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Business, Consumer Services and Housing Agency  
Department of Consumer Affairs  
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VI. Discussion and Consideration of Proposal to Add Title 16, California Code of Regulations Section 1793.9 Related to Remote Dispensing Pharmacy Technicians, Including Review of Public Comments and, Potentially, Modified Text

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**Background:**

At the July 2017 Board meeting, the board approved proposed text to add Section 1793.9 of Title 16, CCR, related to Remote Dispensing Pharmacy Technicians. This proposal establishes the regulatory requirements for pharmacy technicians working in a remote dispensing site pharmacy.

As required by the Administrative Procedure Act, board staff released the proposed text for the 45-day comment period on April 12, 2019, which ended on May 28, 2019. The proposed text and comments are attached following this memo.

**Summarized 45-day Comments Regarding Remote Dispensing Site Pharmacy Technicians with Board Staff Recommendations:**

Written Comments from Dieter Steinmetz, RPh.

Comment: Mr. Steinmetz voiced support for the proposal; however, expressed concern regarding the pharmacist/pharmacy technician ratios that impact all areas of the practice of pharmacy in California.

Board Staff Response to Comment: The board staff recommend that this comment be accepted in part (the support position) and rejected in part (reject the pharmacist/pharmacy technician ratio issue). Board staff recommend that the pharmacist/pharmacy technician ratio issue be rejected as it is outside the scope of the proposed changes within this regulatory action. Supervision requirements are established in statute and remain unchanged by the proposed regulation.

Written Comments from Ellen Kureshi, RPh.

Comment: Ms. Kureshi requested clarification on the pharmacist to pharmacy technician ratios. Ms. Kureshi states she has observed a remote pharmacist covering 8 or 9 remote hospitals and she believes it is a safety issue. Additionally, Ms. Kureshi inquired about how controlled substances would be handled and asked about actual process of running a remote dispensing site pharmacy.

Response to Comment: The board staff recommend that this comment be rejected as it is not responsive to the proposed changes. Board staff notes that Business and Professions (B&P) section 4132(d) states that a pharmacist may supervise up to two pharmacy technicians at each RDSP. Additionally, board staff notes that controlled substances need to be handled consistent with pharmacy law. Nothing within this proposal changes the handling of controlled substances. Finally, this proposal does not define the process of operating a remote site dispensing pharmacy, rather this is done in the statute. Board staff notes that the supervising pharmacy would define their business processes for operating an RDSP consistent with Article 8 of the B&P, specifically, sections 4130 - 4135. The scope of this regulation is limited to the requirements a pharmacy technician must satisfy to work in a remote dispensing site pharmacy.

Written Comments from Jessica Adams, Pharm.D.

Comment: While Dr. Adams expressed concern that the requirement to possess an associate degree in pharmacy technology or a bachelor's degree in any subject could be cumbersome for some, which could potentially delay access to pharmacist care, Dr. Adams expressed support for the board's proposal.

Response to Comment: The board staff recommend that this comment be accepted in part (the support position) and rejected in part (reject the concern about the requirement for an associate degree in pharmacy technology or a bachelor's degree in any subject.) Board staff recommend rejection because the minimum of an associate 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 Remote Dispensing Site Pharmacy (RDSP) without a pharmacist being physically present. Additionally, 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) of this proposal. 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 while being remotely supervised.

Written Comments from Matthew Devine, Pharm.D.

Comment: Dr. Devine opposed the proposal. He indicated that allowing a pharmacy technician to dispense medication is a "bad idea" as they make "very basic errors". Additionally, Dr. Devine indicated that "direct supervision of a pharmacist, which can be done remotely, is laughable" and he questioned how that would be done.

Response to Comment: The board staff recommend that this comment be rejected. The authority for a pharmacy technician to dispense medication from a RDSP while under the remote supervision of a pharmacist is granted in B&P section 4130(d), and 4131(d). Additionally, B&P section 4131(d), specifies that direct supervision can be done remotely via audio and visual technology. The board's proposal does not grant the authority for a pharmacy technician to dispense medication from a RDSP while under the remote supervision of a pharmacist. The board's proposal simply states that if a pharmacy technician does perform these duties, they must meet specific training, education, and work experience requirements.

Written Comments from Nagy Shahid.

Comment: Mr. Shahid requested that the board not pass the proposed regulation and he stated there are plenty of pharmacists in California.

Response to Comment: The board staff recommend that this comment be rejected. The authority for a pharmacy technician to operate the RDSP while under the remote supervision of a pharmacist is granted in B&P section 4130(d) and 4131(d). The board's proposal does not grant this authority, but simply states that if a pharmacy technician does operate an RDSP, they must meet specific training, education, and work experience requirements.

