



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item IX. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications

At the meeting the board will discuss draft language regarding possible regulation regarding patient enrollment in automated refill programs.

Traditionally, pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs ("auto refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto refill programs are limited to drugs identified as maintenance medications. The argued benefit of auto refill programs is that they increase patient compliance with drug therapy by refilling maintenance medications and sending reminders to patients to pick up their prescriptions. From late 2012 through 2013, the board received over 100 complaints directly related to auto refill programs due to the media attention. Many of the complaints were from patients who stated they received prescriptions they did not request and who had difficulty returning the prescriptions for a refund. Other patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued by their prescriber. Some of these events resulted in patient harm.

Discussion

At the January 25, 2017 board meeting, the board discussed the draft policy developed by staff on automated refill programs and heard public comment. As part of the discussion the committee made revisions to the draft policy submitted during the January 25, 2017 Board Meeting. The language was developed after board staff reviewed Texas and Oregon language.

The board asked that the auto refill language be brought back to the full board based on board discussion and modification. The board requested that staff refine the auto refill language in several areas. **Attachment 1** shows the updated language as requested by the board. Also included in **Attachment 1** are excerpts from the January 25, 2017 Board Meeting minutes involving the auto refill program.

Attachment 1

**Title 16. Board of Pharmacy
Proposed Text**

Add section 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 an automatic refill program (program) for prescription medication for patients provided the following conditions are met:
 - 1) Written notice regarding the program shall be given to the patient or patient's agent.
Notice shall include instructions on how to withdraw a prescription medication from the program.
 - 2) The patient or patient's agent shall provide written consent to participate in the program. If available, consent may be given through an online enrollment option. The pharmacy shall keep enrollment acknowledgement on file for one year from date of dispensing.
- b) A pharmacy shall have written policies and procedures in place that outline specifics of the program. Policies and procedures shall reference medications that are eligible for inclusion in the program.
- c) A patient or patient's agent shall have the option to withdraw from the program at any time.
- d) A drug regimen review shall be completed on all prescriptions filled as a result of the program.
- e) Each time a prescription is refilled, a reminder notification shall be included confirming that the prescription medication is enrolled in the program.
- f) The pharmacy shall provide a full refund to the patient, patient's agent or payer on any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy was notified regarding withdrawal of enrollment in the program.

Excerpt from January 25, 2017 Board Meeting minutes involving the auto refill program:

e. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications

President Gutierrez explained that traditionally, pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs ("auto-refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications. The argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

From late 2012 through 2013, the board received over 100 complaints directly related to auto-refill programs due to the media attention. Many of the complaints were from patients who received prescriptions they did not request and who had difficulty returning the prescriptions for a refund. Other patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued by their prescriber. Some of these events resulted in patient harm.

President Gutierrez stated that in response to the large number of complaints, Executive Officer Herold and other staff worked with the various agencies to address these concerns and explore possible violations of pharmacy laws and regulations.

President Gutierrez reported that at the October 2016 Board Meeting, staff was asked to develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

President Gutierrez reported that the committee discussed the draft policy developed by staff on automated refill programs and heard public comments about how other states including Oregon and Texas are regulated such programs.

President Gutierrez explained that as part of its discussion the committee made revisions to the draft policy. President Gutierrez reviewed the draft policy as provided below.

**California State Board of Pharmacy
DRAFT Policy on Automated Refill Programs:**

A retail or mail order pharmacy may use a program that automatically refills prescriptions that have existing refills available, in order to improve patient compliance and are consistent with the patient's current medication therapy when all of the following conditions are met:

(1) Written notice or disclaimer of the availability of an auto-refill program shall be given to the patient or patient's agent. The patient or patient's agent must affirmatively indicate if he or she wishes to enroll in such a program and the pharmacy shall maintain documentation of such indication. Notice shall have language that references instructions on how a patient can

discontinue participation in the auto-refill program.

(a) A pharmacy patient or the patient's agent shall consent to participation in an auto-refill program with a "wet" signature or an e-signature. If the pharmacy has an online consent option, the patient may enroll in the auto-refill program through that method. The pharmacy shall keep this acknowledgement on file. If the retail pharmacy has an online consent option, the patient or patient's agent can register in that manner and the pharmacy shall keep the acknowledgment on file for one year from date of dispensing.

(b) A mail order pharmacy patient or the patient's agent shall consent to participation auto-refill program through the mail order pharmacy's website. The pharmacy shall keep this acknowledgment on file. If the mail order pharmacy does not have an online consent option, the pharmacy shall obtain a signature or email confirmation from the patient or patient's agent consenting to the auto-refill program. Acknowledgement of consent to participate in the auto-refill program shall be kept on file by the mail order pharmacy for one year from date of dispensing.

