California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item VII. 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. Attached following this memo are the following:

1. Comments received during the 45-day comment period
2. Board staff prepared review of Auto-Refill Complaints received since 2014
3. Board staff prepared summarized comments with recommendations
4. Board staff recommended modified text
5. The proposed text released for 45-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 45-day comment on July 17, 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 Amendment Language: Accept the Board staff recommended comment responses, approve the modified language, as recommended by Board staff, and initiate a 15-day public 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 Control agencies to complete the rulemaking file.

1. Comments received during the 45-day comment period

Martinez, Lori@DCA

From:	Thomas Finch <Thomas.Finch@SaveMart.com>
Sent:	Friday, July 17, 2020 9:46 AM
To:	Martinez, Lori@DCA
Subject:	Comment re Proposed Regulation 1717.5

[EXTERNAL]: Thomas.Finch@savemart.com

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To Whom it May Concern:

Among the 20,000+ prescription drugs approved by the FDA, a specific and individual list of each medication appropriate for automatic refill is not practical for pharmacies or beneficial to patients. Instead, regulations should allow medications to be included or excluded from automatic refills based on therapeutic categories, drug classes, state and federal schedules, route of administration, and/or prescribed indications.

Eg, "Oral anticonvulsants, antihypertensives, and antihyperglycemics which are not controlled substances" should be acceptable instead of a specific list of medications, which would have to be updated every time a new product came to market.

Thank you for your time,

Thomas K. Finch, PharmD, RPh
Senior Director, Pharmacy Operations
The Save Mart Companies
P: (209) 574-6299 x5006
C: (209) 985-6720
Thomas.Finch@SaveMart.com
TheSaveMartCompanies.com

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July 30, 2020

RECEIVED

AUG 03 2020

California State
Board of Pharmacy

State Board of Pharmacy
2720 Gateway Oaks Dr., Suite 100
Sacramento, CA 92833

Re: Public comment on changes to automatic refill program

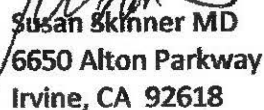
Dear State Board of Pharmacy:

I appreciate you changing the rules regarding the ability to pharmacies to enroll patients in an automatic refill prescription program.

My mother and my father were enrolled in the CVS program without their knowledge or permission. My mother tried multiple times to disenroll and was told each time by CVS staff that this would occur, but it never did. She finally switched to a different pharmacy as a way to escape the automatic refill program at CVS.

The CVS program was abusive of patients and of the insurers who have to pay for these prescriptions and I hope you will take the strongest possible stance to protect patients in the future from such abuses.

Thank you



Susan Skinner MD
6650 Alton Parkway
Irvine, CA 92618

Martinez, Lori@DCA

From:	Chris Givant <chris@lavitarx.com>
Sent:	Tuesday, August 4, 2020 5:03 PM
To:	Martinez, Lori@DCA
Subject:	Comments on Proposed Regulations on Automatic Refill Programs

[EXTERNAL]: chris@lavitarx.com

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To Whom it May Concern,

I wanted to take the time to comment on the proposed language of 1717.5 Article 2 of Division 17 of Title 16 of the California Code of Regulations.

As a pharmacy owner and Pharmacist-in-Charge I am in agreement of this kind of regulation around Automatic Refill Programs. There are too many pharmacies out there abusing this program and sending medications to patients who never wanted them and/or never wanted to be on an auto program. We agree with the board that offering an an Auto Refill Program would greatly promote patient compliance of maintenance type medications and is a nice customer service offering. People get busy and forget to order their medications. And in the compounding space, prescriptions still have to be compounded which takes even more time. So, signing up for an Autos program is a great advantage to the patient.

We agree with most of the language of the proposed regulation. We do have issues with 1717.5 (2) and 1717.5 (6).

1717.5 (2). Currently we obtain verbal authorization from the patient for auto refill *per prescription*. A lot of patients only want certain maintenance Rx's on autos as Dr's routinely fine tune compounded hormone doses so those Rx numbers often change frequently. Many patients don't want to go on autos until the dose and strength are locked in. Occasionally, the patient will authorize all of their maintenance medications to be put on auto refill. Once we have approval we note this approval on the patients profile. The note is specific for which prescriptions are on auto fill and not just a generic auto fill on all maintenance meds. They are then added to the Auto Refill system by Rx number. Over 90% of our prescriptions are mailed out and we never see the patient. Obtaining written, online, or electronic consent to participate in the program would create a rather large barrier. In the real world, it's very difficult to get patients to even call us back let alone fill out a form and mail it to us or to get on the computer and send us authorization. For example, when we sent out the HIPPA notifications that requires patients to sign it, we get back about 20% of them. Then we send it again. And over and over. That is a nightmare waiting to happen when you are talking about the need to get a prescription back quickly to a patient. Verbal consent by Rx # and documenting on the patient profile has been very successful for us and patients have been happy with this service.

Further issues with this result when you factor in how often a doctor changes strengths and doses, especially of a compounded hormone medication. Do we need to get a written consent for each

prescription? And if we just get one general consent we are also going to do verbal consent anyway from the patient on which Rx's the patient wants on the auto program and which ones they don't. So at some point, verbal is coming into play anyway.

I believe if the pharmacy has a way to document which Rx's a patient verbally told us they want and can show this evidence via their software, this evidence should be sufficient without making the patient wait or burdening a pharmacy by chasing down written, online or electronic consents before sending.

1717.5 (6) This step is just complete overkill. The patient has already told us they want us to send out Rx "x" on autofill. And then we send out Rx "x" on autofill as requested. Now we have to stop and try to contact them to tell them we sent what they asked us to send even though they specifically requested us to do this? This could be 100's of phone calls for something the patient requested of us anyway.

as an example of why this doesn't work-when we call a patient to tell them their Dr has called in and ordered Rx "x" for them and they say "great please send it to me" and then we stop everything to call these patients *back* again to tell them we are sending what they just requested us to send it sounds totally redundant and the patient would probably be annoyed. Not only will they think this is unnecessary because they asked us to send it but it's a waste of staff time when we could actually be getting their prescription ready for them. Multiply this scenario by 100's of patients and the result is a lot of unhappy patients and wasted staff time that could be better used in service to our patients.

I appreciate the opportunity to state my comments.

Kind regards,

Christine

Christine Givant
Co-Founder

La Vita Compounding Pharmacy
P-858-453-2500
F-858-453-2501
www.lavitarx.com

August 5, 2020

RECEIVED
AUG 10 2020
California State
Board of Pharmacy

State Board of Pharmacy
2720 Gateway Oaks Dr., Suite 100
Sacramento, CA 92833

Re: Public comment on changes to automatic refill program

Dear State Board of Pharmacy:

I am pleased that you have changed or are planning to change the rules regarding the ability of pharmacies to enroll customers in automatic refill prescription programs.

CVS in particular has abused this ability. Many times I have received a call from them that a prescription of mine has been refilled when I didn't ask for it. Often it is a medicine I no longer take or wish to take.

I assume then that the insurer is billed for it anyway, driving up costs for everyone. Please take a firm stance to end this practice.

Thank you very much,

Patricia Colburn
1559 Oakdale St.
Pasadena, CA 91106

Martinez, Lori@DCA

From: Clint Hopkins <clint@puccirx.com>
Sent: Friday, August 21, 2020 3:15 PM
To: Martinez, Lori@DCA
Cc: Joel Hockman
Subject: 16 CCR § 1717.5

[EXTERNAL]: clint@puccirx.com

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Hello Mrs. Martinez,

I am submitting comments regarding the proposed regulation 16 CCR § 1717.5. I fully understand the need for the regulation. As one of the first pharmacies in the state to have a drug disposal box, we have seen insane amounts of medication coming back because of automatic refill programs, mostly drugs dumped on patients via mail order pharmacies but also from the chains.

Also, when we have patients transfer in to have us package their medications in compliance packaging, they often show up with bags of pills from whatever pharmacy they are coming from. One lady recently brought in over a years' worth of Azilect for her husband along with his other meds which he had anywhere from 90-180 day supplies of each. Having this much medication on hand is problematic for some patients as they become confused and take the same medication from different containers, especially when the drug changes in appearance, resulting in medication overdose.

Further, we've had patients transfer all medications to us from some chain pharmacies and then the following month we are blocked by their insurance from filling refills requested by the patient at our pharmacy because the chain has obtained new prescriptions from the patient's providers to auto-refill in an attempt to "steal" their business back to the chain. My staff or the patient then have to call the chain and wait on hold sometimes in excess of 30 minutes to have the other pharmacy reverse those claims so the patient can receive the medication at their pharmacy of choice.

Let me be clear, I fully support the intent of this regulation! However, there are some requested clarifications that I would like to propose:

- Regarding subsection (a)(6), where it states "written notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program," can the Board clarify that online or electronic consent satisfies the "written notification" to a patient or a patient's agent? This would allow pharmacies like mine to be able to get consent via email or other electronic means. Otherwise, this regulation is going to generate a considerable amount of paper being printed at pharmacies across the state in an era when we are all trying to reduce our carbon footprint. I support this regulation being achieved in a more environmentally friendly way. Even a clarification such as having a required notice posted at each register, on the pharmacy's website, on the front door, at the drive through window, etc would decrease the use of paper.

- Many independent pharmacies, mine included, have transitioned from an auto-refill model for maintenance medications to a medication synchronization or appointment-based model for patients with chronic conditions. The major difference between an auto-refill program and our medication synchronization program is that we proactively contact the patients in advance of refilling the medications to ensure that the patient is compliant with their therapy, that nothing has changed since the last visit, and the staff coordinates for pickup or delivery of the

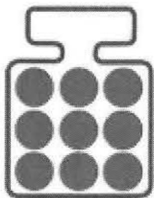
medication at that time. Can the Board clarify whether these medication synchronization programs will be treated the same as auto-refill programs for purposes of this proposed regulation or if they require an exemption the same way that health care facilities are exempted in subsection (b)?

I am extending an invitation to any Board Member and/or Board staff to visit our store in Sacramento so that you can witness how we handle medication synchronization program to determine whether you believe an exemption for this type of program is warranted and how the public is best served.

I am available by email or at the business number listed below to schedule a time when we can meet and discuss this further.

Regards,

Clint Hopkins, PharmD, APh
Owner / Pharmacist in Charge
Pucci's Pharmacy
2821 J St
Sacramento, CA 95816
o: 916.442.5891
f: 916.442.4432
e: clint@puccirx.com
w: www.puccirx.com



PUCCI'S PHARMACY
• SACRAMENTO'S MIDTOWN PRESCRIPTION CENTER •

Martinez, Lori@DCA

From:	Zee, James@DHCS <James.Zee@dhcs.ca.gov>
Sent:	Tuesday, August 4, 2020 7:39 AM
To:	Martinez, Lori@DCA
Subject:	Notice of Proposed Action to add CCR, title 16, section 1717.5

[EXTERNAL]: James.Zee@dhcs.ca.gov

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Lori,

I am glad to see the Notice of Proposed Action to add CCR, title 16, section 1717.5 to "regulate" Automatic Refills. However, the said regulation does not "regulate" automatic **deliveries** of medications after being automatically refilled.

