

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Automatic Refill Programs

Sections Affected: Add Section 1717.5 of Article 2 of Division 17 of Title 16, California Code Regulations

Problems Addressed

The Board of Pharmacy (board) proposes to adopt Section 1717.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of adding to the board's regulations specific requirements for automatic refill programs, as specified below.

Historically, a patient's prescriptions have been refilled at the request of a patient or patient's representative. Technological advancements have allowed for the creation of automatic refill (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 come pick up their prescriptions. Or, in cases of mail order pharmacies, the prescriptions are automatically sent to the patient. Auto-refill programs increase patient medication compliance because the patients are reminded to pick up the prescription before they run out of medication. Most pharmacies will restrict the medications that are included in the auto-refill program to maintenance and noncontrolled prescriptions.

As a result of media coverage during 2012-2013 highlighting the negative consequences of auto-refill programs, the board received over 100 consumer complaints regarding auto-refill programs. Patients reported being enrolled into the auto-refill program without their consent and receiving unwanted or unneeded prescription medications as a result. Upon trying to return unused and unwanted prescriptions, patients had difficulty receiving a refund. Some patients reported ingesting medication they had not requested or ingesting medication previously discontinued by the prescriber. Some of the complaint investigations found consumer harm because of the unauthorized enrollment in auto-refill programs.

In response to the excessive number of complaints regarding auto-refill programs, the board worked with various agencies to address the issue and explore possible violations of pharmacy law. Simultaneously in 2013, the Federal Centers for Medicare & Medicaid Services proposed new regulations resulting in new rules for Medicaid consumers enrolled in auto-refill programs. While these efforts were helpful, they did not remedy the underlying problem of unregulated auto-refill programs.

From 2016 to 2017, the board's enforcement committee made recommendations to the board regarding draft policy and regulations. In May 2017, the board voted to move forward with proposed regulations.

Auto-refill programs can cause harm to patients if they are not operated properly. If a patient's prescription has been discontinued by the prescriber but the pharmacy automatically refills the prescription, the patient may take a medication that is not needed or could adversely interact with a newly prescribed medication.

Another problematic situation may arise when a patient is enrolled without consent in an auto-refill program at Pharmacy A and decides to switch to Pharmacy B. If Pharmacy A has already filled the prescription and billed the insurance for the auto-refill, Pharmacy B would not be able to fill the prescription. This could cause a delay in therapy for the patient while insurance and billing issues are resolved.

An additional problem can occur when the patient receives a duplicate prescription if the patient that is enrolled without consent in an auto-refill program, which includes one prescription medication and then receives another prescription for the same or similar medication (e.g. differing dosages). In such a case, the patient may take the same medication twice without knowing it.

When patients are automatically refilled prescriptions they no longer take, there is an increase in the amount of unused pharmaceutical waste that must be disposed. The state's environment is negatively impacted by an increase of unused pharmaceutical waste. This regulatory proposal may reduce the amount of unused or unneeded pharmaceutical waste that requires appropriate and costly disposal (e.g., incineration).

Because the proposed regulation will decrease the amount of medications patients receive that they did not request, it will also reduce unnecessary medical costs associated with medications that will not be taken but rather destroyed. Additionally, the proposed regulation may decrease the amount of fraudulent billing for unwanted or unneeded prescriptions.

The board's proposal will require resident and nonresident pharmacies to provide several protections for patients including providing written notice to the patient or patient's agent summarizing the auto-refill program and will require the patient or patient's agent to provide written consent to participate in the program. Providing this notice to patients or their agents and requiring patient consent, will provide clarity to patients regarding their decision to participate in an auto-refill program, thereby eliminating the situation in which patients are enrolled unknowingly and without their consent. Additionally, this proposal contains several other safeguards that will protect patients, thereby, assisting the board in meeting its consumer protection mandate.

Benefits

This proposal will establish the parameters for pharmacies that choose to provide auto-refill programs. This proposal will benefit patients by preventing unwanted, unnecessary, or discontinued prescriptions from being auto-refilled. The proposal will also make patients better able to manage their prescriptions and less likely to take a duplicate prescription for the same medication.

These regulations will provide a necessary balance between the benefits of auto-refill programs and consumer protection.

