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 X. Discussion and Consideration of Adoption of Board Approved Regulations, Comments Pending Review by the Board

(a) Proposed Regulations to Add Title 16 CCR Section 1717.5, Related to Automatic Refills

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Background:

At the May 2017 Board meeting, the Board approved proposed text to add Section 1717.5 related to Automatic Refills. This proposal establishes regulatory requirements for automated refill programs.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on July 17, 2020, which ended on August 31, 2020. Several comments were received during the comment period and, following review by the Board at the September Board meeting, amended language was released for 15-day public comment. The 15-day public comment period began on September 25, 2020 and ended on October 10, 2020. Several comments were received during the comment period. Attached following this memo are the following:

1. Comments received during the 15-day comment period
2. Board staff prepared summarized comments with recommendations
3. The proposed text released for 15-day public comment.

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 September 25, 2020.
2. Amend the regulation to address concerns expressed by stakeholders and as recommended by Board staff 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 September 25, 2020. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

1. Comments received during the 15-day comment period

From: ALorenzana@clinicas.org <ALorenzana@clinicas.org>
Sent: Wednesday, September 30, 2020 3:06 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Comments to Proposed Rule - Automatic Refill Programs Title 16, California Code of Regulations Sections 1717.5

Hello Ms. Lori Marinez

I would like to submit comment regarding the Proposed Rule Re: Automatic Refill Programs Title 16, California Code of Regulations Sections 1717.5

While I am in support of some regulation on automatic refill programs, how this current revised text is written does not support independent pharmacies and the patient's my pharmacy serves.

My pharmacy exists as part of a Community Health Center and our automatic refill program was the result of a project to improve patient outcomes due to poor medication adherence.
As a Community Health Center we serve the most vulnerable members of society, the poor, under-educated, often immigrant workers. It is our mission to help them access high quality healthcare, and access to medication is a large piece of it. In addition to providing low-cost medication to those who cannot afford it, we offer other services such as delivery of medication to the patient's clinic at no cost.

Our automatic refill program runs as a collaboration between the patient, Primary Care Provider (PCP) and Pharmacy. Enrollment of prescriptions in our autorefill program can be requested by the patient (or their representative), the patient's PCP or suggested to the patient by our pharmacy staff.
The enrollment by PCP is the result of a patient's visit with their PCP and it if it is determined that the patient has poor adherence with their medication there is a conversation with the patient and pharmacy is contacted for enrollment. Our pharmacy is also are set up to stop inappropriate refills of discontinued medications by a cancellation message sent through our electronic health record, and if it is the autorefill program it is immediately disenrolled and pulled from shelf it has not yet been picked up by the patient.

The current text of the proposed rule would ban such a collaborative model. In the current PCP requested autorefill enrollment procedure there is no direct communication by pharmacy staff with the patient at the time of enrollment as required by proposed text. Pharmacists review all prescriptions before they are then delivered to the patent's clinic location to pick up, however due to the 'remote' nature collecting the documentation required would cause us to discontinue this very patient-focused program as our software does not have the capability to store these required records and notices, and if required would likely require at least 1 year or more for the software vendor to develop. Which would mean that we would have to discontinue the successful program and patients could fall into poor health outcomes as a result.

This regulation will hurt my patients as we would have to discontinue our autorefill program if the rule is implemented today. To date we have had zero instances of patient's being provided medication that was inappropriate and did not need as a result of our program. The few instances where patient did want to take the prescription were the result of financial reasons and using the resources we have available were able to have staff (pharmacy, clinic, heath education staff) get involved to get the patient to a medication regimen that is effective and accessible based on their individual situation, a true win-win for the patient and is the result of our unique position and program.

In the situation a patient truly does not want to be enrolled in our autorefill program, they just need call in and inform staff, and even then staff have a conversation to make sure the patient has the right tools and information to set themselves up for medication adherence success.

Independent and Community Health Center Pharmacies did not cause the problem that has sponsored this regulation, it rests with the large mass volume-chain pharmacies that have performance targets and incentives to management an getting a high percentage of prescriptions refilled in autorefill programs. Insurance companies and PBM's also share responsibility in creating this problem as they financially punish pharmacies for not meeting patient refill adherence performance targets in the form of reimbursement 'claw-backs'. Our autorefill program is, in its roots and in practice, centered around the a patient's overall health not the performance targets for the bottom line or to appease the PBM's and Insurers.

I implore you to change the text of this rule to exempt small independent pharmacies, such as mine, from the requirements as specified.