The proposed regulation identifies requirements to automatic refills. However, it does not identify requirements to automatic deliveries.

I don't see an issue with automatic refills as long as the refilled medications are left in the "will call" area in the pharmacy waiting for patients to pick up. This way, the pharmacies can return refilled medications not picked up back to stock and reverse claims.

The issue lies, when pharmacies, especially non-chain pharmacies, automatically deliver ALL maintenance and PRN medications indiscriminately auto-refilled to the patient's home. These pharmacies argue they have completed the dispensing transactions (since they auto-refilled and auto-delivered all medications to the patient's home) and therefore billing is justified. Plus since medications have left the license premise and therefore they can no longer accept returns pursuant to drug-take back requirements.

My suggestion is to further identify requirements to allow (or disallow) automatic delivery of medications being auto-refilled. In addition, the regulation shall set limits as to what medications can be auto-refilled **and** auto-delivered, instead of allowing pharmacies to set their own auto-refill, auto-deliver drug list. Furthermore, the regulation shall allow only maintenance medications to be auto-refilled and auto-delivered, excluding ALL controlled substances and PRN medications. In addition, the pharmacies shall document patient consent to each auto-refill, auto-delivery of any maintenance medications to avoid potential waste as well.

Sincerely yours,

James Zee, Pharm.D., MBA | Pharmaceutical Consultant I
Department of Health Care Services
Audits & Investigations, Medical Review Branch
Medical Review Section – Los Angeles

311 South Spring Street, Suite 200
Los Angeles, CA 90013
Telephone: (213) 897-9350
Right Fax: (916) 440-5066

DHCS Website

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Martinez, Lori@DCA

From: Gina Frierman-Hunt <ginafhunt@gmail.com>
Sent: Monday, August 3, 2020 9:43 AM
To: Martinez, Lori@DCA
Subject: § 1717.5. Automatic Refill Programs.

[EXTERNAL]: ginafhunt@gmail.com

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I support this proposed new rule. Over the past year, I have received multiple automatic prescription refills from a CVS pharmacy. This was done for one-time prescriptions with no refills allowed from the prescribing physician. Without my approval or request, the pharmacy has contacted the physician for approval of refills that I neither needed nor wanted. On one occasion they have refilled the same prescription 2 additional times after I said I never wanted a refill for this drug. In addition, I have received refills for drugs that did include refills, but I did not request automatic refills because I use the drugs in an irregular manner, not every day; or have older prescriptions that I need to finish before getting more supplies.

I am a senior citizen on Medicare and I believe this practice is abusive and dangerous. I could be using excess amounts of medications that I thought were new drugs prescribed by my physician, especially because I have a rather complicated medication regimen. Pharmacies are trying to make more sales with no regard for patient safety or ability to pay.

I encourage the adoption of this regulation without amendment or changes.

Sincerely,
Gina Frierman-Hunt
Sierra Madre, CA
ginafhunt@gmail.com

Martinez, Lori@DCA

From:	Johnston, Mark D. <Mark.Johnston@CVSHealth.com>
Sent:	Thursday, August 27, 2020 3:07 PM
To:	Martinez, Lori@DCA
Subject:	Public comments on Section 1717.5, pertaining to automatic refill programs
Attachments:	Auto Refill California 2020 CVS Health Comments Final.pdf

[EXTERNAL]: mark.johnston@cvshealth.com

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Dear Ms. Martinez,

Please see the attached comments.

Sincerely,
Mark Johnston
CVS Health

Mark Johnston, R.Ph
Senior Director, Pharmacy Regulatory Affairs
One CVS Drive
Woonsocket, RI 02895
401-601-1968
Mark.Johnston@cvshealth.com

August 27, 2020

Lori Martinez
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
(916) 518-3078
Lori.Martinez@dca.ca.gov

Dear Ms. Martinez,

I am writing to you in my capacity as Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of California through our integrated offerings across the spectrum of pharmacy care at our 1,200+ in-state pharmacies. CVS Health appreciates the opportunity to submit comments to the Board pertaining to Title 16 Code of Regulations Section 1717.5, regarding pharmacy automatic refill programs, intended to increase patient medication adherence.

CVS Health's mission is to help patients on their path to better health. We believe the proposed language in Section 1717.5 will result in unnecessary restrictions imposed on pharmacies and untimely prescription access to patients. Further, these proposed changes may lead to significant detriments to the public health and safety of our patients in California. As such, we would be remiss not to share with you a few of the safety and benefits of automatic refill programs on patient access and patient adherence outcomes found in the literature.

In February 2017, the Agency for Healthcare Research and Quality (AHRQ) and the U.S. Department of Health and Human Services issued a report entitled Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families that detailed *"Despite a field with numerous interventions to improve medication adherence and medication safety by engaging patients through medication lists, few of these strategies have seen widespread adoption. More recently, patient-facing strategies such as sharing medical notes and providing automatic refill reminders have been associated with higher levels of medication adherence among patients."*[1] According to the World Health Organization, medication adherence can have a more direct impact on patient outcomes than the specific treatment itself.[2] Medication adherence can affect quality and length of life, health outcomes, and overall healthcare costs.[3-4] Non-adherence can account for up to 50% of treatment failures, around 125,000 deaths, and up to 25% of hospitalizations each year in the United States.[4]

Automatic refill programs are a technology offered to patients by many community pharmacies that positively impact medication adherence in chronic diseases. These programs consist of automatically filling prescriptions when they are due and then contacting the patient to notify them when their prescription is ready for pickup. Matlin and colleagues conducted a study to evaluate the impact of a national chain pharmacy's automatic refill program on patterns of medication use.[5] Study Participants included were patients on medication for chronic conditions; those receiving a 30-day supply (n = 153,964) and a 90-day supply (n = 100,394) were analyzed separately. The intervention was the

automatic refill program. Measures included medication possession ratio (MPR) and average days excess at the time of refill. Overall, patients receiving 30-day supplies of medication in the automatic refill program had an MPR that was 3 points higher than those not in the refill program; among those receiving 90-day fills and in the refill program, the MPR was 1.4 points higher (*P* <.001 for both 30- and 90-day fills). The MPR was higher for members in the refill program across all therapeutic classes. A secondary analysis of patients receiving more than 365 days of medication, found that patients who received 30-day fills and enrolled in the automatic refill program had 2.5 fewer days' oversupply than those in the control group, whereas automatic refill patients receiving 90-day supplies had 2.18 fewer days' oversupply than the controls (*P* <.001 for both 30- and 90-day fills). For this national pharmacy provider, automatic refill programs result in improved adherence without adding to medication oversupply.[5]

Rosenquist and colleagues conducted a study to determine the medication therapy management (MTM methods used with HIV/AIDS patients in the state of California.[6] The primary study objectives were to describe: specific types of MTM offered and actively used in pilot pharmacies and pharmacist-perceived barriers and benefits of providing MTM to their HIV/AIDS patients. The most frequently reported MTM activity used by a majority (51–100%) of HIV/AIDS patients were counselling by a pharmacist when overuse or underuse was detected and refill reminders by telephone. Of note, pharmacies also indicated that up to 50% of their patients receive reminders, such as automatic refills to increase patient's adherence to medications, improve health outcomes and reduce overall medical costs.[6]

While some have expressed concern that such automatic refill programs might lead to medication oversupply if not properly managed, published evidence does not support this claim. Rather, the data shows a statistically significant increase in medication adherence and a reduction in medication oversupply when patients participate in APR programs.[5,7] Encouraging patients to enroll in these automatic refill programs is a simple way pharmacists can help to increase medication adherence without an oversupply of medication. One study in partnership with the National Institutes of Health (NIH) showed enrollment in automatic refill programs to have a statistically significant impact on Medicare Part D adherence star ratings.[8] Automatic refill programs assisted with non-adherence stemming from cognitive impairment and indirectly increased access to care, particularly with a pharmacist when picking up prescriptions.[9] For patients with physical limitations, automatic refill programs and subsequent delivery of medication to the patient's home also increased access to medication.

These studies give a small sample of the overwhelming amount of safety evidence to support the longstanding practice of pharmacists providing automatic prescription refill for patients. For the last decade, the option for automatic refill programs for patients has become the de facto standard of care that independent, retail, and mail order pharmacies provide and patients rely on day in and day out throughout California. Prevention of this standard of practice and the addition of unnecessary and over burdensome regulations can cause a barrier to care for the patient on chronic medication(s) and result in delays in patient therapy, sometimes escalating to emergency room and unnecessary practitioner office visits. The prevention of this practice directly fragments pharmacists' ability to curtail the estimated $500 billion in annual healthcare costs resulting from non-optimized drug therapy, with non-adherence being a critical factor.[10-11]

In the initial statement of reasons for this pending regulation, the Board refers to complaints received in 2012-2013. CVS Health contends that the industry subsequently reacted and modified these early

automatic prescription refill programs, negating the need for this rulemaking. On August 31, 2016 at the Board's Enforcement Committee meeting, Dr. Anne Hunt, supervising inspector, reported that *"complaints have decreased"*. Eight years after the Board received 100 complaints; four years after Dr. Hunt's statements, and three years after the Board drafted pending regulations, CVS Health believes that these pending rules may cause more harm to public safety than the old problem the Board is trying to solve.

Goal four (4) of the California State Board of Pharmacy strategic plan (2017-2021) is communication and public education.[12] More specifically, goal 4.8 states – *Promote board initiatives to improve patient knowledge, medication adherence, and medication safety*. We believe the Communication and Public Education Committee is better equipped to address and respond to any potential consumers misunderstanding of the importance of automatic refill programs by educating consumers, licensees, and stakeholders about the practice and regulation of the profession. We contend, the evidence is clear that the Board should be promoting all the various practices that increase medication adherence – including automatic refill programs.

CVS Health believes that increasing medication adherence is a critical factor in preserving public safety to be promoted by Boards of Pharmacy. We urge the Board to abandon this rulemaking effort.

If the Board continues with the promulgation, we suggest that the effort be streamlined to only require consent for enrollment and the honoring of a disenrollment request, which appear to be the two most fundamental points of this promulgation. The remaining portions of this pending regulation are overly burdensome with little to no value to public safety and may inhibit adherence to medication regimens. CVS Health believes that medication adherence is a form of public safety to be promoted by Boards of Pharmacy, not restricted. If the Board intends to maintain nine subsections of pending rule 1717.5(a), we request the following edits:

1717.5(a)(1) requires policies and procedures that contain a list of medications that may be refilled through the program. The FDA reports that there are over 20,000 prescription drug products approved for marketing.[13] CVS Health believes that maintaining this expansive list of drugs that change frequently is overly burdensome with no benefit to public safety, and we request the striking of this requirement. Alternatively, CVS Health suggests that a negative formulary of drugs or drug classes that are excluded from the program be maintained.

