## 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 <del>double strikethrough</del> for deleted language and <u>double underline</u> 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 prescription<u>s</u> *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) <u>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.</u>
  - (3) <u>For each prescription to be refilled through the program, the pharmacy shall obtain</u> <u>annual renewal of each prescription from the patient or patient's agent no later than</u> <u>12 months after the prescription was enrolled in the program.</u>
  - (3-4) The pharmacy shall keep a copy of the written <u>or electronic informed</u> 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.

- (<u>54-5</u>) 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 <u>or electronic</u> notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program.
- (7<u>6</u><u>7</u>) 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. <u>The</u> <u>pharmacy shall document and maintain such withdrawal or disenrollment for one</u> <u>year from the date of withdrawal or disenrollment and shall provide confirmation to</u> <u>the patient or patient's agent.</u>
- (8<u>78</u>) 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 <u>medication</u>.
- (9<u>8</u>-9) A pharmacy shall make available any written <u>or electronic</u> 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 prescription<u>s</u> 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.