Written Comments from Patrick Mok, RPh.

Comment: Mr. Mok indicated he was "disturbed" by the proposed regulation change. He indicated that there are unemployed pharmacists in California and there is a training disparity between a pharmacist and a technician. Mr. Mok indicated that many technicians simply passed a test and have no formal training.

Response to Comment: The board staff recommend that this comment be rejected. The authority for a pharmacy technician to operate the RDSP while under the remote supervision of a pharmacist is granted in B&P section 4130(d), and 4131(d). The board's proposal does not grant this authority, but simply states that if a pharmacy technician does operate an RDSP, they must meet specific training, education, and work experience requirements. Board staff notes that the proposal requires formal training, in addition to, maintaining a certification issued by an approved pharmacy technician certifying program. As such, those technicians that simply passed a test will not be able to operate an RDSP.

Written Comments from Richard Rosenfeld, Pharm.D.

Comment: Dr. Rosenfeld requested clarification on five issues:

- (1) Would the change only apply in remote areas?
- (2) How is oversight by a pharmacist defined?
- (3) Could a pharmacist at a chain store perform these functions?
- (4) Who is liable for errors?
- (5) How many of these technicians could a pharmacist oversee at one time.

Additionally, Dr. Rosenfeld indicated that he felt that only medication for immediate use and only a three-day supply should be dispensed, and the rest provided by a mail-order pharmacy.

Response to Comment: Board staff recommend that this comment be rejected. The questions posed by Dr. Rosenfeld go beyond the scope of this regulation. As previously indicated this regulation establishes the minimum requirements a pharmacy technician must satisfy to work in an RDSP. Dr. Rosenfeld's questions speak to the policy of the underlying legislation. Such policy was determined by the legislature and approved by the governor.

With that noted, to specifically address each of Dr. Rosenfeld's questions, the board staff notes the following:

- (1) This proposal only applies to pharmacy technicians working within an RDSP. An RDSP can only be located in a medically underserved area, which is a location that does not have a pharmacy that serves the general public within 10 road miles of the RDSP [B&P 4130(c)(1)].
- (2) This proposal does not define the oversight of the pharmacist. Board staff notes that the pharmacist-in-charge (PIC) of the supervising pharmacy is designated as the PIC of the RDSP. The responsibilities of the PIC and supervising pharmacy are specified within B&P sections 4131, 4133, 4134, and 4135.
- (3) This proposal does not define the functions of the pharmacist. Board staff notes that the statutory authority for an RDSP does not restrict a chain store from operating an RDSP location.
- (4) This proposal does not define the possible disciplinary action for an RDSP and the staff. Board staff notes that investigation and enforcement procedures for an RDSP and the staff would remain consistent with the investigation and enforcement procedures for other licensees.
- (5) This proposal does not define the ratio of pharmacist/pharmacy technicians. Board staff notes that B&P section 4132(d) states that a pharmacist may supervise up to two pharmacy technicians at each RDSP.

Board staff also notes that the statutory authority to dispense medication from an RDSP is granted by Article 8 of the B&P, specifically, sections 4130 – 4135 and is not the subject of this proposal.

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**Staff Recommendation:** Adopt the regulation language as noticed. Should the board agree, the following motion could be used.

**MOTION:** Adopt the regulation language as noticed on April 12, 2019, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by a Control agency to complete the rulemaking file.

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**Title 16. Board of Pharmacy  
Proposed Text**

**Add section 1793.9 in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1793.9. Pharmacy Technician in a Remote Dispensing Site Pharmacy.**

A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:

- (a) Possess a pharmacy technician license that is in good standing.
- (b) Possess and maintain a certification issued by an approved pharmacy technician certifying program.
- (c) (1) Possess a minimum of an associate degree in pharmacy technology;  
(2) Possess a minimum of a bachelor's degree in any subject; or  
(3) Complete a course of training specified by the board as provided in section 1793.6.
- (d) 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.

Note: Authority cited: Sections 4005 and 4132, Business and Professions Code.

Reference: Sections 4005, 4026.5, 4044.3, 4052, 4115, 4132 and 4202, Business and Professions Code.

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Pharmacy Technicians**

A hardcopy of the comments received during the 45-day comment period which ended on May 28, 2019, will be made available at the meeting or upon request. Requests may be emailed to [lori.martinez@dca.ca.gov](mailto:lori.martinez@dca.ca.gov).