> 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~~.

1717.5(a)(2) requires a written, online or electronic consent. CVS Health believes that consent is paramount to an auto-refill program, however we request that verbal consent also satisfies this requirement, especially in consideration of the "new normal", post-pandemic. If this regulation is enacted intact during the current pandemic, CVS requests immediate waiver from patient written consent, as to avoid patient contact with pens and stylists.

> The patient or patient's agent shall enroll by written, online, verbal or electronic consent to participate in the program.

In the initial statement of reasons, the Board is concerned with disposed waste, however 1717.5(a)(4) requires written notice, which will result in much paper waste. CVS Health requests that the notice requirement be satisfied by an electronic format, which the Board has determined is distinctly different than a written format in 1717.5(a)(2). We request that this notification requirement be satisfied by an e-mail, fax, text, sign or other communication that directs the patient to an electronic summary of the program.

> When 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. This requirement may be satisfied if the notice, which may be an e-mail, fax, text, sign or other form of communication, directs the patient to an electronic summary of the program.

1717.5(a)(5) requires a drug regimen review of all refilled prescriptions, which is inconsistent with 1707.3, which does not require a pharmacist's review of a patient's drug therapy and medication record when a drug has been previously dispensed to a patient in the same dosage form, strength, or the same directions. This conflicting pending requirement would discourage the use of auto refill programs at the jeopardy of public safety by simply adding cost as a deterrent. Conducting a drug regimen review when refilling a prescription is duplicative with the drug regimen review that was initially conducted if no new information is present in the patient's profile. CVS Health requests the striking of 1717.5(a)(5) in full, but if the Board desires to retain it, we highly suggest the following change:

> The pharmacy shall complete a drug regimen review for each filled and each prescription refilled through the program at the time of refill if any new information is present in the patient's profile.

1717.5(a)(6) requires written notification. As pointed out above, the Board has determined that "written" and "electronic" are distinctly different terms, and the Board is concerned with disposed waste. Additionally, Board minutes from May 3rd, 2017 determine "the intent... is to provide the patient a reminder (either on the label or on the receipt)". CVS Health requests the following changes to reflect the Board's intent.

> 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. Notification portrayed on the prescription label satisfies this requirement.

Thank you for considering these changes, and I look forward to the pending regulation hearing.

Sincerely,

Mark Johnston, R.Ph
CVS Health, Senior Director, Pharmacy Regulatory Affairs

CVSHealth

References:

1. Agency for Healthcare Research and Quality. Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families. 2017. Available from: https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patient-family-engagement/pfeprimarycare/envscan-report.pdf (Accessed August 26, 2020).
2. Brown MT, Bussell JK. Medication adherence: WHO cares? Mayo Clin Proc. 2011;86(4):304-314.
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Martinez, Lori@DCA

From: Judith Wright <judith464@gmail.com>
Sent: Friday, July 24, 2020 9:53 AM
To: Martinez, Lori@DCA; Damoth, Debbie@DCA
Subject: Automatic Refill Programs

[EXTERNAL]: judith464@gmail.com

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My PERS insurance includes a drug plan through CVS. Their automatic refill program has been nothing but a problem for all the years I have had to get prescriptions through them. I am constantly barraged with notifications that there is a shortage in my drug, better refill now and/or that my (unordered) refill is ready. I have complained in person repeatedly. I have called various numbers to opt-out of a program I never opted in to. I am offered refills for drugs for which the prescribing doctor has not authorized a refill.

Please fight to maintain the proposed regulations and to prevent their being watered down by CVS and similar pharmaceutical companies with a vested interest in the status quo.

Thank you, and good luck!

Judith Wright
464 N Avenue 51
Los Angeles, CA 90042

Judith464@gmail.com

Martinez, Lori@DCA

From: Rob Geddes <rob.geddes@albertsons.com>
Sent: Friday, August 21, 2020 2:46 PM
To: Martinez, Lori@DCA
Subject: Comments Title 16, California Code Regulations Sections 1717.5
Attachments: CA Automatic Fill Comments Final 8-21-20.pdf

[EXTERNAL]: rob.geddes@albertsons.com

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Lori,

Please accept my comments to the Board in reference to the Automatic Refill Programs that are in the open comment period.

Rob Geddes, PharmD
Director, Pharmacy Legislative and Regulatory Affairs
Albertsons Companies, Inc.
(M) 208.513.3470
(O) 208.395.3987
(F) 623.336.6641
Rob.geddes@albertsons.com

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August 21, 2020

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

Re: Title 16, California Code of Regulations Sections 1717.5 Automatic Refill Programs

Dear Mr. Lippe,

I hope this letter finds you and the rest of the Board Members well. Albertsons Companies expresses gratitude for your hard work and diligence during these challenging times. We operate 373 community pharmacies across the state under 5 well known banners: Albertsons, Safeway, Vons, Pavillions, and Sav-on. Our pharmacies and staff provide patients with critical access to life saving medications, immunizations, and critical advice. Now more than ever, pharmacies play an important role in patient care and allow for ready access to health care services when many provider offices have been shuttered due to the COVID-19 pandemic. I would like to take an opportunity comment on the above reference proposed regulation.

One of the important tools our pharmacies use to help patients improve adherence to medication regimens is an automatic refill program. This program allows for patients to enroll in a service that will automatically fill their active medications that have refills. A patient can enroll all eligible prescriptions or select individual prescriptions they would like to place on the service. There are many patients who rely on this service to aid them in managing highly complex medication regimens. Without ready access to automatic refill programs, there will be patients who become nonadherent to their medications. Often, the result of this is health complications and an overall decline in health. This increases the burden and adds cost to an already overburdened and expensive health care system.

In review of the Initial Statement of Reasons associated with this proposed regulation the impetus behind enacting these regulations is based on outdated information. The media coverage, as well as the customer complaints being referenced, are from 2012 and 2013 Additionally, the current proposed regulations were approved over three years ago at the May 2017 Board meeting. The industry has changed tremendously since then. The automatic refill programs currently offered by pharmacies are much different from the programs in place which drove the need for drafting these regulations. It is our suggestion that these regulations be sent back to the committee phase to allow the current board members as well as stakeholders to revisit and revise based on current information and processes. Because the Department of Consumer Affairs has added additional staff to speed up the pre-review process, sending this back to committee for additional consideration should not take as much time as traditionally required at this stage and, we believe, is a reasonable request given the changes to the industry.

Outside of the possibility of this being sent back to committee I submit the following comments for the Board members to consider in their discussion at the next meeting:

(a) (1) ...as well as a list of medications that may be refilled through the program.

Maintaining a list of medications that are eligible for an automatic refill program would present a logistical challenge. There are thousands of individual medications that make up classes of medication. Based on the availability of specific medications from a contracted wholesaler, this list would be impossible to maintain. In place of this requirement, I would suggest the following change:

(a) **(1) ...as well as a list of medications classes that ~~may~~ are ineligible to be refilled through the program.**

This would be a minor change in the words but would make a significant impact in how we will be able to feasibly manage these documents.

(a) **(6) 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 requirement is unnecessary based on the patient previously consenting to being enrolled in an automatic refill program. If an issue arises each electronic system has task tracking capabilities that will enable a pharmacy to know that the prescription is enrolled in an automatic refill program. I would suggest this requirement be stricken from the regulation altogether.

In summary, we believe these regulations would benefit from additional revisions. We ask that you consider sending these back to the committees for reconsideration. If this is not a viable option for the Board or staff to consider, please take the opportunity to discuss these regulations fully during the next Board meeting to allow for sufficient input and revisions from industry members.

If you have questions regarding the suggested changes contained in this letter 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.

Martinez, Lori@DCA

From: Emily Haugh <emily@pillpack.com>
Sent: Friday, August 28, 2020 5:05 PM
To: Martinez, Lori@DCA
Subject: Public comments - auto refill
Attachments: 1717.5 comments.pdf

[EXTERNAL]: emily@pillpack.com

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Dear Ms. Martinez,

Thank you for the opportunity to comment on proposed regulation 1717.5 related to automatic refill programs. My comments are attached. Please feel free to contact me if you have any questions.

I hope you have a nice weekend.

Best regards,

Emily Haugh
Pharmacist
emily@pillpack.com

--
Emily Haugh
Pharmacist
617-285-0814
PillPack | Pharmacy Simplified

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August 28, 2020

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

Re: Proposed Regulation: Automatic Refill Programs

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 and appreciate the Board's efforts to ensure these programs run safely.

Offering an auto refill program is critical to ensuring that patients do not miss a dose of their medications. Regulation of these programs should allow for innovation in the design and implementation so pharmacies can develop unique service offerings. Regulations must also ensure that all auto refill programs have sufficient guardrails in place to ensure patient safety.

Key guardrails for auto refill programs:

- Policies and procedures that outline the program
- Consent to enroll in the program and recording of this consent
- Ability to opt out upon patient request or prescriber discontinuation

PillPack serves multichronic patients and dispenses in multipacks, which are delivered to the patient. Pharmacies serving long term care facilities or dispensing in multipacks can serve as models for implementation of effective and safe auto refill programs. In order to manage these programs, such pharmacies have found ongoing medication reconciliation and effective communication with prescribers and patients are vital to prevent dispensing of outdated doses. While these practices aren't directly related to auto refill, we believe highly-skilled upstream efforts are vital to making these programs operate safely.

Based on our experience with providing auto refill services to our patients, PillPack is further respectfully requesting the Board consider the following changes to the proposed rules. The aim of these changes is

to enable pharmacist clinical judgement to inform the operations of these programs and allow pharmacies to issue auto refill notices in formats that suit different patients' preferences.

Section (a)(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.
Regarding section (a)(1), we request the Board reconsider the requirement for pharmacies to maintain an inclusive list of medications that can be placed on auto refill. We are concerned an inclusive list may be difficult to generate and maintain, as new medications are released frequently. It may also place an administrative burden on the pharmacist to reference this list during their drug utilization review processes.

Pharmacists are trained to use clinical judgement when considering patient requests and prescription features to determine whether or not it is appropriate to set a medication on auto refill for any individual patient. The administrative burden to generate a static list of medications, which will quickly become outdated as new drugs are added, will not serve to improve patient care. We request the Board instead allow pharmacists to use clinical judgement and tailor their approach to the individual patient.

