

**TITLE 16. BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** No hearing scheduled.

**Subject Matter of Proposed Regulation:** Automated Patient Dispensing Systems (APDS) Consultation

**Section Affected:** Amend Title 16, California Code of Regulations (CCR) section 1713

**Background and Statement of the Problem**

The California State Board of Pharmacy (Board) is a state agency vested with the authority to license and regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Profession Code (BPC) section 4000, et seq.). The Board's mandate and mission are to protect the public (BPC section 4001.1).

BPC sections 4427 through 4427.7 generally establish the requirements for the use of automated drug delivery systems (ADDS) in California. BPC section 4427.6 generally establishes the requirements for the use of automated patient dispensing systems (APDS). Specifically, subdivision (f) provides that all prescribed drugs and devices dispensed to a patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

Existing regulation at Title 16, CCR section 1713(d) provides authority for a pharmacy to use an APDS to deliver prescription medications to patients under specified conditions, including that the pharmacy provides immediate consultation with a pharmacist, either in-person or via telephone, upon the request of the patient; however, existing regulation conflicts with statute. To address the conflict and ensure licensees understand the consultation requirements for first-time dispenses from an APDS, the proposed regulation mirrors the statutory language in BPC section 4427.6, requiring consultation with a Board-licensed pharmacist via a telecommunications link with two-way audio and video when prescription drugs and devices are dispensed to a patient from an APDS for the first time.

**Anticipated benefits from this regulatory action:**

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. The Board has determined that this regulatory proposal will benefit the health and welfare of California residents because the proposal removes a conflict between statutory requirements and existing regulations. The proposal will also benefit the health and welfare of California residents by ensuring access to a consultation with a licensed pharmacist via audio and video

telecommunication when prescription drugs and devices are dispensed to a patient from an APDS for the first time.

This regulatory proposal does not affect employee safety or the state's environment.

### **Specific purpose of, and rationale for, proposed changes**

The Board's proposal makes the following changes:

Section 1713 is amended as follows:

Subdivision (d)(3) is amended to add "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." The current language does not differentiate between technology requirements, leading to some confusion among the regulated public regarding when two-way audio and video are required. The purpose of this change is to have the regulatory requirement align with the statutory requirement. Adding this sentence to (d)(3) is necessary to eliminate the conflict between the regulation and the statutory requirements. This addition is also necessary to ensure that the regulated public is aware that patient consultation must be provided via a telecommunications link with two-way audio and video when a patient is receiving a medication for the first time. This addition is not unnecessarily duplicative, as it will eliminate the confusion caused by the conflict between the requirements in the statute and regulation.

Additionally, the existing language within subdivision (d)(3) was amended to read, "Further, the pharmacy is able to provide an immediate consultation (...)." The addition of the language is a grammatical change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). The current language requires that the pharmacy provide immediate consultation when requested by the patient, and the amendment requires that the pharmacy be able to provide immediate consultation when requested by the patient. A pharmacist is already required to provide oral consultation upon request (CCR section 1707.2); restating that requirement within this regulation is duplicative and unnecessary. The Board determined that reminding the regulated public that they must be able to provide the consultation required in BPC section 4427.6 would eliminate any confusion about the requirements.

### **Underlying Data**

1. Relevant Meeting Materials and Minutes from the Licensing Committee Meeting held April 10, 2024 (Meeting Materials Agenda Item VIII, Meeting Minutes)
2. Relevant Meeting Materials and Minutes from Board Meeting held April 24-25, 2024 (Meeting Materials Agenda Item XIII(e), Meeting Minutes)

## **Business Impact**

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

The proposed amendment clarifies that requirements for the use of a two-way telecommunications (audio and video) link to provide patient consultation with a Board-licensed pharmacist when prescription medication is dispensed from an automated patient delivery system to a patient for the first time, as required by BPC section 4427.6. The proposed amendment will remove the conflict between statute and regulation, which will benefit businesses that utilize an APDS and will not have an adverse effect on businesses.

## **Economic Impact Assessment**

The Board has determined that this regulatory proposal will not:

- (1) create jobs within California;
- (2) eliminate jobs within California;
- (3) create new businesses within California;
- (4) eliminate existing businesses within California; and
- (5) expand businesses currently doing business in the State of California.

The Board determined that this proposal will not create or eliminate jobs or businesses. It removes a conflict between statutory requirements and existing regulations. The proposal will also benefit the health and welfare of California residents by ensuring access to a consultation with a licensed pharmacist via audio and video telecommunication when prescription drugs and devices are dispensed to a patient from an APDS for the first time.

This regulatory proposal does not affect employee safety or the state's environment.

## **Specific Technologies or Equipment**

This regulation mandates the use of specific technologies or equipment, specifically, a two-way telecommunications system with audio and video. This mandate is required as use of the specific technology is required by BPC section 4427.6.

## **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 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 not adopting the proposed regulation; however, the Board determined that alternative was not reasonable, as a conflict would exist between the Board's regulation and statute.

## **Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business.**

No such alternatives have been proposed; however, the Board welcomes comments from the public.