



**California State Board of Pharmacy**  
2720 Gateway Oaks Drive, Ste 100  
Sacramento, CA 95833  
Phone: (916) 518-3100 Fax: (916) 574-8618  
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency  
Department of Consumer Affairs  
Gavin Newsom, Governor



**To: Board Members**

**Subject: Agenda Item III. Discussion and Consideration of Adoption of Board Approved Regulation, 16 California Code of Regulations Section 1717.5 Related to Automatic Refill Programs, and Discussion and Consideration of Public Comments Received during the 15-day comment period on the proposed new modifications to the Regulation**

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**Background:**

At the October 2020 Board meeting, following 45-day and 15-day public comment periods, the Board voted to adopt the regulation text to add Section 1717.5 related to Automatic Refills. This regulation establishes the regulatory requirements for automated refill programs.

On March 30, 2021, the final rulemaking package was submitted to the Office of Administrative Law (OAL) for formal review. Following their review, OAL requested that the Board memorialize its policy decisions identified in the Final Statement of Reasons from the July and October 2020 Board meetings into the regulation text.

On May 27, 2021, the Board amended the regulation text based on OAL and Board staff's recommendations and voted to initiate a 15-day public comment period. The 15-day public comment period began on May 28, 2021 and ended on June 12, 2021. The regulation text, staff recommendations, and the comments received are attached following this memo.

**At this Meeting:**

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed for 15-day comment on May 28, 2021.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

**Possible Adoption Language:**

Accept the Board staff recommended comment responses and adopt the regulation language as noticed for 15-day comment on May 28, 2021. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Office of Administrative Law to complete the rulemaking file.

Proposed text released on  
May 28, 2021 for a 15-day  
public comment period.

**California State Board of Pharmacy  
Department of Consumer Affairs  
California Code of Regulations  
Title 16. Professional and Vocational Regulations  
Division 17. Board of Pharmacy**

**Proposed Second Modified Text**

Modified changes to the proposed regulation text are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Second Modified changes to the proposed regulation text are shown by ~~italicized double strikethrough~~ for deleted language and *italicized double underline* for added language.

**Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1717.5. Automatic Refill Programs.**

- (a) A pharmacy may offer a program to automatically refill prescriptions medications provided the pharmacy complies with this section.
- (1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section, ~~as well as a list of medications that may be refilled through the program.~~
- (2) Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program. The patient or patient's agent shall enroll by written, online, or electronic informed consent to participate in the program for each new prescription wherein there is a change in the prescription medication, strength, dosage form, or directions for use.
- (3) For each prescription to be refilled through the program, the pharmacy shall obtain annual renewal of each prescription from the patient or patient's agent no later than 12 months after the prescription was enrolled in the program.
- ~~(3)~~ (4) The pharmacy shall keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing.
- ~~(4)~~ ~~When a patient enrolls, the pharmacy shall provide a written notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program.~~

- ~~(54.5)~~ The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.
- ~~(65.6)~~ Each time a prescription is refilled through the program, the pharmacy shall provide a written or electronic notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program.
- ~~(76.7)~~ The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and shall provide confirmation to the patient or patient's agent.
- ~~(87.8)~~ The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if the pharmacy ~~is~~was notified that the patient did not want the refill, regardless of the reason, ~~and~~or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription medication.
- ~~(98.9)~~ A pharmacy shall make available any written or electronic notification required by this section in alternate languages as required by state or federal law.
- (b) A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescriptions medications for its patients need not comply with the provisions of this section.
- (c) Pharmacies automatically refilling prescriptions ~~medications~~ for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section if the facility has written policies and procedures describing how a patient may request that a medication be automatically refilled and how a patient may refuse the medication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

Board staff summarized  
comments with  
recommendations



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## **Proposed Regulation to Add Title 16 CCR Section 1717.5 Related to Automatic Refill Programs**

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### **Summarized 15-day Comments Regarding Automatic Refill Programs with Board Staff**

#### **Recommendations:**

#### **Written Comments from Thomas Finch, PharmD., Save Mart, dated June 9, 2021**

**Comment 1:** Dr. Finch states that the newly added subdivision (a)(3) creates an unnecessary burden on pharmacies and patients since prescribers must already confirm the prescription every 12 months. Dr. Finch believes that the added language will result in reams of additional paperwork when the prescriber has already confirmed it is necessary.

**Response to Comment 1:** Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Staff refers the commenter to the Board's response regarding annual consent in the comments made by Dr. John Michael O'Brien during the 45-day comment period. The Board's previous review and consideration of this topic supports the Board staff's recommendation here. The previous review and consideration for this topic is available with the September 2020 Board's meeting materials (agenda item Vii(a) – comments 1 and 2), and webcast, which can be found on the Board's website, available at [https://www.pharmacy.ca.gov/about/meetings\\_full.shtml](https://www.pharmacy.ca.gov/about/meetings_full.shtml).

**Comment 2:** Dr. Finch indicates that changing the terms “and” for “or” in subsection (a)(8) creates unnecessary ambiguity in the language and will burden pharmacies by requiring refunds be issued when notice was not provided.

**Response to Comment 2:** This comment is outside of the scope of the text the Board proposed to modify during this comment period. Staff refers the commenter to the Board's response to the comment made by Ms. Michelin during the first 15-day comment period. The Board's previous review and consideration of this topic supports the Board staff's recommendation here. The previous review and consideration for this topic is available with the October 2020 Board's meeting materials (agenda item X – comment number 4), and webcast, which can be found on the Board's website, available at [https://www.pharmacy.ca.gov/about/meetings\\_full.shtml](https://www.pharmacy.ca.gov/about/meetings_full.shtml).

### **Written Comments from Rob Geddes, PharmD., Albertsons, dated June 10, 2021**

**Comment 1:** Dr. Geddes requests the Board move the implementation date from January 1, 2022 to July 1, 2022 to allow additional time for implementation.

**Response to Comment 1:** Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that that proposed changes in the second 15-day comment period are minor and the marketplace has been aware of the implementation date of January 1, 2022 since October, 2020. Board staff do not believe additional delays in implementation are necessary because of the minor changes or in the best interest of consumers.

**Comment 2:** Dr. Geddes requests the Board strike the requirement from subdivision (a)(7) for pharmacies to confirm disenrollment from the auto refill program.

**Response to Comment 2:** This comment is outside of the scope of the text the Board proposed to modify during this comment period. Staff refers the commenter to the Board's response to Dr. Hensic's comment during the 45-day comment period. The Board's previous review and consideration of this topic supports the Board staff's recommendation here. The previous review and consideration for this topic is available with the September 2020 Board's meeting materials (agenda item Vii(a) – comment number 4), and webcast, which can be found on the Board's website, available at [https://www.pharmacy.ca.gov/about/meetings\\_full.shtml](https://www.pharmacy.ca.gov/about/meetings_full.shtml).

**Comment 3:** Dr. Geddes requests the Board strike the requirement in subdivision (a)(8) that a pharmacy provide a refund to the patient if the pharmacy was notified that the patient did not want the refill, regardless of the reason.

**Response to Comment 3:** This comment is outside of the scope of the text the Board proposed to modify during this comment period. Staff refers the commenter to the Board's response to Dr. Geddes previous comment during the first 15-day comment period. The Board's previous review and consideration of this topic supports the Board staff's recommendation here. The previous review and consideration for this topic is available with the October 2020 Board's meeting materials (agenda item X – comment number 4), and webcast, which can be found on the Board's website, available at [https://www.pharmacy.ca.gov/about/meetings\\_full.shtml](https://www.pharmacy.ca.gov/about/meetings_full.shtml).

### **Written Comments from Rachel Michelin, California Retailers Association**

**Comment 1:** Ms. Michelin requests the Board move the implementation date from January 1, 2022 to July 1, 2022 to allow additional time for implementation.

**Response to Comment 1:** This comment is duplicative of a comment from Dr. Geddes, dated June 10, 2021. The Board incorporates its response to that comment herein by reference.

Comments received during the  
15-day comment period,  
which ended on June 12, 2021



**From:** Thomas Finch <Thomas.Finch@SaveMart.com>  
**Sent:** Wednesday, June 9, 2021 4:20 PM  
**To:** Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>  
**Subject:** Re: Notice of Second Modified Text – Automatic Refill Programs

[EXTERNAL]: [Thomas.Finch@savemart.com](mailto:Thomas.Finch@savemart.com)

**CAUTION:** THIS EMAIL ORIGINATED OUTSIDE THE DEPARTMENT OF CONSUMER AFFAIRS!  
**DO NOT:** click links or open attachments unless you know the content is safe.  
**NEVER:** provide credentials on websites via a clicked link in an Email.

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To whom it may concern,

The newly added section (3) adds an unnecessary burden on both pharmacies and patients. Prescribers already must confirm that a prescription is still required at minimum every 12 months by issuing additional refills. This added line creates an additional eight to twelve *reams* of paperwork (4,000-6,000) pages per year in an average California pharmacy on re-confirmation of what has already been confirmed by the prescriber: that a medication is still necessary for their patient. The extra burden will reduce adherence to cheap but life-saving maintenance medications like metformin, lisinopril, and atorvastatin and end up costing the state money through excess hospital admissions and lost time in the workplace.

The substitution of "or" for "and" in (a)(8), formerly (a)(7), creates unnecessary ambiguity. The modified text does not set a standard for what it means for the patient to notify the pharmacy that they do not want the refill or even seem to indicate that this notice must come before the prescription is picked up from the pharmacy. The confirmation provided per (a)(7), formerly (a)(6), that the pharmacy had disenrolled the medication from automatic refill should be required to seek a refund. It is inappropriate to hold struggling pharmacies accountable for an ambiguously defined notice they may or may not have received.

Thank you,

Thomas K. Finch, PharmD, RPh  
Senior Director, Pharmacy Operations  
The Save Mart Companies  
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TheSaveMartCompanies.com

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June 10, 2021

Lori Martinez  
California Board of Pharmacy  
2720 Gateway Oaks Drive  
Sacramento, CA 95814

**Re: Proposed Automatic Refill Program Regulations – Second Modified Text**

Dear Ms. Martinez,

Albertsons Companies, Inc. appreciates the opportunity to submit additional comments on the modified proposed regulations for automatic refill programs. We also want to thank the Board for the work that has already been done to revise these regulations and accepting much of the feedback stakeholders have submitted.

It is our experience that automatic refill programs improve medication adherence of patients by ensuring they have adequate medication on hand when they need it. This is accomplished by filling their needed prescriptions in advance of their current on-hand supplies being exhausted. This often involves communicating with their doctor to renew refills on prescriptions. It is not uncommon during this outreach that we are made aware of a patient needing to be seen by their provider for routine follow up. On average, a high-risk Medicaid patient visits their pharmacy 35 times a year, which far exceeds the visits to any other health care provider<sup>1</sup>. This frequent interaction allows for a pharmacist to make an impact on the care of a patient to ensure appropriate routine follow up occurs. Impeding the ability of a patient to easily sign up for services such as automatic refill by increasing administrative burden on a pharmacy runs the risk of sacrificing the benefits of a valuable program.

We appreciate the additional time granted during the October 28, 2020 board meeting prior to the regulations going into effect. The motion that was approved allowed for these to become effective January 1, 2022. Because the regulations have not yet been finalized, we would like to take this opportunity to request the effective date be extended an additional 6 months to 7/1/2022. We are unable to begin many of the IT development efforts related this measure until we see the final wording of the regulations. Additionally, we would suggest the following changes to the language.