Specific Purpose of Proposed Changes and Rationale

The board's proposal makes the following additions:

Adopt 16 CCR Section 1717.5 Automatic Refill Programs:

Subdivision (a) adds "A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section." This is added to require pharmacies to meet the requirements of the section before they provide an auto-refill program for their patients. It is necessary to establish the auto-refill program requirements because patients were being harmed by ingesting medications previously discontinued by the prescribers and other negative effects described above. The benefit of this regulation is that the pharmacies will provide auto-refill programs to patients only with the added safeguards required by the regulation, which will prevent unwanted or unnecessary prescription medications from being automatically refilled and ingested in error as well as other negative effects.

Subdivision (a)(1) adds "The pharmacy shall have written policies and procedures in place 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." This requirement will ensure pharmacies have established policies and procedures describing their auto-refill programs. The policies and procedures must contain, at a minimum, how the pharmacy will comply with the regulation, as well as which medications are eligible for the program. The policies and procedures are necessary to ensure the pharmacy thinks through how it will operate its program and how it will comply with the regulation, memorializes those practices so that the pharmacy operates the program consistently, and so that inspectors can evaluate the operation of the program. The pharmacy must identify and reference which medications are appropriate for participation in the auto-refill program, because some drugs are not appropriate for auto-refill. Memorializing the drugs that are eligible in the policies and procedures will facilitate the operation and review of the program by the pharmacy and review by the board.

Subdivision (a)(2) adds "The patient or patient's agent shall enroll by written, online, or electronic consent to participate in the program." This is necessary to ensure that all pharmacies obtain a written consent to enroll a patient in the auto-refill program, and that the acceptable forms of writing include online or electronic means. This written consent will ensure patients are not unwillingly enrolled in an auto-refill program and that there is a record of their consent.

Subdivision (a)(3) adds "The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing." This is necessary to ensure that the board can verify compliance with the requirement to obtain patient consent. Board inspectors will investigate patient complaints alleging unconsented enrollment in auto-refill programs and must review documentation to determine if a patient did or did not provide

consent to enrollment. Without the requirement to maintain proof of enrollment, the board inspectors will not be able to determine if a patient has consented to enrollment in the auto-refill program. It will also assist pharmacies and patients to confirm whether the patient should be enrolled, which may allow the pharmacy and patient to review the records (or absence thereof) and resolve any questions about consent. The pharmacy must maintain the record for one year because this will provide a reasonable amount of time for the board to conduct an inspection, but it is not so long that it will be an unreasonable record-keeping burden on pharmacies. If a patient has a concern, the patient is also likely to discover the error within one year.

Subdivision (a)(4) adds “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.” This requires that, upon enrollment, all pharmacies must provide a written notice to patients summarizing the program, which informs them, at a minimum how they may withdraw a prescription medication from refills through the program, or how to disenroll entirely from the auto-refill program. This addition is necessary to ensure all patients are aware, as soon as they enroll, of their participation in an auto-refill program and are provided with written instructions on how to withdraw a single prescription medication from the program or how to disenroll entirely from the program.

Subdivision (a)(5) adds “The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.” This requires a pharmacist to review a patient’s drug regimen, known to pharmacists as a “drug regimen review,” when refilling an automatically refilled prescription to identify potential adverse effects and drug reactions. This will ensure a pharmacist reviews a patient’s drug therapy and medication record for potential drug interactions or problems with the prescription being delivered to the patient. Many pharmacies only allow maintenance medications and noncontrolled substances to be in an auto-refill program, as these are seen as less harmful, and a routine drug regimen review is not always performed. The drug regimen review is necessary to ensure that all medications refilled by the auto-refill program are currently prescribed for the patient and have not been replaced with another medication that could result in an adverse interaction.

Subdivision (a)(6) adds “Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient’s agent confirming that the prescription medication is being refilled through the program.” This requires a pharmacy to provide written notice every time a medication is refilled. This requirement is necessary to ensure patients are aware that a specific medication has been enrolled in the auto-refill program. The written notification is necessary to remind the patient with each refill that the medication has been automatically refilled because of the program. Often, patients enroll in the auto-refill program but forget.