Sections (a)(4), (a)(6), and (a)(9) related to notice format.
In terms of notices the proposed rule requires, we ask the Board consider clarifying that such notices may be provided in a variety of written formats. In today's digital world, patients communicate with their pharmacy in a variety of ways, including SMS, phone, digital dashboards, online messages and smartphone apps. These communication methods allow patients to decide auto refill status in real time. For patients using these services, printed written notices may be unnecessary or obsolete upon receipt, as patients have the choice to make this change online at any time.

We appreciate the Board's time in considering PillPack's feedback to help empower pharmacists and help pharmacies meet patients where they are with technology. Please feel free to contact me with any questions.

Sincerely,

Emily Haugh

Pharmacist

emily@pillpack.com

Martinez, Lori@DCA

From:	Lindsay Gullahorn <lgullahorn@capitoladvocacy.com>
Sent:	Friday, August 28, 2020 3:40 PM
To:	Martinez, Lori@DCA
Cc:	Sodergren, Anne@DCA; Damoth, Debbie@DCA
Subject:	CRA Comments: Automatic Refill Program Regulations
Attachments:	CRA Comments - BoP AutoRefill Regs.pdf

[EXTERNAL]: lgullahorn@capitoladvocacy.com

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Hi Lori. Please see attached for comments from my client, the California Retailers Association, regarding the Board's proposed automatic refill program regulations. Please let me know if you have any questions.

Thank you,
Lindsay

Lindsay Gullahorn
Capitol Advocacy
1301 I Street
Sacramento, CA 95814
916-221-8708 mobile
916-444-0400 main
Lgullahorn@capitoladvocacy.com

August 28, 2020

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

Re: **CRA Comments re: Proposed Automatic Refill Program Regulations**

Dear Ms. Martinez,

The California Retailers Association (CRA) appreciates the opportunity to comment on the California Board of Pharmacy's proposed regulations 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 these regulations and the mission of the Board of Pharmacy to protect California pharmacy consumers. 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:

Sec. 1717.5 (a)(1) – List of Medications

The proposed regulations require pharmacies to have written policies and procedures in place describing their automatic refill program that disclose a list of medications that may be refilled through the program. Requiring pharmacies to delineate the entire list of medications that can be refilled is burdensome not only logistically for the pharmacy, but lengthy and potentially confusing for patients. Instead, we urge the Board to require pharmacies to disclose the classes of medications that are NOT able to be refilled through the program. Such a modification will make the disclosure clearer and more concise for patients and make implementation more efficient for pharmacies.

Sec. 1717.5(a)(2) – Written Enrollment

This section requires patients to enroll in automatic refill programs by written, online or electronic consent. To increase the available options for patients to communicate their participation, this section should be amended to also allow for verbal enrollment, as well as verbal disenrollment.

Sec. 1717.5(a)(3) – Logging Written Consent
The proposed regulations require pharmacies to keep a copy of a patient's written consent to enroll in an automatic refill program on file for one year from date of dispensing. This is unnecessary and only adds an overly burdensome administrative mandate on pharmacies that distracts from serving patients. In addition, requiring pharmacies to log a patient's written consent for one year does nothing to further patient safety.

1717.5(a)(4) and 1717.5(a)(6) – Written Notice
The proposed regulations contain a number of provisions that require pharmacies to provide written notification to patients, e.g. written notice must be provided to patients upon enrollment in the program and must include instructions regarding how to withdraw a medication or disenroll from the program completely. Like the requirement to keep a record of written consent, this requirement is burdensome and unnecessary. Patients are not bound to accept medications and are always able to decline a prescription at pick-up. Similarly, the proposed requirement for pharmacies to inform patients at each fill that a medication is being refilled via an automatic refill program is duplicative and unnecessary. The proposed regulations already contain a requirement that patients provide consent to enroll.

Sec. 1717.5(a)(5) – Drug Regimen Review
This section requires a drug regimen review of all refilled prescriptions, which is inconsistent with Sec. 1707.3, which does not require a pharmacist's review of a patient's drug therapy and medication record when a drug has been previously dispensed to a patient in the same dosage form, strength, or the same directions. This appears to be included to simply add cost as discouragement for companies to utilize auto refill programs.

Sec. 1717.5(a)(9) – Alternate Languages
This section requires pharmacies to make any written notification available in alternate languages as required by state or federal law. If this is already a legal requirement, this section seems duplicative and unnecessary.

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 strongly urge you to consider our comments and make our suggested changes, especially since these proposed regulations were considered by the Board and sent to the Department of Consumer Affairs for review over three years ago. Automatic refill

programs and pharmacy practices have changed since then, which necessitates careful consideration and public feedback in any related regulations going forward. We are eager to work with you to ensure that any 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

Martinez, Lori@DCA

From: Hensic, Lori A <Hensic.Lori@scrippshealth.org>
Sent: Monday, August 31, 2020 3:58 PM
To: Martinez, Lori@DCA
Subject: Comments re: proposed CCR 1717.5
Attachments: 1717_5_45d commentary submission_20200831.pdf

[EXTERNAL]: Hensic.Lori@scrippshealth.org

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Dear Ms. Lori Martinez,

Respectfully requesting the CA Board of Pharmacy review and consider the attached comments concerning the proposed rulemaking action related to CCR 1717.5.
Thank you for the opportunity to provide this commentary.

Respectfully,

Lori Hensic, PharmD, PRS, BCACP
Director of Medication Safety, Risk and Compliance
Scripps Health, Corporate Pharmacy
10010 Campus Point Drive, Mail Drop CPC102
San Diego, CA 92121
Office: (858) 678-7123
Email: Hensic.Lori@scrippshealth.org

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Corporate Pharmacy Department
Scripps Health

10010 Campus Point Drive, CPC102
San Diego, CA 92121

Tel 858-678-7133 *Fax* 858-678-6663

August 31, 2020

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

Dear Ms. Lori Martinez,

Scripps Pharmacy is respectfully requesting the California Board of Pharmacy review and consider the following commentary pertaining to the proposal to add 1717.5 in Article 2 of Division 17 Title 16 to the California Code of Regulations:

1) Request that subdivision (a)(2) be edited to read: "The patient or patient's agent shall enroll by **<u>verbal,</u>** written, online, or electronic consent to participate in the program."
    a. As acknowledged by the Board within the Initial Statement of Reasons, "a patient's consent is typically provided verbally." Permitting verbal consent is aligned with workflows that patients currently rely on, while also supporting convenience to patients and means to quickly implement requests for automatic refill program enrollment.
        i. For example, patients are currently able to request refills verbally. Permitting verbal consent would allow the patient to easily and conveniently communicate their verbal consent to enrollment in the refill program during the same time at which they are verbally requesting prescription refills.
    b. Requiring written consent may create a barrier for patients from being enrolled in a timely manner as compared to them providing upon their verbal request. Particularly for those patients who do not regularly visit the pharmacy in person and instead interact with pharmacy personnel via phone. Documentation of such consent can still be captured with an indication that it was received verbally.
    c. Keeping mechanisms in place to permit verbal consent, and therefore enrollment in a timely manner, are aligned with supporting patients' consumer protections, safety, and health considering patients enrolled in both 30-day and 90-day automatic refill programs have been shown to have significantly higher adherence and significantly fewer days of oversupply compared to control groups (Matlin O, et al. *Am J Manag Care*. 2015;21(11):785-791).
        i. Typically, adherence rates of 80% or more are needed for optimal therapeutic efficacy. However, it is estimated that adherence to chronic medications is around 50%. Nonadherence can account for up to 50% of treatment failures, around 125,000 deaths, and up to 25% of hospitalizations each year in the United States. (Sabaté E. *Geneva: World Health Organization*. 2003; DiMatteo MR, et al. *Med Care*. 2002;40(9):794-811.).

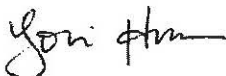
2) Request that subdivision (a)(3) be edited to read: "The pharmacy shall keep ~~a copy~~**<u>documentation</u>** of the ~~written~~ consent to enroll on file for one year from date of dispensing."
    a. Requesting these changes to align with above request that verbal consent be permissible. Documentation of such consent can still be captured with an indication that it was received verbally. Thereby providing records for inspectors to use when investigating any patient complaints, and/or for pharmacies and patients to confirm whether the patient should be enrolled ant to resolve any questions about consent.

3) Request that subdivision (a)(4) be edited to read: "~~When a patient enrolls, t~~The pharmacy shall provide a written notice summarizing the program to the patient or patient's agent **no later than with the first prescription dispensed as part of the automatic refill program**. 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."
   a. Request these changes to align with above requests pertaining to verbal consent. This change retains the intent as listed within the Initial Statement of Reasons to ensure all patients are aware of their participation in the program and how to withdraw a prescription or disenroll entirely. This would accommodate those patients who wish to provide verbal consent to enroll in the program.
      i. Furthermore, providing this written notice with the first prescription dispensed as part of the program would be more appropriate timing versus at time of enrollment, particularly for patients who already have some of their prescriptions enrolled in the program but are desiring to add additional prescriptions to the automatic refill process.

4) Request subdivision (a)(7) be moved to create subdivision (a)(4)(i), and edited to read: "~~The patient or patient's agent shall at any time be able to~~ **The pharmacy shall provide a method for a patient or patient's agent** to withdraw a prescription medication from automatic refill or to disenroll entirely from the program."
   a. Request these changes in alignment with the intent as listed within Initial Statement of Reasons to ensure there must be a method for a patient or patient's agent to disenroll from the auto-refill program. The Initial Statement of Reasons noted that "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." This edited language retains that intent while allowing the pharmacy to establish the method within their policies and procedures.
   b. Removing "at any time" would remove potential confusion in terms of a pharmacy's requirement to respond during non-operating hours and/or for a prescription enrolled in the program that may already be en route to the patient at the time of the withdraw/disenroll request (i.e., via mail delivery, etc.).
   c. These changes would also allow pharmacies to implement documentation of such withdraw and/or disenrollment requests for facilitation of any investigations or resolving any questions about consent (as described within the Initial Statement of Reasons).

5) Request subdivision (a)(8) be edited to read: "~~T~~**Upon patient or patient agent's request, t**he pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication ~~refilled~~**dispensed** through the program ~~if~~**after withdrawal or disenrollment from the program.** ~~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.~~"
   a. These changes are aligned with, and still retain, the intent as listed within the Initial Statement of Reasons. However, there may be times that the patient will still want and/or need the medication that was dispensed via the program despite it being done so after withdrawal or disenrollment. Thus, adding "upon request" would clarify that this action would be taken if the patient does not want and/or need the medication so is actively seeking a refund.
   b. Omitted reference to "not [wanting] the refill, regardless of reason" since this is inherent in a patient's withdrawal or disenrollment from the program, and thus otherwise captured by that language.
   c. Pharmacies should not be held responsible for filling prescriptions for which a patient did not provide clear communication regarding a request to withdrawal, or disenroll entirely, from the program.

