



California State Board of Pharmacy

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Business, Consumer Services and Housing Agency

Department of Consumer Affairs

Gavin Newsom, Governor



To: Board Members

Subject: Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1713 Related to Automated Patient Delivery Systems (APDS) Consultation

Background:

At the April 24, 2024, Board meeting, the Board approved the proposed regulation text to amend Section 1713 related to Automated Patient Delivery Systems (APDS) Consultation. This proposal amends the Board's regulations regarding the consultation requirements for prescription medication dispensed from an automated patient delivery system.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on February 21, 2025, which ended on April 7, 2025. No comments were received during the comment period. Attached to this memo is the proposed text that was released for the 45-day public comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue, including adopting the regulation text as noticed on February 21, 2025.

Possible Adoption Language:

Adopt the proposed regulation at Section 1713 as noticed on February 21, 2025, and authorize the Executive Officer to take all steps necessary to complete the rulemaking. Further, delegate to the Executive Officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Department of Consumer Affairs
Title 16. Pharmacy

Proposed Regulatory Language
Automated Patient Dispensing Systems (APDS) Consultation

Legend: Added text is indicated with an underline.
Deleted text is indicated as ~~strikeout~~

Amend § 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy.

- (a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
- (b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
- (c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
- (d) A pharmacy may use an automated patient dispensing system (APDS) to deliver prescription medications to patients provided:
 - (1) A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to that patient.
 - (2) The APDS has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.
 - (3) A patient shall receive consultation by a pharmacist when a prescribed drug is dispensed from an APDS for the first time, as specified in Business and Professions Code section 4427.6, via a telecommunications link that has two-way audio and video. Further, ~~The~~ the pharmacy is able to provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
 - (4) Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
- (e) Any pharmacy making use of an APDS shall maintain, and on an annual basis review, written policies and procedures providing for:
 - (1) Maintaining the security of the APDS and the dangerous drugs within the APDS.

- (2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS and for which patients, including when consultation is needed.
 - (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.
 - (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS.
 - (5) Orienting participating patients on use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of prescription medications.
 - (6) Ensuring the delivery of medications to patients in the event the APDS is disabled or malfunctions.
- (f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS.

NOTE: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code.
Reference: Sections 4005, 4017.3, 4052, 4116, 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7 and 4427.8, Business and Professions Code.