

TITLE 16. BOARD OF PHARMACY

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 August 17, 2020.

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: Section 4005, 4075, 4114, 4119.11, and 4427.7 of the Business and Professions Code (B&P) and Section 2 of Chapter 677, Statutes of 2000 authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4413, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4416, 4117, 4119.1, 4119.11, 4125, 4126, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7 and 4427.8 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

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

Existing law at B&P section 4105.5 establishes the requirement that a pharmacy that owns or provides dangerous drugs to an automated drug delivery system (ADDS) must register the ADDS with the board within 30 days of installation of the device.

Assembly Bill 2037 (Bonta, Statutes of 2018, Chapter 647) added, among other things, B&P Section 4119.11. This new statute established two separate classifications of ADDS, specifically, Automated Patient Dispensing System (ADPS) and Automated Unit

Dose System (AUDS). Additionally, Senate Bill (SB) 1447 (Hernandez, Chapter 666, Statutes of 2018) added, among other things, B&P Sections 4427.2, 4427.3, 4427.4, 4427.6, and 4427.7. These new statutes established the board's authority to issue an ADDS license; established ownership, placement, and operation requirements; established recordkeeping and quality assurance requirements; and established the requirement for the completion of an annual self-assessment by the pharmacy holding the ADDS license.

This proposal will amend 16 CCR section 1711 to require that records related to the use of an ADDS developed as part of the quality assurance review, established by B&P section 4427.6(i), be submitted to the board. Additionally, this proposal will amend 16 CCR section 1713 to align the board's regulation with the newly established APDS license and clarify its use. Finally, this proposal will add 16 CCR Section 1715.1 to identify the specific requirements for the completion of the self-assessment with respect to the use of an ADDS as required by B&P section 4427.7.

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, as well as benefiting employee safety. The proposed regulation will ensure that the board is aware of possible quality issues and/or complaints related to the use of an ADDS. This will allow the board to inspect or investigate possible concerns with respect to the use of the systems. Additionally, the proposed regulation provides clarity to the regulated public with respect to the use of an APDS. This benefits the health and welfare of California residents by ensuring that they are properly counseled and that their medications are appropriately labeled and accurately dispensed. Finally, the proposal identifies the specific requirements for the self-assessment form. The self-assessment form aids licensees in assessing their compliance with federal and state law and regulations. This annual review can increase compliance and accountability, which will result in increased consumer safety and improved operations with respect to employee safety. The Board determined that this proposal will not impact the state's environment.

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. 12/18)].

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 business, including the ability of California businesses to compete with businesses in other states. This proposal does not impose a fee; however, there may be a minor cost to businesses related to paper, storage, and staff time to complete the self-assessment and to submit the quality assurance records to the board.

Cost Impact on Representative Private Person or Business:

The board estimates that there may be a minimal expense to the pharmacy for supply costs to complete the self-assessment form (i.e. paper) and the time it will take the pharmacist-in-charge (PIC) to complete the self-assessment evaluation. The board estimates that the process should not take more than an hour or two, unless the licensed premises is out of compliance, which will require additional time to identify and implement corrective actions. The proposal does require that any record related to the use of an ADDS must also be submitted to the board within 30 days of completion of the quality assurance review. This submission can be done via mail or fax. The cost associated would be the cost of the paper and the staff time to print and mail or fax the documents to the board. The board believes these costs to be minor and absorbable. The board anticipates no costs to an individual.

Effect on Housing Costs: None

Effect on Small Business:

The board does not have nor does it maintain data to determine if any of its licensees are a “small business” as defined in Government Code § 11342.610. However, the board anticipates that most, if not all, of the pharmacies that will utilize an ADDS system will not be small businesses. While it is possible for a small business pharmacy to operate an ADDS, it is unlikely due to the size of the small business and the staffing

requirements to maintain complete oversight and ensure proper operation of the device.

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 of existing businesses within California;
- (5) this proposal will not expand businesses currently doing business in the State of California.

Benefits of Regulation:

The board has determined that this regulatory proposal benefits the health and welfare of California residents, and worker safety. The proposed regulation will ensure that the board is aware of possible quality issues and/or complaints made with respect to the use of ADDS by requiring the quality assurance reports be submitted to the board. This will allow the board to inspect or investigate possible concerns with respect to the use of the systems. Additionally, the proposal identifies the specific requirements for the self-assessment form. The self-assessment form aids licensees in assessing their compliance with federal and state law and regulations. As the PIC completes the self-assessment form, they will identify any areas where the pharmacy's use of an ADDS may be out of compliance. This awareness can increase self-correction by providing useful information to the PIC about controlling statutes and regulations. This periodic review and accountability will result in increased consumer safety and will improve operations with respect to employee safety. This proposal will 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:	Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:	Debbie Damoth
Address:	2720 Gateway Oaks Drive Ste. 100 Sacramento, CA 95833
Phone No.:	(916) 518-3090
Fax No.:	(916) 574-8618
E-Mail Address:	Debbie.Damoth@dca.ca.gov

Website Access

Materials regarding this proposal can be found at the board's website: www.pharmacy.ca.gov.