Respectfully,



Lori Hensic, PharmD, PRS, BCACP
Corporate Director of Medication Safety, Risk and Compliance
10010 Campus Point Drive, CPC 102
San Diego, CA 92121

Martinez, Lori@DCA

From:	OBrien, John Michael <jm@jmob.com>
Sent:	Monday, August 31, 2020 3:23 PM
To:	Martinez, Lori@DCA
Cc:	Damoth, Debbie@DCA
Subject:	Comments on 16 CCR 1717.5 (auto-refill) proposal
Attachments:	083120 OBrien 16 CCR 1717.5 Comment Letter.pdf

[EXTERNAL]: jm@jmob.com

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Dear Ms. Martinez,

Thank you for the opportunity to comment on proposed changes to Title 16, California Code of Regulations, Sections 1717.5 relating to automatic refill programs. As a pharmacist with a keen interest in the public health benefits of improving medication adherence, I commend you for wanting to balance the important issues of medication compliance, patient preferences, and avoiding unnecessary patient and taxpayer costs. A letter responsive to your request for comments is attached to this email.

Please feel free to contact me if I may be helpful to your deliberations on this topic.

Best,

John Michael O'Brien, PharmD, MPH
202-957-7756

John Michael O'Brien, PharmD, MPH
750 N. Tamiami Trail
Suite 617
Sarasota, FL 34236

August 31, 2020

Lori Martinez
California Board of Pharmacy
2720 Gateway Oaks Drive,
Sacramento, CA 95814
Via electronic mail to: Lori.Martinez@dca.ca.gov

Dear Ms. Martinez,

Thank you for the opportunity to comment on proposed changes to Title 16, California Code of Regulations, Sections 1717.5 relating to automatic refill programs. As a pharmacist with a keen interest in the public health benefits of improving medication adherence, I commend you for wanting to balance the important issues of medication compliance, patient preferences, and avoiding unnecessary patient and taxpayer costs.

However, after carefully reviewing the current proposal, I believe the net effect of these proposed changes would be to reduce medication adherence more than unwanted dispensing. The Board seems more concerned than the data would warrant about the problem of unwanted dispensing, perhaps in response to press coverage generated by a public relations war against pharmacy benefit managers and mail-order pharmacies. The Board also incorrectly states current federal policy permitting Part D plans to auto-ship medications with appropriate enrollee protections.

As the former Senior Advisor to the Secretary of the U.S. Department of Health and Human Services responsible for drug pricing issues when the Centers for Medicare and Medicaid Services (CMS) proposed and finalized their current auto-ship policies, I appreciate the opportunity to clarify current Medicare policy and urge you to avoid policy changes that could decrease medication adherence.

The Board Incorrectly States Federal Auto-Ship Policy

The Board's Initial Statement of Reasons correctly notes that "in 2013, the Federal Centers for Medicare & Medicaid Services proposed new regulations resulting in new rules for Medicaid consumers enrolled in auto-refill programs." I am not aware of a federal policy prohibiting automatic refills in *Medicaid*. CMS annually asks state Medicaid agencies if they permit automatic refills in their Medicaid programs, and the majority of states permit the practice.

Furthermore, in 2019 CMS finalized new *Medicare* provisions after evaluating evidence and receiving stakeholder comments. The current CMS Policy permits Part D sponsors to allow their network pharmacies to offer a voluntary auto-ship program (i.e., no affirmative consent prior to shipping or delivering each new or refill prescription) if accompanied by the following enrollee protections:

- Pharmacy requires enrollees to opt-in to auto-ship refills on a drug-by-drug basis after an initial fill and permits enrollees to opt-out of auto-ship refills anytime;
- Pharmacy provides a minimum of 2 shipping reminders before each auto-shipped refill; and

- Pharmacy provides a refund for any unwanted fills. This applies to both new prescriptions ordered by the prescriber (consistent with the December 12, 2013 memo) and auto-shipped refills, and does not require return as a condition of refund.[1]

In finalizing this policy, CMS based their decision on years of experience under the previous policy, and reviewed comments from patients' groups as well as national pharmacy associations and the pharmacies they represent. Of note, the American Pharmacists Association expressed concern that the previous policy was "cumbersome and difficult for patients to fully comprehend," requested clarification of the term "opt-in voluntary auto-ship program" and noted the legal concerns of requiring unwanted medications to be returned. The above auto-ship policy finalized by CMS addresses these concerns.

The Board's Proposal is Duplicative and Conflicts with Payor Policies

As of the last Drug Utilization Review Annual Report submitted to CMS, Medi-Cal does not prohibit automatic refills. At a recent Global Medi-Cal DUR Board Meeting, the DUR Board recommended to the California Department of Health Care Services (DHCS) that Medi-Cal follow Medicare policy of requiring annual consent to automatically refill medications. According to DUR Board minutes, DHCS is presently reviewing that recommendation. This information and details about the DUR Board's deliberations should have been presented in the Board's Initial Statement of Reasons. If the Board and DHCS ultimately adopt conflicting policies, it could be confusing to pharmacists and payors, and create a situation where a pharmacist could be disciplined by the Board for correctly following Medi-Cal policy. Because of these differences in policy, the Board should defer to the preferences of individual payors and the laws pertaining to them.

Is Unwanted Dispensing Really a Problem?

The Board's Initial Statement of Reasons cites over 100 consumer complaints from 2013 regarding auto-refill programs related to "patients being enrolled without consent and receiving unwanted or unneeded prescription medicines as a result."[2] As the Medicare Part D Program represents a significant share of prescriptions dispensed each year, it is likely that many of these concerns have been addressed over the ensuing seven years. It is also worth noting that over 330 million prescriptions were dispensed in California last year.[3] Thus, the Board's rationale for action is based on old complaints that may already have been substantively addressed, and a complaint-per-prescription rate of 0.0000303%.

Furthermore, the fiscal impact of this regulation is perplexing, as the "benefits" of this regulation include reducing the dispensing of unwanted or unneeded medications, but the fiscal impact does not anticipate cost savings. It appears there is a subjective belief in the effectiveness of this policy not supported by economic analysis. Indeed, significant evidence exists supporting the effect of automatic refill programs on improving medication adherence, and research published in the Journal of Managed Care finds these programs not only improve adherence but decrease medication over-supply. It is also important to keep

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[1] Centers for Medicare and Medicaid Services. Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf
[2] CA Board of Pharmacy. Initial Statement of Reasons. https://www.pharmacy.ca.gov/laws_regs/1717_5_isr.pdf
[3] Kaiser Family Foundation. State Health Facts. Number of Retail Prescription Drugs Filled at Pharmacies by Payer. https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

in mind that increases in medication adherence have been found in multiple studies to result in cost savings, as medication serves a critical role in preventive care. Declines in medication adherence increase costs elsewhere in the healthcare system.

Lastly, while the proposed policy will increase burden on patients and pharmacies, it will not solve the problems caused by patients using multiple pharmacies or receiving duplicate prescriptions.

Other Policy Concerns

As a former pharmacy policymaker, I appreciate the challenge of improving refill accuracy without creating unnecessary burden. Much work also needs to be done to improve the "last mile of pharmacy adherence," closing the gap between receiving a medication and using it correctly to achieve a desirable health outcome. Unfortunately, these goals may be lost as community and mail-order pharmacies wage a decades-old fight in the court of public opinion and exploit pharmacy regulations to thwart each other's business practices.

Conclusion

I again commend the Board for their tireless pursuit of improving medication use. However, the proposed changes related to automatic refills may be more likely to decrease medication adherence, increase pharmacy burden and regulatory risk, potentially result in cost increases in other parts of the health care system, and further confuse consumers. They also represent a significant over-reach to solve a public affairs problem refuted by published evidence and subsequent developments in federal regulation and pharmacy practice.

The impact on patient adherence, convenience and understanding of how pharmacy works is too important to get wrong. I urge you to study the actions taken at the federal level and the experience of other states to ensure you get it right before making or implementing these amendments.

Please contact me if I may provide additional information in support of my comments. I'd welcome the opportunity to work with you on other solutions to improve medication use.

Sincerely,

John Michael O'Brien, PharmD, MPH

Cc: Debbie Damoth (Debbie.Damoth@dca.ca.gov)

Martinez, Lori@DCA

From: Walmsley, Lorri <lorri.walmsley@walgreens.com>
Sent: Tuesday, August 18, 2020 11:54 AM
To: Martinez, Lori@DCA; Sodergren, Anne@DCA
Cc: Zimmerman, Nicole
Subject: Walgreens Comments CA 1717.5
Attachments: CA _ 1717.5 Automated Refill Programs_Final.pdf

[EXTERNAL]: lorri.walmsley@walgreens.com

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Hi Anne and Lori,

Please see attached comments regarding proposed CA 1717.5 on behalf of Walgreens.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs

Walgreen Co. | 5330 E. Washington D-105, Phoenix, AZ 85034
Mobile 602 214 6618

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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

July 28, 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.

While Walgreens appreciates the Board's desire to regulate automated refill programs to prevent unauthorized enrollments in these programs, we also urge the Board to consider the substantial benefits to the patients, health plans, providers, and pharmacy staff. Some of the benefits of automated refill programs are highlighted below, including citations from peer-reviewed journals substantiating the evidence.

Medication Adherence
Approximately 50-75% of adult patients are considered non-adherent to therapy, with the estimated cost of non-adherence being 300 billion dollars annually in the US. [2,3,4] Automated Refill programs are a proven way for pharmacies to improve medication adherence for patients and to improve the proportion of days covered (PDC).[5] PDC has been proven so crucial to patient adherence and, ultimately, patient care that it is now included as a Medicare Part D Star Measure and impacts how pharmacies are reimbursed for the prescriptions that are filled.

Workflow and Workload Demands for Pharmacies and Prescribers
Automated refills allow pharmacies to manage the workflow of chronic maintenance medications more effectively. A study from the Journal of the American Pharmacists Association, prescriptions filled using an automated refill program, had a longer pickup lag, allowing pharmacies to smooth the workload demands for the pharmacy staff.[1] Allowing pharmacies to more effectively manage their workflow and work demands for these anticipated prescriptions enables pharmacy teams to several days to fill medications before the patient's arrival, ultimately reducing stress for the pharmacy staff and improving convenience for the patient. This additional lag-time for pick up also provides pharmacies the opportunity to obtain refills from prescribers before the patient running out of medication if their prescription lacks refills, is expired, or to order medications for patients.

Additionally, the Board cites in its statement of reasons for the regulation that automatic refill programs increase the amount of unused pharmaceutical waste. This statement is not true and is refuted in a peer-reviewed study showing that automated refill programs not only improve medication adherence but also reduce medication waste. Specifically, this study found that patients who received medications through an automated refill program had 2.5 fewer days of oversupply than the control group.[6] I would ask the Board to provide evidence or studies that demonstrates where there is waste, and that waste outweighs the benefits of increased adherence levels of automated refill programs.