Subdivision (a)(7) adds “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.” This is added to provide that there must be a method for a patient or patient’s agent to disenroll from the auto-refill program. When auto-refill programs were

established not every pharmacy had a method for disenrolling a patient's medication and therefore a patient, even if they no longer required the medication, could not stop the automatic refilling of the prescription.

Subdivision (a)(8) adds "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 notified that the patient did not want the refill, regardless of the reason, and the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription." This is added to provide a clear requirement for pharmacies to refund payment for any medication, where the prescription medication was withdrawn or the patient disenrolled from the program. This change is necessary to ensure the patient, the patient's agent, or payer will gain a refund if a prescription is billed and paid for that was not enrolled in the program or was withdrawn from the program. The requirement for a full refund under specified terms is also necessary to prevent fraudulent billing. The benefit of adding this is to ensure that patients and other parties have a recourse if the pharmacy fills and bills for a prescription that is reported as unneeded or unwanted or if the patient disenrolled entirely from the program. The payer is included to reflect that any person who paid the pharmacy for an erroneously automatically refilled prescription should be made whole if the prescription was inappropriately refilled. The language does not currently require a time frame within which the pharmacy must issue the refund because with multiple sources of payment, reimbursement timing may be complicated; however, the board can address the topic in the future should it be necessary. The language also requires that the pharmacy must issue a refund regardless of the reason the patient declines that refill as consumer protection will be best served if the rule is clear that if the pharmacy fills it after being told not to, then the person who paid for the prescription can get a refund without argument. Finally, because the language identifies no restrictions, the pharmacy must issue a refund regardless of who notified the pharmacy (e.g., the patient, agent, or payer) or how the pharmacy is notified (e.g., in person, by phone, fax or email) as consumer protection is best served if anyone can "notify" the pharmacy of the patient's needs or wishes, and, for the same reason, it should not matter how the notification is submitted. The policy reflected is that, if the pharmacy refilled the prescription despite direction to the contrary, the pharmacy should be responsible for the cost of its actions. Making the pharmacy fiscally responsible will also create an incentive for a consumer's needs or desires to be efficiently communicated throughout the pharmacy.

Subdivision (a)(9) adds "A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law." This is added to make it clear that these regulations must be applied consistent with existing state and federal law. This provides clear instructions to pharmacies regarding notifications that must be provided to patients. Additionally, this change will make it more likely that a patient receives written notification regarding an auto-refill program in their primary language and remind pharmacies that it may have a duty to do so. Making notifications available in alternate languages is necessary to ensure that more Californians, regardless of primary language, obtain the notices required by this regulation in a language they understand. Certain state and federal requirements require translations be provided under certain circumstances; including this provision makes it more likely pharmacies will comply with any obligations to do so. (See, e.g.,

Bus. & Prof. Code § 4076.5; CCR, tit. 16, § 1707.6; § 1557 of the Affordable Care Act; and 45 CFR 92.)

Subdivision (b) adds “A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescription medications for its patients need not comply with the provisions of this section.” This is added to exempt certain licensed health care facilities from compliance with the auto-refill program regulation. This exemption is necessary because patients of health care facilities defined by Health and Safety Code section 1250 require care for a 24-hour stay or longer, and the auto-refill programs do not pose the same risks for retail patients because medications are being managed by health care professionals in these settings. The regulation requires the qualifying health facility to be licensed because, in other provisions of the Health and Safety Code, such health facilities must obtain a license from the Department of Public Health. The board, as another regulatory agency, supports compliance with all provisions of California law.

A note with the authority and references is added for rulemaking compliance. It reads: “Authority cited: Sections 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063, and 4076.6 of the Business and Professions Code and 1250 of the Health and Safety Code.”

