicians working in remote site dispensing pharmacies as required by statute. These minimum qualifications may impact qualified potential employees for remote dispensing pharmacies, but does not negatively affect worker safety in California or the environment.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The board considered the following alternatives:

- (1) The board considered not implementing the minimum qualifications for pharmacy technicians working in a remote dispensing site pharmacy and pursuing a statutory change to require an advanced pharmacy technician license. The board determined that this alternative was unacceptable because the board is required by statute to develop the minimum qualifications.
- (2) The board considered varying hours of pharmacy technician experience and determined that 1,000 hours of experience is the appropriate amount, as requiring more hours could be unreasonably restrictive to pharmacy technicians, and requiring fewer hours could jeopardize patient safety.