

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 on August 31, 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: Pursuant to the authority vested by section 4005 of the Business and Professions Code, and to implement, interpret or make specific sections 4001.1, 4005, 4063 and 4076.6 of the Business and Professions Code, and section 1250 of the Health and Safety Code, the board proposes to add and adopt section 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations.

INFORMATIVE DIGEST

A. Informative Digest

The board proposes this rulemaking for the purpose of adding to the board's regulations specific requirements for automatic refill (auto-refill) programs as part of the board's efforts to prevent abuses associated with the auto-refill programs. This regulation will establish standards pursuant to which pharmacies may enroll patients in auto-refill programs.

B. Policy Statement Overview

The board proposes to establish regulatory guidelines for pharmacies offering prescription medication auto-refill programs to patients.

Existing law specifies that protection of the public shall be the highest priority for the

board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Further the board is authorized to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. Pharmacy law also specifies requirements for refilling prescriptions.

Historically, a patient's prescriptions have been refilled at the request of a patient or patient's agent. Technological advancements have allowed for the creation of auto-refill programs which allow pharmacies to enroll patients in a program whereby their prescription medications are automatically refilled at regular intervals and the patient is notified when to pick up their prescriptions. Or, in cases of mail order pharmacies, the prescriptions are automatically sent to the patient. These auto-refill programs were developed to increase patient medication compliance. Most pharmacies restrict the medications that are included in the auto-refill program to maintenance and noncontrolled prescriptions.

Currently, there are no regulations specific to auto-refill programs. This regulatory proposal will specify the requirements a pharmacy must follow when offering an auto-refill program. These requirements will ensure that the patients' health, safety, and general welfare are protected by establishing standards and procedures pharmacies must follow to participate and offer an auto-refill program.

Anticipated Benefits of Proposal

Auto-refill programs encourage increased patient prescription medication compliance because patients are reminded to pick up the prescription before they run out, or in cases of mail order pharmacies, receive their prescription before they run out of medication. However, there is a negative side to the auto-refill programs that could be harmful to the patient. Often, medications are automatically refilled by the auto-refill program without the patient's knowledge. The patient is notified a prescription is ready to be picked up. In some cases, the patient is unaware of what medication is refilled but assumes that the medication is needed which may result in patients taking multiple forms of the same medication (e.g. different doses) or taking discontinued medications.

This proposal will address the negative consequences of unregulated auto-refill programs by establishing notification and authorization requirements which will ensure patients are informed of their enrollment in the auto-refill program. This will decrease unintended ingestion of discontinued or duplicative medication and decrease overall patient harm resulting in overall improved health for Californians.

The regulatory proposal benefits the state's environment because the proposed regulation will decrease the amount of medications patients receive that they did not request. By reducing the amount of unwanted medication, it will reduce unnecessary medical costs associated with medications that will not be taken but rather must be appropriately destroyed.

C. Consistency and Compatibility with Existing State Regulations

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

FISCAL IMPACT 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 made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees, including the ability of California businesses to compete with businesses in other states. The following types of businesses would be affected by this regulation: resident and nonresident pharmacies that have auto-refill programs.

Cost Impact on Representative Private Person or Business:

The board made an initial determination that the proposed regulatory action would have no significant cost impact on representative private persons or businesses.

For those pharmacies opting to use electronic records of a patient/patient's agent's enrollment in an auto-refill program, there may be minor programming costs to update current pharmacy software. However, the pharmacy may also keep a written documentation to reduce costs.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS:

The proposed regulations may affect small business. While the board does not have nor does it maintain data to define if any of its licensees are a “small business” as defined in Government Code section 11342.610, the board made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses.

The board provides licensure to approximately 7,200 resident and nonresident licensed pharmacies that may be impacted by the proposed regulation.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The board concludes that it is:

- (1) Unlikely that the proposal will create or eliminate any jobs within California;
- (2) Unlikely that the proposal will create new, or eliminate existing, businesses in California; and
- (3) Unlikely that the proposal will expand businesses currently doing business within the state.

The board has determined that this regulatory proposal will not have an impact on the creation of jobs or new businesses, or the elimination of jobs or existing businesses, or the expansion of businesses in the State of California.

This proposal adds requirements for a pharmacy offering an auto-refill program. These new administrative requirements are minimal additions to existing business practices. The board has determined these additional duties are absorbable without impacting jobs or businesses in California. Additionally, this determination is supported by the absence of public testimony during public meetings where this proposal has been discussed, during the April 18, 2017, enforcement committee meeting and the May 3-4, 2017, public board meeting.

This regulatory proposal does not affect worker safety because it is not relevant to worker safety as these changes are administrative duties required to offer an auto-refill program at a licensed pharmacy.

The board already ensures compliance with the statutory requirements made specific by the proposed regulations through its inspection and enforcement programs. Any additional workload and costs are anticipated to be minor and absorbable within existing resources.

Benefits of the Regulation:

This regulatory proposal will benefit the health and welfare of California residents and the state's environment. Ensuring that there are requirements a pharmacy must meet to offer an auto-refill program will better protect patients and the environment by eliminating the dispensing of unwanted or unneeded medications.

When a patient's prescriptions are automatically refilled without their knowledge or consent, the patient may suffer harm by taking discontinued, duplicative, or unnecessary medication that could adversely interact with another prescribed medication. Additionally, when unnecessary medications are dispensed to the patient, there is an increase in the amount of unused pharmaceutical waste that must be disposed. When these medications are dispensed, it can result in fraudulent billing for prescriptions not needed or used by the patient. Finally, by reducing the amount of unwanted medication, it will reduce unnecessary medical costs associated with medications that will not be taken but rather destroyed.

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 during the written comment period at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy 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 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <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, Suite 100 Sacramento, CA 95833
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The backup contact person is:

Name:	Debbie Damoth
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Website Access: Materials regarding this proposal can be found at the Board of Pharmacy's website: www.pharmacy.ca.gov.