Underlying Data

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held May 3-4, 2017
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 24-25, 2017
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Enforcement and Compounding Committee Meeting held January 4, 2017
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 26-27, 2016
5. Relevant Meeting Materials and Minutes from Board of Pharmacy Enforcement and Compounding Committee Meeting held August 31, 2016
6. Texas Administrative Code, Title 22, Part 15, Chapter 291, Subchapter F, Rule Section 291.105
7. Oregon Board of Pharmacy, Division 41: Operation of Pharmacies (Ambulatory and Residential Drug Outlets), 855-041-1120
8. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Memorandum dated October 28, 2013, regarding Clarifications to the 2014 Policy on Automatic Delivery of Prescription for Employer Group Waiver Plans
9. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality Patient Care – Booklet 4: Billing Practices

10. License Type Totals – Current Licenses By License Type, California State Board of Pharmacy, http://www.pharmacy.ca.gov/about/license_total.shtml, October 21, 2017
11. “CVS customers say unauthorized prescription refills still...,” Los Angeles Times, April 11, 2013, David Lazarus “Prescription refill pressure bothers CVS pharmacists too,” Los Angeles Times, October 25, 2012, David Lazarus
12. “CVS Caremark has become a frequent subject of government probes,” Los Angeles Times, October 24, 2012, Chad Terhune
13. “Target, Rite Aid, Walgreens refill drugs without OK patients say,” Los Angeles Times, October 23, 2012, David Lazarus
14. “U.S. investigating CVS prescription refills,” Los Angeles Times, October 19, 2012, David Lazarus
15. “State probes CVS refill allegations,” Los Angeles Times, October 16, 2012, Marc Lifsher
16. “CVS Caremark prescription refills under scrutiny, source says” Los Angeles Times, October 12, 2012, David Lazarus
17. “CVS customers say prescription refills weren't OKd,” Los Angeles Times, October 9, 2012, David Lazarus
18. “Don't need that drug refill? Here it is anyway,” Los Angeles Times, October 5, 2012, David Lazarus
19. “CVS should require signatures for automatic prescription refills,” Los Angeles Times, July 20, 2012, David Lazarus

Business Impact

The board made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the board's assessment on the impact of this regulation on business.

Under current law, pharmacies are providing automatic refill programs to patients and required to maintain pharmacy practice policies and procedures, as specified.

The board determined that under current practice, a patient's consent is typically provided verbally. Because the proposed regulations require a patient's consent to be provided in either written, online, or electronically, and require the pharmacy to maintain copies of the patient's consent for a period of one year, a pharmacy may incur additional costs of compliance.

Those pharmacies opting for written notifications will incur minimal development, printing, and record retention costs, which will likely be absorbed within resources.

Those pharmacies opting for an online or electronic format will incur minimal information technology development workload, which would likely be performed as standard maintenance or during a cyclical update. Any additional costs are anticipated to be minimal.

The proposed regulation does not require the use of specific computer software. The board anticipates pharmacies will be able to make minor changes to currently used software to allow for the required acknowledgment and consent in enrollment to auto-refill programs. Pharmacies also have the option to track the consent through a physical paper copy as an alternative option or electronically stored information.

Economic Impact Assessment

The board concluded that:

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

It is unlikely that this proposal will have any effect on the creation or elimination of jobs or business, or the expansion of businesses because this regulatory proposal only establishes requirements on programs that are already operating throughout the state.

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation will decrease patient harm by decreasing the issuance of unwanted or discontinued medication. This will result in improved health for Californians. The regulatory proposal also benefits patient protection by providing a structure for which refunds are provided if medication is filled and billed by error through the auto-refill program. Additionally, the proposal will result in fewer unused medications that become waste and must be disposed of into the environment.

This regulatory proposal does not affect worker safety because this proposal is not relevant to worker safety. This initial determination is based on the fact that the proposed regulatory changes only affect individuals and pharmacies using auto-refill programs.

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, therefore, it will reduce the number of medications that will need to be disposed.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome in achieving the purpose of the regulation. The only alternative the board considered would be to not implement regulations establishing minimum standards for

auto-refill programs. As the board continued to receive consumer complaints regarding auto-refill programs, the board attempted to resolve the issue by working with various agencies to address the issue and explore possible violations of pharmacy law. Nonetheless, the problem remained; consumers reported receiving and ingesting medications they had not requested or that their prescriber had previously discontinued. Thus, the board rejected this alternative.

Fiscal Impact Assessment

The board will be required to ensure pharmacies comply with the proposed regulations through its inspection compliance and enforcement programs. Any additional workload and costs are anticipated to be minor and absorbable within existing resources.