Anthony Lorenzana, Pharm.D.
Pharmacist-in-Charge
Clinicas Del Camino Real Inc.
805-659-0119
alorenzana@clinicas.org

October 9, 2020

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Re: Proposed Regulation: Automatic Refill Programs [Modified Text]

Dear Ms. Martinez:

My name is Emily Haugh and I'm a pharmacist at PillPack LLC ("PillPack"). We'd like to thank the Board of Pharmacy for the opportunity to comment on the 1717.5 draft rules related to automatic refill programs. Additionally, we'd like to thank the Board and its staff for their consideration and acceptance of our comments on the first draft of the rule. We strongly believe that these amendments will serve to increase patient satisfaction and improve communication.

With respect to the modified proposed rule, we are seeking clarification regarding the underlined language in proposed Section 1715(a)(2) below:

> *The patient or patient's agent shall enroll by written, online, or electronic informed consent to participate in the program <u>for each prescription.</u>*

Specifically, it is not clear whether the Board intends to require consent to auto refill each *medication* or each *prescription numbe*r. In order to share the key differences between the two and shed more light on our request, we will explain our program in more detail.

In order to operate a responsible auto refill program, PillPack has developed a **medication-centric** view of a patient's prescriptions. This differs from a prescription-centric notion in key ways and enables the kind of control that we believe the Board is intending here. For example, a patient may have multiple prescriptions on file for the same medication (e.g. multiple prescriptions for metformin with the same dose and directions). PillPack has developed systems to recognize that these different prescriptions are part of the same treatment and we understand the relationship these prescriptions have to each other. In practice, this means that the patient does not need to remember which prescription is current, pause or change settings every time an individual prescription expires or changes, or select their preferences

individually for each prescription. We've structured this system to cater to our patients' way of managing and understanding their medication regimens.

Additionally, PillPack has logic that recognizes when an old prescription has been replaced by a new form of the same medication, or a therapeutic substitution has occurred, and prevents doubling up of the medication or sending medications the patient no longer needs. This logic enables patients to much more easily control their medications, but with careful clinical oversight by our pharmacists. It also prevents a wasteful accumulation of medication because we are consistently able to understand when one prescription has been retired and another for the same medical purpose has taken its place.

In brief, requiring patients to set preferences for each prescription number can be very confusing, cumbersome and may cause errors. For example, if one prescription number is missed by the patient, they may end up either receiving a medication they do not want or going without one they need.

Therefore, given the potential for unintended consequences, we respectfully request that the Board replace the proposed language in Section 1715(a)(2) that reads "for each prescription" with language that reads "for each medication." Alternatively, we ask that the Board confirm that the existing proposed language means that consent is needed for each medication. This would allow patients to manage their medications in a holistic sense and not have to worry about pausing or unpausing multiple prescription numbers for one medication.

We appreciate the Board's time in considering PillPack's feedback to help patients manage their autofill preferences more easily and reduce unwanted fills. Please feel free to reply with any questions you may have.

Sincerely,

Emily Haugh, Pharm.D.

Pharmacist

emily@pillpack.com

October 9, 2020

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

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 grapples 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 and appreciate several of the changes, including the removal of the requirement for pharmacies to disclose a list of medications that may be refilled through the program. This would have been burdensome not only logistically for the pharmacy, but lengthy and potentially confusing for patients. We also thank the board for clarifying that the consent and notice requirements can be fulfilled electronically. We believe this change will increase the available options for patients to communicate with pharmacies.

However, in order to ensure patients can continue to safely and efficiently access automatic refill programs and stay current on their medications, we urge you to consider the following concerns focused primarily on the new amendments in the modified text of the regulation:

Sec. 1717.5 (a)(2) – Patient Consent
Section (a)(2) requires patients to enroll in automatic refill programs via written or electronic informed consent for each prescription. It also requires pharmacies to provide

patients with information summarizing the program prior to patient enrollment. We respectfully request clarification that this section will be applied ***only prospectively*** so that patients who are already enrolled in automatic refill programs are able to continue to receive their medications without interruption. Some patients are on multiple medications and we believe the requirement that a patient must consent to each medication currently filled via automatic refill once this regulation becomes effective would place an unnecessary burden on the pharmacy and the patient. We therefore suggest that this section be amended to be effective for new medications enrolled in automatic refill programs as of the effective date of the regulation once it is approved. Patients would then, prospectively, be required to consent to each new medication filled via automatic refill.

Further, we request clarification that by requiring "informed consent for each prescription" in this section, the Board means "for each medication." Patients typically manage their regimens based on medication, rather than focusing on prescription numbers. Some patients may have several active prescription numbers for the same medication, dose, and directions, based on how their prescriber manages their care. Requiring patients to set auto fill preferences for each prescription number instead of each medication is confusing and cumbersome, and can lead to unintended errors or waste.