First, **Sec. 1717.5 (a)(7)** requires the pharmacy to provide confirmation to the patient or patient’s agent following withdrawal or disenrollment from the automatic refill program. Providing confirmation back to the patient is not a function of pharmacy systems today and would require programming

<sup>1</sup> Gaskins RE. Innovating Medicaid: the North Carolina Experience. NC Med J. 2017. <https://www.ncbi.nlm.nih.gov/pubmed/28115558>



enhancements, if possible, to accommodate this provision. We request the board consider revising this section in the following manner:

*(7) The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment ~~and shall provide confirmation to the patient or patient's agent.~~*

Second, **Sec. 1717.5 (a)(8)** requires a pharmacy to provide a full refund to a patient who does not want a prescription they received. We would suggest the Board consider revising the section in the following manner:

*(8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if ~~the pharmacy was notified that the patient did not want the refill, regardless of the reason, or~~ the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription medication.*

This revision will remove the conflict between a patient and the pharmacy when the patient had not requested removal from the automatic refill program. Patients have the opportunity to review the medications prior to pick up at a community pharmacy and there should not be a blanket requirement to refund a patient if they decide days, weeks, or months later they did not need the medication.

Thank you again for the opportunity to comment on these proposed regulations. If there are any questions related to these comments and suggestions please reach out to me at [rob.geddes@albertsons.com](mailto:rob.geddes@albertsons.com) or 208-513-3470.

Sincerely,



Rob Geddes, PharmD  
Director, Pharmacy Legislative and Regulatory Affairs  
Albertsons Companies, Inc.



June 11, 2021

Lori Martinez  
California Board of Pharmacy  
2720 Gateway Oaks Drive  
Sacramento, CA 95814  
Via Email: [Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov)

**Re: CRA Comments re: Proposed Automatic Refill Program Regulations – Modified Text**

Dear Ms. Martinez,

The California Retailers Association (CRA) appreciates the opportunity to comment on the California Board of Pharmacy's modified text of the proposed regulation related to automatic refill programs.

Automated refill programs are a safe, efficient way to ensure patients adhere to their medications, especially those with chronic conditions managing multiple medications. These programs are always beneficial for patients, and even more so now as the State has grappled with the COVID-19 Pandemic. CRA understands and appreciates the intent of this regulation and the mission of the Board of Pharmacy to protect California pharmacy consumers.

We have reviewed the modified text of the proposed regulation. We appreciate the removal of a change in prescriber as criteria that would require a patient's consent to reenroll in an automatic refill program. Because of the additional time needed to approve the regulations due to the questions from the Office of Administrative Law, we urge you to consider delaying the effective date of the regulations to July 1, 2022. This will allow sufficient time for our members to prepare for implementation and ensure their systems are updated to comply with the new requirements.

As you know, pharmacies are playing an even more critical role in delivering patient care during the current Pandemic than ever before. Our members are on the front lines providing immunizations, testing, medication consultation, and ensuring patients can readily access critical medications. Automatic refill programs play an important role in medication adherence and are a convenience that many patients greatly appreciate. In order to ensure the regulations are implemented effectively, we respectfully request sufficient time to come into compliance and believe a July 1, 2022, effective date will allow our members to achieve this goal.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, restaurants, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware and home stores. CRA works on behalf of California's retail industry, which prior to the Pandemic operated over 400,000 retail establishments with a gross domestic product of \$330 billion annually and employs over 3 million people—one fourth of California's total employment.

Thank you for your work on these regulations and your consideration of our comments. Please do not hesitate to contact Lindsay Gullahorn with Capitol Advocacy at (916) 221-8708 or [lgullahorn@capitoladvocacy.com](mailto:lgullahorn@capitoladvocacy.com) if you have any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Rachel Michelin".

Rachel Michelin, President  
California Retailers Association

cc: The Honorable Seung Oh, President, Board of Pharmacy  
Members, Board of Pharmacy  
Anne Sodergren, Executive Officer, Board of Pharmacy