Given the substantial evidence for the value of automated refill programs, we urge the Board not to go "too far" with prescriptive regulations on how these programs are managed. Over-regulation of automatic refill programs will create unnecessary burdens for patients to participate and pharmacies to comply. This also creates added compliance risk that will lead to pharmacies deciding to discontinue these valuable programs all together. No one benefits when this occurs. While the board has concerns, the board should consider a more moderate step approach instead of large over sweeping requirements. Walgreens recommends that the Board consider the approach taken by the Texas Board of Pharmacy in 22 TAC 291.105. This language achieves the same intent of the California Board of Pharmacy without creating unnecessary burdens for patients and pharmacies.

22 TAC 291.105: Records (Class E: Non-resident pharmacies)
(b) Auto-Refill Programs. A pharmacy may use a program that automatically refills prescriptions that have existing refills available in order to improve patient compliance with and adherence to prescribed medication therapy. The following is applicable in order to enroll patients into an auto-refill program.

(1) Notice of the availability of an auto-refill program shall be given to the patient or patient's agent, and the patient or patient's agent must affirmatively indicate that they wish to enroll in such a program and the pharmacy shall document such indication

(2) The patients or patient's agent shall have the option to withdraw from such a program at any time.

(3) Auto-refill programs may be used for refills of dangerous drugs, and schedule IV and V controlled substances. Schedule II and III controlled substances may not be dispensed by an auto-refill program.

(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.

Alternatively, Walgreens offers the following amendments, as highlighted below.

§ 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) ~~The patient or patient's agent shall enroll by written, online, or electronic consent to participate in the program.~~ The patient or the patient's agent must affirmatively indicate that they wish to enroll in such program.

(3) ~~The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.~~ The pharmacy shall discontinue the automatic refill program when requested by the patient or the patient's agent.

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

(6) ~~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.~~

(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.~~

(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 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.

(9) ~~A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.~~

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.

References:

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5. Lester, Corey A., Mott, DA, Chui, MA. The influence of a community pharmacy automatic refill program on Medicare Part D Adherence Metrics. Journal of Managed Care and Specialty Pharmacy 7 (2016) 801-807
6. Matlin, OS, Kymes, SM, Averbukh, et al., Community pharmacy automatic refill program improves adherence to maintenance therapy and reduces wasted medication. American Journal of Managed Care 2015;21(11):785-791

2. Board staff prepared review of Auto-Refill Complaints received since 2014

Summary of Auto Refill Complaints

	Summary of Complaint	Type of Pharmacy*
1	Auto refilled Breo Ellipta after medication was changed to Dulera	I
2	Allegation pharmacy continued to refill oxcarbazepine prescription after discontinued.	C
3	Auto refilled old prescription for atorvastatin 10mg while patient was getting atorvastatin 80mg	C
4	Old strength of levothyroxine was auto-refilled.	C
5	Auto-refilled old strength of BC pill with estrogen. Nursing. Took 4 tablets	I
6	Old strength of levothyroxine was refilled.	C
7	Allegation pharmacy filled prescription without authorization	I
8	Complaint that prescriptions were not ready all together.	C
9	Auto-refilled Latuda after it was discontinued. Prescription was changed to Zyprexa and clonazepam	I
10	MD complained pharmacy sends authorization requests for meds after he sent the pharmacy a new prescription.	C
11	Pharmacy filled two prescriptions; valsartan and clopidogrel after discontinued by MD. Meds were on auto-refill.	C
12	Patient complained pharmacy sent 90 supply every 60 days resulting in surplus of meds	M
13	Patient 's insurance was billed $2095 three times for Pennsaid 2% pump	I
14	Pharmacy filled two electronic prescriptions on the same day for the same drug. Possibly due to multiple auto-refill requests sent to MD.	C
15	Pt declined auto refill, but an unknow tech (floater) stated everyone is signed up for auto refill; pharmacy’s policy requires patient consent.	C
16	Pharmacy auto refilled Benicar HCT without authorization- Insurance was charged full price for DAW-1	M
17	Patient complained pharmacy continues to auto-refill meds despite his requests to disenroll from program. Twice while travelling patient couldn't get med filled at another CVS because it was already filled	C
18	Auto-refilled fluoxetine 60mg 6 days after filling fluoxetine 80mg	C
19	Patient complained pharmacy failed to transfer prescription, then auto-filed it.	C
20	Patient had five prescriptions on auto refill and was running low but did not get a call to pick up meds. When patient went to pick up meds, CVS filled an old prescription he was no longer taking and the other 4 prescriptions were not ready. Meantime, patient called md to ask for new prescription to fill and cancel the older prescriptions. The pharmacy refused to back out the old prescription.	C
21	Auto refilled old prescription for citalopram, patient was on escitalopram. Pharmacy request refill for wrong med. The physician denied the request.	C
22	Pt complained pharmacy continued to refill prescriptions without consent-	M
23	Pt complained pharmacy continued to refill prescription without consent-	M
24	Auto refilled diltiazem 120mg on same day as diltiazem 180mg	I

25	Pharmacy called doctor for refill on Pro-air inhaler which patient did not request	C
26	Pt doctor called asking why she was requesting old prescription for lorazepam and diazepam refilled, that was filled locally. Pt was surprised and did not request for any refills.	M
27	Pharmacy auto-refilled a prescription the patient didn't want. Wife picked up by mistake could not return for refund.	C
28	MD requested CVS to turn off auto refill requests; she received 5 to 15 requests daily not requested by the patient. All requests required checking patient's electronic health record; Dr worked independently which increase her workload, confused patients, added 2 hours to her day. Example: 60 refill requests in 3 days from CVS, mostly duplicates	C
29	Pharmacy requested 90-day supply without patient consent; Physician complained, a new prescription was written for a 30-day supply anticipating to change the dose; Walgreens electronically sent a request for 90-day supply; staff approved thinking patient requested the 90-day supply; patient called md asking why a 90 day supply was approved. Pt did not make the request for 90-day supply	C
30	Refilling prescriptions without patient knowledge or authorization; patient asked to remove from auto refill and failed to remove. Had doctor send two prescriptions and wanted them on hold and not auto refilled	C
31	Dr. complained pharmacy sent request to convert new RX for a 30-day supply of doxepin for itching to a 90-day supply automatically	C
32	Pt received old prescription for carvedilol 6.25mg instead of current strength 3.125mg	C
33	The pharmacy enrolled her without her knowledge or consent in a program called ScriptSync and proceeded to refill prescriptions she did not need.	C
34	DDS complained pharmacy sends requests for 270 tablets of IBU for pt without pt authorization.	C
35	Allegation pharmacy sent medications (Symbicort Inhaler and levothyroxine) she no longer took	M
36	MD and multiple patients complained pharmacy delivers meds not requested. Do not recall signing up for auto-refill	I
37	Allegation pharmacy dispensed allergy med without MD authorization. Received monthly refill reminder calls	C
38	Originally signed up for auto refill but received excessive reminders; requested to remove from auto refill but calls continued	C
39	Allegation pharmacy auto-refilled Xarelto after it was transferred to CVS	C
40	The pharmacy dispensed a previous prescription that was discontinued due to increase in strength. Auto refill was not deactivated after the dose was increased.	C
41	Allegation pharmacy auto refilled rxs and got mad if pt didn't pick them up. Reversed the rxs and pt lost a refill	C
42	Phy contacted MD for a refill on anastrozole after d/c'd and chg'd to tamoxifen. Fax stated "pt expected to pick up rx at 1-1-2019 at 12:00"	C
43	Phy auto-refilled old rx for diclofenac 50mg 2 days after pt picked up rx for Celebrex 200mg	C

44	Pt tried auto-refill but cancelled because phy refills everything even rxs she doesn't need.	C
45	General complaint about continuously getting previously discontinued rxs	C
46	Phy auto refilled medications multiple times after pt requested to be dis-enrolled	C
47	Daughter of pt claimed pharmacy refilled medication that pt didn't need	I
48	Complaint phy filled old rx for gabapentin with old sig of BID instead of new sig TID	C
49	c/o of CVS refilling doxycycline when there was no refill on the original rx and did not request for a refill	C
50	Phy contacted Dr. for refill without pt's authorization to request for refill. Phy making medical decisions for minor daughter and would fill rx w/out aapproval. Also harassed to refill rx for erythromycin (antibiotic); receiving multiple text messages	C
51	Never signed up for auto refill; applied pressure to refill rx;	C
52	Asked to be removed from auto refill but continue to get text messages to refill rx. When answered no, a fax was still sent to md to request for a refill	C
53	Complain of auto refilling needles and syringes for a full supply but only receives a partial.	C
54	Refilling without request or authorization, for meds infrequently used; charged and not allowed to return	C
55	c/o Phy signing up pt for auto refill without consent	C
56	C/o phy auto refilling meds when she explicitly asked phy to update profile as "no auto refills."	C
57	Was on auto refill but prescriptions were not dispensed timely when due; also missed doses since phy states no refills were left, but there were refills available.	C
58	Did not refill med that was on auto refill	C
69	Duplicate refill thru the auto refill program	C
60	So frustrated phy; no matter how often I tell this pharmacy to quit pushing drugs , it insist on either auto dialing or texting a refill is ready that I didn't order; especially it’s a PRN med; this can cause people to be confused over which med to take and over abundance of extra meds	C
61	Auto refill without consent	I
62	MD allege the pharmacy is filling the wrong dosage of medication for patient and failing to contact her office for clarification about the rx;	C
63	faxed prescriber refill request without patient permission; fill meds without consent and bills insurance automatically and changed 30-day prescription to 90-day (psych drug); Asked to stop but continue to ask for refills for rx with no refills.	C
64	continue to refill rx that have not ordered or authorized	C
65	Refill prescription patient and doctor did not approve	C
66	Pt was on Flovent HFA for a temporary condition. Received call was ready for pick up a 3-month supply for Flovent. Pt did not set up auto refill	C
67	Changed pharmacy, but phy continue to auto refill despite telling them 6 times she changed phy. They kept sending refill request to md no longer using d/t insurance and med no longer covered d/t insurance.	I