Sec. 1717.5 (a)(6) – Confirmation of Disenrollment

New language in Section (a)(6) requires a pharmacy to notify a patient or patient's agent to confirm disenrollment in an automatic refill program. While we understand disenrolling a patient from automatic refill, we believe providing a confirmation to patients upon disenrollment is an extra, unnecessary step. Many of our members do not currently have the systems in place to provide such a confirmation. Keeping documentation – as the previous draft of the regulations required – should suffice as confirmation of patient's disenrollment. Patients are aware of their withdrawal from an automatic refill program when they make the request. Providing additional confirmation is a duplicative, unnecessary administrative burden.

Sec. 1717.5(a)(7) – Refund

The new Section (a)(7) requires a pharmacy to provide a full refund to a patient for any automatic refill if the pharmacy was notified that the patient did not want the refill, regardless of the reason, ***or*** if the pharmacy had been notified of disenrollment from the program before dispensing the prescription. The new language replaces "and" with "or", which will increase potential abuse of this provision and allow patients to request a refund, even if a medication has been filled appropriately. This provision will also place an additional financial burden on pharmacies, which will be unable to take the medication back for resale.

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

other states where regulations that place restrictions on automatic refill programs have been adopted, patient participation has also decreased. Without these programs, patients may miss doses of essential medications and end up in the emergency room or worse, which will put even more pressure on our healthcare delivery system at a time it can least afford it.

We respectfully ask that you consider our comments and accordingly modify the regulation. Automatic refill programs and pharmacy practices are constantly evolving to better serve patients, and patient safety is a top priority for our members. We are eager to continue to work with you to ensure that the regulations ultimately adopted both safeguard patients while preserving access to medications.

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 currently operates 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 consideration of our comments. Please do not hesitate to contact Lindsay Gullahorn with Capitol Advocacy at (916) 221-8708 or lgullahorn@capitoladvocacy.com if you have any questions.

Sincerely,

Rachel Michelin
President
California Retailers Association

cc: Anne Sodegren, Executive Officer, Board of Pharmacy
Greg Lippe, President, Board of Pharmacy

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs
Walgreen Co.
5330 E Washington, D-104
Phoenix, AZ 85034
p: 602-214-6618
Lorri.Walmsley@Walgreens.com

October 8, 2020

Mr. Greg Lippe
President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Proposed Regulations to Add Section 1717.5 Automatic Refill Programs

Dear President Lippe:

On behalf of all Walgreens owned pharmacies in California, Walgreens thanks the Board for the opportunity to submit comments on the proposed regulations to add Section 1717.5 to Article 2 of Division 17 of Title 16 of the California Code of Regulations related to Automated Refill Programs.

Walgreens currently offers automated refill programs in several ways, offering the patient choice and multiple opportunities based on their engagement with our pharmacy system. A patient may enroll through our Interactive Voice Response (IVR) system when they call in refills for their prescriptions. Based on the patient's medication type and history, the system offers customized solutions to improve their adherence, including automated refill for chronic medications. Since this interaction happens at the time of the call, it would be impossible to provide written or electronic notice before the call. We encourage the Board to amend 1717.5(a)(2) as suggested below to allow pharmacies the flexibility to implement the automated refill programs using innovative means but still achieve the regulation's intent by receiving specific, informed consent and written notice before dispensing.

1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.

(2) Before a prescription is dispensed to the patient for the first time using an automated refill program, ~~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 prescription

Walgreens

In addition to this proposed modification, Walgreens would also encourage the Board to consider applying enforcement discretion for one year after adoption. Many patients in California already participate in these programs and depend upon them to maintain their therapies. When the regulation relating to automated refill programs were adopted in Oregon, we received complaints from patients that did not receive all of their medications because they had previously relied on these services. Allowing a phased-in approach will allow pharmacies to have sufficient time to develop all the needed system, policy and procedure changes, and time to educate patients properly to minimize disruptions in therapy.

Walgreens thanks the Board for the opportunity to provide feedback on these proposed regulations. Please do not hesitate to contact me with any questions or for further information.

Sincerely,

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs
Walgreen Co.

October 8, 2020

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

Re: **CRA Comments re: Proposed Automatic Refill Program Regulations – 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[1]. 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.

These regulations are attempting to address a very small percentage of overall prescriptions filled under an automatic refill program. Staff comments prepared and submitted to the Board as part of the September 17, 2020 full board meeting included a summary table of complaints the Board has received regarding automatic refill since 2014. Since 2014, there have been a total of 76 complaints, which may, without context, appear to be an overwhelming problem. However, this number of complaints over a six-year period – an average 12.7 consumer

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

complaints per year – should be viewed in comparison to the millions of prescriptions filled through automatic refill programs on an annual basis. For these reasons we again request the Board considers sending this proposed regulation back to the committee for further evaluation and work to ensure the regulations accomplish the overall objective of the Board to protect public safety.

