

**TITLE 16. BOARD OF PHARMACY**  
**NOTICE OF PROPOSED ACTION CONCERNING**  
**SELF-ASSESSMENT OF AN ADDS**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, 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 by December 27, 2022.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations 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 will be available for 15 days prior to its adoption from the person designated in this Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Sections 4119.11 and 4427.7 of the Business and Professions Code (BPC) authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, and 4427.7 of the Business and Professions Code.

**Informative Digest/Policy Statement Overview**

The board is a state agency vested with the authority to 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).

Existing law at BPC section 4119.11 establishes the licensure requirement for an automated drug delivery system (ADDS). Additionally, the statute establishes two separate classifications of ADDS, specifically, Automated Patient Dispensing System (ADPS) and Automated Unit Dose System (AUDS).

Further, BPC Sections 4427.2, 4427.3, 4427.4, 4427.6, and 4427.7 establish the ownership, placement, and operation requirements; the requirement for an exempt AUDES to comply with all other requirements of an ADDS; recordkeeping and quality assurance requirements; and the requirement for the completion of a self-assessment by the pharmacy.

This proposal will amend 16 CCR section 1715.1 to update the self-assessment form that pharmacists-in-charge must complete (Automated Drug Delivery System Self-Assessment [17M-112]) to reflect current laws and regulations since the last revision in 2018.

### **Anticipated Benefits of the Proposed Regulations**

Protection of the public is the board's highest priority in exercising its licensing, regulatory and disciplinary functions. This regulatory proposal benefits the health and welfare of California residents. This proposal will update the form incorporated by reference to reflect current laws and regulations. Therefore, the pharmacists-in-charge (PIC) of pharmacies throughout California will be conducting self-assessments based on current and up-to-date laws, rather than inaccurate references to laws that have been repealed, superseded, or are no longer applicable. The form aids licensees in assessing their compliance with federal requirements, state laws, and state regulations, as well as identifying any areas in which they are noncompliant. This awareness can increase self-correction and make the facility site inspection process more meaningful. Periodic review and accountability will result in increased consumer safety and improve facility operations with respect to employee safety and the state's environment.

As the PIC is the person responsible for completing the self-assessment form, this requirement helps to educate the PIC and ensure that the PIC has knowledge of all applicable laws and regulations. In turn, this helps to ensure that pharmacies operating ADDS are following standard practices, thus protecting the safety and quality of pharmaceutical medications. The self-assessment form is being updated to reference current law and regulations and does not impose the new laws. PICs are already obligated to comply with pharmacy laws and regulations; the self-assessment form is simply a tool provided by the board to aid them in doing so.

### **Consistency and Compatibility with Existing State Regulations**

During the process of developing these regulations and amendments, the board conducted a search of similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

## **Incorporation by Reference**

Automated Drug Delivery System Self-Assessment [17M-112 (Rev. 1/22)].

## **Fiscal Impact and Related Estimates**

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

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, including the ability of California businesses to compete with businesses in other states because, as discussed below under Small Business Effect, the requirement to complete the self-assessment already exists and this regulation is updating the statutes and regulations listed within the self-assessment form incorporated by reference. As completion of the self-assessment form is already required by statute and regulation, the proposed regulation does not increase the workload or costs for these licensees to comply.

Cost Impact on Representative Private Person or Business:

The board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. Pharmacies licensed by the board that operate an ADDS are already required to complete the self-assessment form, when applicable, under existing law.

Effect on Housing Costs: None

## **Effect on Small Business:**

The board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses, as discussed below. While the board does not have specific data to determine if its pharmacy licensees are a “small business” as defined in Government Code section 11342.610, a smaller community retail pharmacy may fall into that definition.

Completion of a self-assessment form is required by existing regulation and based on certain events; the completed forms are also required to be maintained. The updates will change some of the questions on the forms, but do not ask significantly more questions. It is therefore not anticipated that the pharmacy will use more time completing, or more space storing, the revised self-assessment form. As the requirement to complete and maintain these forms already exists in regulations, this proposal will not have an impact on small businesses.

### **Business Reporting Requirements**

This regulatory proposal does require pharmacists or pharmacies to fulfill reporting requirements because the ADDS self-assessment form is to be completed by the PIC and maintained at the pharmacy. The board reviews the self-assessment form during site inspections to ensure completion and identify that any areas of non-compliance have been remedied. It is necessary for the health, safety, or welfare of the people of the state that the regulation apply to businesses.

### **Results of Economic Impact Assessment/Analysis:**

#### **Impact on Jobs/New Businesses:**

The board concludes that:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California;
- (5) this proposal will not expand businesses currently doing business in the State of California.

#### **Benefits of Regulation:**

The regulatory proposal will benefit the health and welfare of California residents because pharmacies who provide drugs to California consumers will be conducting the self-assessment based on current and up-to-date laws, rather than outdated laws, which will make it more likely that pharmacies will follow current laws and regulations. When PICs are actively engaged in reviewing the current laws and regulations, they are more likely to identify and remedy any violations of pharmacy law and regulations, which exist primarily for consumer safety. This regulatory proposal benefits worker safety because it will help educate PICs, which helps ensure that the pharmacy is operating the ADDS in compliance with state and federal laws and regulations. The proposal does not impact the state's environment.

## **Consideration of Alternatives**

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period.

## **Initial Statement of Reasons and Information**

The board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

## **Text of Proposal**

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of 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>.

## **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 Person**

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

Name: Lori Martinez  
Address: 2720 Gateway Oaks Drive Ste. 100  
Sacramento, CA 95833  
Phone No.: (916) 518-3078  
Fax No.: (916) 574-8618  
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Usha Mutschler  
Address: 2720 Gateway Oaks Drive Ste. 100  
Sacramento, CA 95833  
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### **Website Access**

Materials regarding this proposal can be found at the board's website:  
[https://www.pharmacy.ca.gov/laws\\_regs/pending\\_regs.shtml](https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml).