



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item IV. Discussion and Consideration of Board Approved Regulation, Title 16 California Code of Regulations (CCR) Section 1717.5 Related to Automatic Refill Programs to Address Comments by the Office of Administrative Law

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 has 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.

Specifically, OAL has requested the Board further define “each prescription” in subsection (a)(2) to clarify when enrollment for each prescription is required. The modified language states that consent to participate in the program is required for “each new prescription wherein there is a change in the prescription medication, strength, dosage form, prescriber, or directions for use.” This proposed amendment is consistent with both the Board’s policy discussion, and rules regarding when new prescriptions must be created as set forth in Title 16, CCR section 1717(b)(4) as memorialized in the Board’s meeting materials and subsequent vote to approve on October 28, 2020.

Additionally, OAL has requested that the Board memorialize its policy discussion and decision regarding the need for annual consent for each refill. The recommended language reads: “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.” This addition is consistent with the meeting materials and subsequent vote on October 28, 2020.

Finally, during the review of the regulation text with OAL, OAL questioned whether the Board’s proposal consistently used the terms “prescription” and “prescription medication.” Board staff recommend that the Board clarify the terms “prescription” and “prescription medication” in several subsections.

At this Meeting:

The Board will have the opportunity to discuss the changes requested by OAL and initiate a 15-day comment period as requested by OAL. Attached following this memo is the recommended amended regulation text and excerpts from the October 2020 Board meeting materials.

Possible Amendment Language:

Approve the amended regulation text and initiate a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Office of Administrative Law to complete the rulemaking file.



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Excerpt from October 2020 Board Meeting:

Regarding "each prescription" and "annual renewal"

As with the duty to consult (16 CCR section 1707.2), if a new prescription is issued for a medication already enrolled in automatic refill and the medication is the same dosage form, strength, written instructions, and within the same year, a new consent for automatic refill would not be required. To avoid duplicative drug therapy, a patient needs to give consent to enroll annually and if there is a change in dosage form, strength, or written instructions. This is consistent with rules regarding when new prescriptions must be created as set forth in Title 16, CCR section 1717(b)(4).

The Centers for Medicare and Medicaid Services (CMS) released a Draft Calendar Year (CY) 2000 Call Letter to allow mail order pharmacists to auto-ship refills under specified conditions. Such conditions included a requirement for members to confirm enrollment in the auto-ship program at least annually and requires plan sponsors to send two reminders to the beneficiary well in advance of shipments. With this Medicaid auto-ship program, members are permitted to choose to participate or not, and include all or a subset of their medications.

**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, prescriber, 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)~~ (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.