68	Lack of manpower to deal with auto refill issues	C
69	Not related directly to auto refill; faxes are sent to prescriber requesting for refills with quantity changed to 90 day supply. Increasing prescriber's workload to deny each time. Included because the request for refills is auto requested.	C
70	For many months, I have been requesting only a single rx be set for auto refill. Instead they auto refilled 15-20 rxs which appeared most were refilled before the earliest refill date. ; Auto refill issue is becoming highly annoying ; one rx request went to the wrong doctor; auto refill issues cost him money and making the doctor think he was abusing bultabital/ASA/Caffeine with the continuous request and requiring he take a lab test.	C
71	10-15 times requested CVS to stop auto refills, in person, online and calling customer service; filled w/out permission and when mom passed away, she had hundreds of pillls and meds that were auto refilled and never used that had been changed.	C
72	Auto refilling without approval	C
73	Account was set up not to auto charge and required no auto refills; charge card was billed without authorization	C
74	Husband went to pick one rx and came home with 2 rxs filled. One was auto refilled and not requested; Was told by pharmacist they place maintenance drugs on auto refill. This is a scam; cost $25. complained and gave her a gift card for $25	C
75	Receiving multiple ununsolicited, automated electronic rx requests daily asking for 90 day supplies with 4 refills; patients says they did not request; many are short term rx, dcd rx, rxs that they had ADR; asked to stop mulitple times but didn’t change tactics; had to discontinue fax accessibility; refuse to turn off patient auto refill;	C
76	Doxycycline was refilled when there were no refills on the original rx and did not request for the refill.	C

*(C) Chain Store Pharmacy; (I) Independent Retail Pharmacy; (M) Mail Order Pharmacy; (P) Prison

3. Board staff prepared summarized comments with recommendations

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

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Summarized 45-day Comments Regarding Auto Refill Programs with Board Staff Recommendations:

Written Comments from Thomas Finch, PharmD., Save Mart

Comment 1: The commenter expressed concern that maintaining a specific list of medications appropriate for auto refill is not practical for pharmacies because there are 20,000+ FDA approved prescription drugs and such a list would not provide benefit to patients. The commenter recommends that medications should be included or excluded based on therapeutic categories, drug classes, controlled substance schedule, route of administration, and/or prescribed indications. The commenter provided the example of “Oral anticonvulsants, antihypertensives, and antihyperglycemics” which are not controlled substances and should be accepted instead of listing the specific medication, which would need to be updated for every new product.

Response to Comment 1: Board staff recommend that this comment be accepted in part however recommends an alternate solution. Board staff recommend striking language requiring a list of medications that may be refilled through the program. This will permit the pharmacy to establish the specific procedures for their pharmacy and their patients.

Written Comments from Susan Skinner, MD.

Comment 1: The commenter expressed support of the Board’s regulation. The commenter indicates that her parents were enrolled in an Auto refill program without their knowledge or permission and could not disenroll after multiple attempts. She indicates that they had to change pharmacies to get out of the program. She hopes that the Board takes a strong stance to protect patients.

Response to Comment 1: Board staff acknowledges the commenter’s support of the regulation.

Written Comments from Christine Givant, La Vita Compounding Pharmacy

Comment 1: The commenter expressed support for the regulations due to the pharmacies abusing the program; however, she expressed concern about the requirement for written consent, online, or electronic consent. She indicated her pharmacy obtains verbal consent per prescription and records the consent via their computer software. She indicated that 90% of the prescriptions filled by her pharmacy are mail order, so they do not see the patient to obtain the written consent and mailing out forms for patients to sign and following up will be a large barrier.

Response to Comment 1: Board staff recommend that this comment be rejected. Board staff notes that the Board continues to receive complaints from patients that indicate they did not authorize enrollment in the program. By only obtain verbal consent, the pharmacy cannot substantiate that the patient authorized enrollment. Written, online, or electronic consent must be obtained. Board staff believes this can be done on paper, through email, through SMS text messaging, or other electronic means, as along as the record is maintained. Additionally, Board staff does not believe this process will pose an enrollment barrier due to the various technological options available.

Comment 2: The commenter questioned whether written consent is required to be obtained for every prescription as opposed to a general consent noting that as patients do not always want every prescription on auto refill.

Response to Comment 2: Yes, we are altering the text in response to this comment to clarify that consent must be obtained for each prescription.

Comment 3: The commenter expressed concern about the requirement to notify the patient that a prescription was refilled through the auto refill program. The commenter provided an example of when they notify a patient over the phone that their doctor has called in a prescription and the patients requests that it be sent to them, once they send it, they would have to call the patient again to notify them that it was sent. The commenter indicated that they believe this is overkill and a waste of staff time.

Response to Comment 3: Board staff recommends that this comment be rejected. Board staff believes that notification to the patient that the prescription was refilled as part of the auto refill program is a necessary reminder for the patient. Additionally, the language does not require that the patient be notified via telephone. The notification could be as simple as a statement on the receipt, an electronic notification (for example an email or text message), or even a small label attached to the prescription container. The Board has amended the text of former subdivision (a)(6) to permit electronic notifications. Board staff does not believe this needs to be a time-consuming process.

<u>Written Comments from Patricia Colburn</u>

Comment 1: The commenter expressed support of the Board's regulation. She indicates she has received a call from her pharmacy many times that a prescription has been refilled that she didn't ask for and no longer takes or wishes to take and she assumes that the insurance is still billed. The commenter hopes that the Board takes a firm stance to end the practice.

Response to Comment 1: Board staff acknowledges the commenter's support of the regulation.

<u>Written Comments from Clint Hopkins, PharmD., Pucci's Pharmacy</u>

Comment 1: The commenter expressed support for the intent of the regulation. He indicates he has seen the "insane amounts of medication" coming in for drug disposal because of auto refill

programs. The commenter provided that example of a patient that brought in over a year's worth of medication for disposal and expressed concern about patients experiencing a medication overdose due to confusion amongst all the medication. He also explained that his staff have waited on hold in excess of 30 minutes to have pharmacies reverse unauthorized auto refill claims so that they can fill the patient's prescription. The commenter has requested clarification if online or electronic consent meets the requirement of written notification that a prescription is being filled via auto refill (1715.5(a)(6)) as this would allow email consent to avoid excessive paper waste of printing the notices.

Response to Comment 1: Board staff recommend that this comment be accepted. Board staff recommends that section 1715.5(a)(6) be amended to add "or electronic" to allow the notification to be provided through electronic means.

Comment 2: The commenter indicates his pharmacy has transitioned from an auto refill model to a medication synchronization model. He indicates that prior to refilling the prescriptions, they contact the patient to ensure compliance with treatment, inquire about any changes, and coordinate pickup or delivery. The commenter has requested clarification as to whether this type of program is considered auto refill or if an exemption would be needed. The commenter has offered to provide a demonstration of the program if it would help to best serve the public.

Response to Comment 2: The Board does not possess sufficient information to answer the question based on the facts provided. No changes to the text are required in response to this comment.

Written Comments from James Zee, PharmD.

Comment 1: The commenter expressed concern that the proposed regulation does not address "automatic deliveries" of automatically refilled medication. Dr. Zee recommends that the regulation be amended to identify requirements for automated delivery of medications and set limits as to what medications can be auto-refilled and auto-delivered instead of allowing the pharmacies to decide. Further, he states only maintenance medication, excluding controlled substances and RPN medications, should be permitted. Dr. Zee also recommends that patient consent should be documented for each medication to avoid potential waste.

Response to Comment 1: Board staff recommend that this comment be rejected in part as it is outside the scope of this regulation. This regulation is not addressing auto-delivery of medications. However, Board staff notes that should this be a topic the Board is interested in discussing, it could be placed on a future agenda or referred to a committee. Board staff recommends that the comment on requiring consent for enrollment of each prescription be accepted.

Written Comments from Gina Frierman-Hunt

Comment 1: The commenter has expressed support for the proposed regulation. The commenter states that over the past year she has received multiple automatic refills that she did not request

or approve and that did not contain refills. She said one prescription was filled two additional times after the pharmacy was notified she did not want the first auto refill of the prescription. The commenter states that she is a senior citizen and the current auto refill practice is abusive and dangerous because she could accidently use excess medication that she thought were new drugs. The commenter encourages the Board to adopt of the regulation without amendment.

Response to Comment 1: Board staff acknowledges the commenter's support of the regulation.

Written Comments from Mark Johnston, R.Ph., CVS Health

Comment 1: The commenter indicated that medication adherence is a critical factor in preserving public safety and states that auto refill programs improve medication adherence. Mr. Johnston urges the Board abandon the rulemaking. The commenter indicates if the regulation is going to continue, they recommend the following changes (see comments 2 – 6).

Response to Comment 1: Board staff recommend that this comment be rejected as the Board continues to receive complaints about auto-refill programs. Consumer protection is the Board's highest priority.

Comment 2: Mr. Johnston expressed concern that maintaining a specific list of medications appropriate for auto refill as there are 20,000+ FDA approved prescription drugs. Mr. Johnston states that maintaining this list of drugs would be overly burdensome with no public benefit. He recommends that the list requirement be stricken from 1717.5(a)(1).

Response to Comment 2: Board staff recommend that this comment be accepted. Board staff recommend that maintaining the list of drugs be removed from the text. This will permit the pharmacy to establish the specific procedures for their pharmacy and their patients.

Comment 3: Mr. Johnston expressed concern about the requirement for written, online, or electronic consent and requests that verbal consent be added to 1717.5(a)(2).

Response to Comment 3: Board staff recommend that this comment be rejected. The Board continues to receive complaints from patients who state they did not authorize enrollment in the program. By only obtaining verbal consent, the pharmacy cannot substantiate that the patient authorized enrollment. Written, online, or electronic consent must be obtained. Board staff believes this can be done on paper, through email, through SMS text messaging, or other electronic means as along as the record is maintained. Additionally, Board staff does not believe this process will pose an enrollment barrier due to the various technological options available.

Comment 4: Mr. Johnston expressed concern about the requirement for written notice summarizing the program. He recommends that the language be amended to allow electronic notice. Mr. Johnston further recommends that the sentence *"This requirement may be satisfied if the notice, which may be an email, fac, text, sign, or other form of communication, directs the patient to an electronic summary of the program"* be added to 1715.5(a)(4).

Response to Comment 4: Board staff recommend that this comment be accepted. Board staff is recommending that section (a)(4) be moved to (a)(2) so that the patient will receive the notice of the program prior to enrolling. Additionally, Board staff is recommending that the language be amended to add “or electronic” to allow for the notice to be provided to the patient via electronic means.

Comment 5: Mr. Johnston expressed concern about the requirement to complete a drug regimen review for each filled prescription. He states the requirement conflicts with section 1707.3 and is duplicative if no new information is present in the patient’s profile. He recommends that the language be stricken or that *“if any new information is present in the patient’s profile”* be added to the end of section 1717.5(a)(5).

Response to Comment 5: Board staff recommend that this comment be rejected. Board staff does not agree that the requirement to conduct a drug regimen review conflicts with Title 16, section 1707.3. Board’s policy decision with the development of the regulation is to ensure consumer protection. Performing drug therapy review will ensure duplication in therapy does not occur, drug interactions are identified, discontinued medications are not dispensed, etc. are identified and remedied before the medication is provided to a patient.

Comment 6: Mr. Johnston expressed concern about the requirement for written notification that the prescription was filled through the auto-refill program. Mr. Johnston recommends that electronic notification be permitted and that notification via the prescription label be acceptable.

