

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Automated Patient Dispensing Systems (APDS) Consultation**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview, after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under "Contact Persons" in this notice.

WRITTEN COMMENT PERIOD

Written comments relevant to the action proposed, 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 no later than April 7, 2025, or must be received by the Board at the hearing, should one be scheduled.

Authority and Reference: Pursuant to the authority vested by Business and Professions Code (BPC) sections 4005 and 4075, the Board proposes amending section 1713 of Division 17 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board is a state agency vested with the authority to license and regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (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 an 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 of Proposal

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.

Evaluation of Consistency and Compatibility with Existing State Regulations

During the development of this regulatory proposal, the Board searched for similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The regulations do not result in a fiscal impact to the state.

The regulations do not result in a fiscal impact to the state in the form of federal funding or any cost or savings to any state agency.

Nondiscretionary Costs/Savings to Local Agencies: None

Cost to any Local Agency or School District for which Government Code Sections 17500 - 17630 Require Reimbursement: None

Mandate Imposed on Local Agencies or School Districts: None

Significant Effect on Housing Costs: None

Business Impact Estimates:

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 the requirements for using 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. This 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.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

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. 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.

Business Reporting Requirements

This regulatory proposal does not require businesses to file a report with the Board.

Effect on Small Business:

The Board has determined that the proposed regulatory action may affect small businesses, as defined in Government Code section 11342.610. The proposed

regulation text removes a conflict between the regulatory text and the requirements in BPC section 4427.6, which requires consultation with a Board-licensed pharmacist via a telecommunications link that has two-way audio and video when prescription drugs and devices are dispensed to a patient from an APDS for the first time.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board has determined that no reasonable alternative it considered to the regulation, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposal described in this Notice, or more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments—relevant to the above determinations—in writing, at the address listed below for the Contact Persons, during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, 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 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals 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, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

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 Persons

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

Name: Lori Martinez
Address: Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel
Address: Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text ,if any, can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.