If the Board chooses to continue forward with these regulations, there are a few additional areas of concern we ask the Board to consider.

First, **Sec. 1717.5 (a)(2)** requires patients to enroll in an automatic refill program by giving informed consent for each prescription. To avoid an interruption in care for patients that are already enrolled in an automatic refill program, we ask that the Board clarifies this section to apply to any patient who signs up following the effective date of this regulation. This will prevent a pharmacy from having to disenroll and reenroll thousands of patients per location. If a pharmacy does have to disenroll all patients it will create a large administrative burden. There is also a concern that during the transition period some patients who rely heavily on automatic refill programs to help keep their complicated medication regimens organized and filled on time will potentially have a lapse in their therapy.

Second, **Sec. 1717.5 (a)(6)** 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 enhancements, if possible, to accommodate this provision. The confirmation is duplicative to the original request to cease participation in the automatic refill program and we ask that this requirement be removed to reduce the fiscal impact to all pharmacies large and small.

Finally, **Sec. 1717.5 (a)(7)** requires a pharmacy to provide a full refund to a patient who does not want a prescription they received. This does not provide any checks or balances that allow for patients to take responsibility for the medications they pick up from a pharmacy. This provision seems to be an effort to curb "force feeding" of prescriptions to patients who have requested removal from a program or who have a surplus of medication on hand. In general, a traditional community pharmacy already has a mechanism in place where a patient reviews the prescription as they pick them up from the pharmacy. The patient chooses to accept or reject a prescription fill prior to paying for and leaving the premises with their prescriptions. The way this proposed regulation is written creates a mechanism whereby the patient can decide days, weeks, or months later they do not want a medication they actively participated in picking up,

and the pharmacy would be required to refund their money with no recourse to hold a patient accountable. We believe this provision will lead to further customer service issues. We respectfully request the Board considers removal of this provision or placing guidelines to specifically target actions that are deemed abusive of patient's rights and privileges.

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 or 208-513-3470.

Sincerely,

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

2. Board staff prepared summarized comments with recommendations

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

Summarized 15-day Comments Regarding Automatic Refill Programs with Board Staff Recommendations:

Written Comments from Anthony Lorenzana, PharmD.

Comment 1: Dr. Lorenzana states that his pharmacy serves the poor and undereducated members of society. He states that his pharmacy enrolls patients in automatic refill at the request of the primary care physician and not the patient if the patient has poor medication adherence and the pharmacy does not communicate with the patient. Dr. Lorenzana expressed concern that the current proposed text does not allow a physician to enroll their patient.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As authorized by section 1717.5(a)(2), prescribers may serve as the patients' agent should the patient authorize the prescriber to do so.

Comment 2: Dr. Lorenzana states that his computer software does not have the ability to store required notices and records. Commenter requests that small, independent pharmacies be exempted from the automatic refill requirements.

Response to Comment 2: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. The regulation is silent on how the records are stored by the pharmacy, as such, the pharmacy can establish the specific procedures that meet the needs of their pharmacy and patients.

Written Comments from Emily Haugh, PharmD., PillPack

Comment 1: Dr. Haugh requests clarification on proposed section 1715(a)(2), specifically, regarding the phrase, "each prescription." Dr. Haugh inquired on whether the phrase means each "medication" or each "prescription number." Dr. Haugh explains that a patient may have multiple prescriptions for the same medication as it may be ongoing treatment. If one prescription is expiring and they get a new prescription for the same medication, automatic refill would continue as the medication is the same. Dr. Haugh requests that the language be amended from "prescription" to "medication" or the Board confirm that the existing language applies to each medication.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As the term "medication" is overly broad, the term would not

be appropriate here. 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.

Written Comments from Rachel Michelin, California Retailers Association

Comment 1: Ms. Michelin requests clarification on whether those already enrolled in an automatic refill program prior to the effective date of the regulation will be required to reenroll in the program or if the requirements will only apply to those enrolled after the effective date of the regulation.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. The regulation will become effective after it is approved by the Office of Administrative Law. Additionally, a pharmacy may opt but is not required to proactively make changes to meet the regulation requirements prior to its effective date.

Comment 2: Ms. Michelin requests clarification on section 1715(a)(2), specifically, regarding the phrase "each prescription" and whether the phrase means each "medication." Ms. Michelin states that managing automatic refill medications by prescription number will be confusing to patients and could lead to errors.

Response to Comment 2: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As the term "medication" is overly broad, the term would not be appropriate here. 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. The regulation does not require management of automatic refills by prescription number.

Comment 3: Ms. Michelin states that requiring a pharmacy to provide confirmation of disenrollment from the automatic refill program (as required in section 1715.5(a)(6)) is duplicative and an unnecessary administrative burden.

Response to Comment 3: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. 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.b.), and webcast, which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Comment 4: Ms. Michelin expresses concern about the requirement to provide a patient a refund even if the prescription was filled appropriately based on the use of the phrase "or" because it will lead the potential abuse by patients. Additionally, the language places a financial burden on the pharmacy because they will not be able to take the medication back.

Response to Comment 4: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As the regulation states, if the pharmacy was notified that the patient did not want the medication and the pharmacy still filled the prescription, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription, the patient should receive a refund as the pharmacy was told that the patient did not want the prescription or the patient disenrolled from automatic refill prior to the filling/dispensing, the pharmacy should not have filled/dispensed the prescription. A detailed explanation of the refund requirement is available is the Initial Statement of Reasons (page 5).

Written Comments from Lorri Walmsley, RPh, Walgreens.

Comment 1: Ms. Walmsley expresses concern about the written or electronic notice required to be provided to the patient before enrolling in an automatic refill program. Ms. Walmsley states that Walgreens allows patients to enroll by phone via their interactive voice response (IVR) refill system. Ms. Walmsley recommends the language be amended to read "Before a prescription is dispensed to the patient for the first time using an automated refill program," replacing "Before a patient enrolls[.]"

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As enrollment through the IVR would be considered electronic, it appears that IVR messaging could be modified to provide a description of the program and the process to withdraw or disenroll to the patient or patient's agency before the patient or patient's agent selects the option to enroll. If the patient listens to the recording about the program and selects to enroll, that would be considered electronic consent.

Written Comments from Rob Geddes, PharmD., Albertsons

Comment 1: Dr. Geddes recommends the language be returned to committee for further evaluation to ensure that the regulations accomplish the goal of public safety given that the number of complaints have decreased to a minimum amount when compared with the overall number of prescriptions filled.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. The Board's previous review and consideration of this topic supports the Board staff's recommendations. Additionally, the data provided at the previous Board meeting was a sample of data and was not the totality of the complaints the Board continues to receive. The previous review and consideration for this topic is available with the September 2020 Board's meeting materials (agenda item VII.b.), and webcast, which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Comment 2: Dr. Geddes expresses concern that pharmacies will need to disenroll all patients and reenroll patients in the auto refill program in order to obtain the informed consent required by section 1717.5(a)(2). Dr. Geddes requests clarification on whether those already enrolled in the program prior to the effective date of the regulation will be required to reenroll in the program.

Response to Comment 2: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. The regulation will become effective after it is approved by the Office of Administrative Law. Additionally, a pharmacy may opt but is not required to proactively make changes to meet the regulation requirements prior to its effective date.

Comment 3: Dr. Geddes states that section 1717.5(a)(6) is not necessary and will require programming enhancements and have a fiscal impact to provide proof of withdrawal from the auto refill program. He recommends that the section be removed.

Response to Comment 3: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. The Board's previous review and consideration of this topic supports the Board staff's recommendation here. This requirement will provide confirmation to the patient or patient's agent that they have been removed from the program and can be as simple as screen print, text, email, or other means determined by the pharmacy that meets the needs of their practice. The previous review and consideration for this topic is available with the September 2020 Board's meeting materials (agenda item VII.b.), and webcast, which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Comment 4: Dr. Geddes expresses concern about the requirement to provide a patient a refund if they accept the medication at the pharmacy and decide days, weeks, or months later that they do not want the prescription. Dr. Geddes requests that the section be removed from the regulation.

Response to Comment 4: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As the regulation states, if the pharmacy was notified that the patient did not want the medication and the pharmacy still filled the prescription, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription, the patient should receive a refund, as the pharmacy was told that the patient did not want the prescription or they the patient disenrolled from automatic refill prior to the filling/dispensing, the pharmacy should not have filled/dispensed the prescription. A detailed explanation of the refund requirement is available is the Initial Statement of Reasons (page 5).

3. The proposed text released for 15-day public comment.

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 Modified Text

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language

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

(3) 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.~~

(~~5~~ 4) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

(~~6~~ 5) 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.

(~~7~~ 6) 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.

(~~8~~ 7) 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.

(~~9~~ 8) 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 prescription medications for its patients need not comply with the provisions of this section.

(c) Pharmacies automatically refilling prescription 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.