(2) The pharmacy shall have written policies and procedures in place to ensure only medications that are for the auto-refill program are enrolled in the program.

(3) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient's agent in a timely manner.

(4) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

(5) The retail or mail order pharmacy must reaffirm annually each prescription to be enrolled in the auto-refill program.

(6) Upon a receipt of a new prescription from a provider, the patient or patient's agent shall identify if the prescription is to be included in the auto-refill program, even if the new prescription is a continuation of existing therapy.

(7) Each time a prescription is refilled a reminder notification will be provided to the patient or patient's agent, affirming that the prescription is enrolled in the auto-refill program.

(8) Pharmacies that use an auto refill program will have policies and procedures in place that address the auto-fill program. These policies and procedures will be available for inspection upon request of the board.

(9) The pharmacy shall provide a full refund to the patient or the patient's agent and the payer for an auto-refill prescription that is reported as unneeded or unnecessary if the patient or patient's agent can provide evidence or documentation that they did not register for the auto-

refill program or the patient notified the pharmacy of disenrollment.

Board Member Law thanked the Enforcement Committee for working on this important subject.

Mr. Weisser explained that auto refill can cause a financial hardship for patients that find that their medications are not covered by their provider. Ms. Veale stated that patients do not get billed unless the patient picks up the prescription.

Ms. Veale expressed concern that the board may be overregulating the practice of pharmacy in the area of auto refill programs. Ms. Veale stated that many health plans ask for patients to be automatically enrolled in the auto refill program because they see benefits to the program (she noted that she has found at least three articles highlighting the benefits of auto refill programs).

Mr. Weisser stated that many patients seem to have problems with being enrolled in auto refill programs and not realizing that they no longer need the medication and then have no way of getting refunded. He encouraged the board to research the issue to see how widespread the problem really is and if it requires board regulation.

Ms. Veale explained PBMs will allow pharmacies to return medications to stock within 14 days if not dispensed.

President Gutierrez stated that many pharmacists' job performance evaluations include how many patients they enroll in auto refill programs.

Ms. Veale stated that she is not totally against regulation in this area; however, she feels that the draft language goes too far. She suggested removing #9 from the language. She also suggested that the board look at the regulation Texas created.

Mr. Law stated that for maintenance medications it is beneficial for the patient to receive his or her medications on a regular basis.

Dr. Wong stated that he would like to remove #7 from the language. Ms. Sodergren clarified that #7 was intended to simply remind the patient that he or she is receiving the medication because the patient is enrolled in an auto refill program, it was not meant to have a patient opt-in every time he or she gets a prescription.

The board expressed their desire to have patients opt-in to auto refill programs; however, there were differing opinions on how often they should have to opt-in.

Board Member Munoz stated that she would like to keep #9 in the language as it may hold pharmacies accountable.

Mr. Lippe motioned to have staff condense the language based on the board's discussion and bring it back to the full board. Ms. Freedman recommended that the board be more specific in what items they would like removed from the language. Mr. Lippe withdrew his motion.

Mark Johnson, representing CVS Health, recommended removing #5 and #6 from the language as they may they may cause a delay in therapy for the patient. He added that personally auto

refill helps keep him compliant with his maintenance medications.

Steve Sailor, retired pharmacist, stated that the language was overregulating the practice of pharmacy.

The board took a break from the discussion to recognized Steve Sailor for his service as a pharmacist for 50 years.

The board resumed the discussion on auto refill programs.

Stan Goldenburg, pharmacist, stated that seniors often take multiple medications and they may have difficulty remembering to refill the prescription, however they may also be receiving medications that are actually harming them. He suggested that pharmacists may consider reviewing patient’s prescriptions to determine if their medications are appropriate and if they would benefit from an auto refill program.

Dr. Gray asked if the board would need to pursue legislation to make a statutory change. Ms. Freedman and Ms. Kellogg responded that at this time they did not believe that legislation would be required.

Motion: Remove #5 and #6 from the language. Have staff refine the language and bring it back to the full board for further discussion.

M/S: Lippe/Veale

Support: 4 Oppose: 3 Abstain: 1

Note: Mr. Schaad and Ms. Munoz were not present for the vote.

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		x		
Gutierrez	x			
Law		x		
Lippe	x			
Munoz				x
Sanchez			x	
Schaad				x
Veale	x			
Weisser		x		
Wong	x			

Ms. Herold clarified that the language was to be brought back to the full board. President Gutierrez confirmed this.