Response to Comment 6: Board staff recommend that this comment be accepted. Board staff believes that notification to the patient that the prescription was refilled as part of the auto refill program is a necessary reminder for the patient. The notification could be as simple as a statement on the receipt, an electronic notification (for example an email or text message), or a small label attached to the prescription container.

<u>Written Comments from Judith Wright</u>

Comment 1: The commenter has expressed support for the proposed regulation. The commenter states that she constantly gets notifications of a drug shortage and she needs to refill now, or that a refill she didn’t authorize if ready for pick-up. She states she has complained and opt-out of the program that she never opted in to and complained repeatedly to the pharmacy. She states she’s even been offered refills for drugs that the prescribing doctor did not authorize refills. Commenter hopes the regulations will be maintained as is and “not watered down by pharmaceutical companies with a vested interest in the status quo.”

Response to Comment 1: Board staff acknowledges the commenter’s support of the regulation.

Written Comments from Rob Geddes, PharmD., Albertsons

Comment 1: Dr. Geddes expressed concern about the amount of time that has passed and recommends that the language be returned to committee for further discussion given that auto refill programs are run differently now.

Response to Comment 1: Board staff recommend that this comment be rejected. Board staff note that the Board continues to receive complaints from patients about auto-refill programs. This demonstrates that problems continue to exist with such programs.

Comment 2: Dr. Geddes expressed concern that maintaining a list of medications eligible for auto refill would a logistical challenge because of the thousands of individual medications. Dr. Geddes suggests amending the language in 1717.5(a)(1) to read ".... a list of medication classes that are ineligible to be refilled...."

Response to Comment 2: Board staff recommend that this comment be rejected. Board staff recommend that maintaining the list of drugs be removed from the text. This will permit the pharmacy to establish the specific procedures for their pharmacy and their patients.

Comment 3: Dr. Geddes indicates that he believes section 1717.5(a)(6) is not necessary as the patient has previously consented to the auto refill and the pharmacy can track the prescription electronically to confirm that information. He recommends that the section be removed.

Response to Comment 3: Board staff recommend that this comment be rejected. Board staff believes that notification to the patient that the prescription was refilled as part of the auto refill program is a necessary reminder for the patient. Additionally, the pharmacy's ability to track a prescription does not provide meaningful information to the patient.

Written Comments from Emily Haugh, Pharmacist, PillPack

Comment 1: Ms. Haugh expressed concern about the requirement to maintain a static list of medications as new medications are frequently released and the list will be difficult to maintain. Ms. Haugh requests that pharmacists be able to use clinical judgment and tailor the approach based on the patient and not have a list.

Response to Comment 1: Board staff recommend that this comment be accepted. Board staff recommend that maintaining the list of drugs be removed from the text. This will permit the pharmacy to establish the specific procedures for their pharmacy and their patients.

Comment 2: Ms. Haugh expressed concern about the written notice requirements of sections (a)(4), (a)(6), and (a)(9). Ms. Haugh requested that electronics notices be permitted via SMS, phone, digital dashboards, online messages, and smartphone apps.

Response to Comment 2: Board staff recommend that this comment be accepted. Board staff have amended the regulation text to add in "or electronic" where appropriate to allow for the notifications to be sent electronically.

Written Comments from Rachel Michelin, California Retailers Association

Comment 1: Ms. Michelin expressed concern about the requirement to maintain a list of medications as it will be logistically burdensome for the pharmacy and confusing for patients. Ms. Michelin requests that pharmacies maintain a list of medication classes that are not eligible for auto refill as it will be clearer and more concise.

Response to Comment 1: Board staff recommend that this comment be rejected. Board staff recommend that maintaining the list of drugs be removed from the text. This will permit the pharmacy to establish the specific procedures for their pharmacy and their patients.

Comment 2: Ms. Michelin expressed concern about the requirement for written, online, or electronic consent and requests that verbal consent to enroll and disenroll be added to 1717.5(a)(2) to increase communication options.

Response to Comment 2: Board staff recommend that this comment be rejected. Board staff notes that the Board continues to receive complaints from patients that indicate they did not authorize enrollment in the program. By only obtain verbal consent, the pharmacy cannot substantiate that the patient authorized enrollment. Written, online, or electronic consent must be obtained. Board staff believes this can be done on paper, through email, through SMS text messaging, or other electronic means, as along as the record is maintained. Additionally, Board staff does not believe this process will pose an enrollment barrier due to the various technological options available.

Comment 3: Ms. Michelin expressed concern about the requirement to keep a copy of the written consent for one year as it will not further patient safety and poses an administrative burden on the pharmacy.

Response to Comment 3: Board staff recommends that this comment be rejected. Board staff recommends that the language be amended to read "written or electronic informed consent..." This will allow for the consent to be stored electronically and would be accessible to the pharmacy and board inspectors should an auto-refill complaint be received by the Board.

Comment 4: Ms. Michelin expressed concern about the requirement for written notification in sections 1715(a)(4) and (a)(6). She states that the patient has also consented to enroll and patients can decline any prescription they do not want to pick up. She recommends that the notice requirements be removed from the regulation as they are burdensome to the pharmacy.

Response to Comment 4: Board staff recommend that this comment be rejected. Board staff agrees that patients can decline any prescription they do not wish to pick up, but if someone other

than the patient picks up the medication, that person may not know that the prescription is an auto-refill that should not be picked up. Additionally, Board staff believes that notification to the patient or patient's agent that the prescription was refilled as part of the auto refill program is a necessary reminder for the both parties. The notification could be as simple as a statement on the receipt, an electronic notification (for example an email or text message), or a small label attached to the prescription container.

Comment 5: Ms. Michelin expressed concern about the requirement to complete a drug regimen review for each filled prescription as she states the requirement conflicts with section 1707.3 when the prescription was previously dispensed.

Response to Comment 5: Board staff recommend that this comment be rejected. Board staff does not agree that the requirement to conduct a drug regimen review conflicts with 1707.3. The Board's policy decision with the development of the regulation is to ensure consumer protection. Performing drug therapy review will ensure duplication in therapy does not occur, drug interactions are identified, discontinued medications are not dispensed, etc. are identified and remedied before the medication is provided to a patient.

Comment 6: Ms. Michelin expressed concern about the requirement for notices be available in alternate languages as it is already required by state and federal law.

Response to Comment 6: Board staff recommend that this comment be rejected. The notice requirements within other sections of law are not specific to auto-refill. Adding the alternative language requirement to this regulation makes the regulation consistent with other sections of law, e.g., CCR Section 1707.6.

<u>Written Comments from Lori Hensic, PharmD., Scripps</u>

Comment 1: Dr. Hensic expressed concern about the requirement for written, online, or electronic consent and requests that verbal consent to enroll be added to 1717.5(a)(2). Dr. Hensic indicates that verbal consent aligns with current workflow for auto refill programs and requiring written consent will create a barrier for patients to be enrolled in a timely manner, especially those patients who interact with the pharmacy via phone and do not regularly visit the pharmacy.

Response to Comment 1: Board staff recommend that this comment be rejected. Board staff notes that the Board continues to receive complaints from patients that indicate they did not authorize enrollment in the program. By only obtain verbal consent, the pharmacy cannot substantiate that the patient authorized enrollment. Written, online, or electronic consent must be obtained. Board staff believes this can be done on paper, through email, through SMS text messaging, or through other electronic means, as along as the record is maintained. Additionally, Board staff does not believe this process will pose an enrollment barrier due to the various technological options available.

Comment 2: Dr. Hensic expressed concern about the requirement to keep a copy of the written consent for one year. Dr. Hensic recommends that the language be amended to require documentation of consent instead. This will allow for verbal consent to be documented with an indicator and the pharmacy can provide records to inspector investigating complaints should issues arise.

Response to Comment 2: Board staff recommend that this comment be rejected. Board staff does not recommend that verbal enrollment be permitted due to the ongoing complaints the Board receives complaints from patients about being enrolled in auto refill programs without the patient's consent for such enrollment.

Comment 3: Dr. Hensic expressed concern about the requirement to provide a written notice summarizing the program at the time of enrollment. She recommends that written notice be provided "no later than with the first prescription dispensed as part of the automatic refill program." Dr. Hensic states that this will allow verbal consent and will be more appropriate timing for patients who are already enrolled in the program and are adding additional medication.

Response to Comment 3: Board staff recommend that this comment be rejected. Again, Board staff does not recommend that verbal enrollment be permitted due to the ongoing complaints the Board receives about unauthorized enrollment. Additionally, Board staff believes that the consumer needs to receive the program information prior to enrolling to make an informed decision to enroll.

Comment 4: Dr. Hensic recommends that section 1715.5(a)(7) be moved to section 1715.5(a)(4)(i) and read "The pharmacy shall provide a method for a patient or patient's agent to withdraw a prescription medication from automatic refill or to disenroll entirely from the program." Dr. Hensic states that these changes would retain the intent of the regulation language while allowing the pharmacy to establish the method within their policies and procedures on how patients or patient's agent can disenroll.

Response to Comment 4: Board staff recommend that this comment be rejected. Board staff further recommend that withdraw or disenrollment from the auto-refill be completed via written, online, or electronic means with a confirmation being provided to the patient. As the Board continues to receive complaints that patients have been unable to disenroll from the program after repeated requests. As recommended to be amended, this requirement, will provide confirmation to the patient or patient's agent that they have been removed from the program. Board staff believe this confirmation to be patient can be as simple as screen print, text, email, or other means determined by the pharmacy.

Comment 5: Dr. Hensic recommends the section 1715.5(a)(8) be edited to read: "~~T~~**Upon patient or patient agent's request, t**he pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication ~~refilled~~ **dispensed** through the program ~~if~~ **after withdrawal or disenrollment from the program.** ~~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.~~"

Dr. Hensic states that her proposed amendments retain the intent of the regulation but address the times that the patient will still want the medication that was dispensed via the program despite it being done so after withdrawal or disenrollment. She states that adding "upon request" would clarify that the refund would be issued if the patient is actively seeking a refund. Dr. Hensic believes that "pharmacies should not be held responsible for filling prescriptions for which a patient did not provide clear communication regarding a request to withdrawal, or disenroll entirely, from the program."

Response to Comment 5: Board staff recommend that this comment be rejected. Board staff does not agree that the patient should have to request the refund. If the pharmacy was notified that the patient did not want the medication, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription, the patient should receive a refund.

Written Comments from John Michael O'Brien, PharmD.

Comment 1: Dr. O'Brien expressed concern that the Board has incorrectly stated the Federal Auto-Ship Policy.

Response to Comment 1: Board staff recommend that this comment be rejected. Other than stating that the Federal Centers for Medicare & Medicaid Services proposed new regulations in 2013 resulting in new rules for Medicaid consumers enrolled in auto-refill. Board staff was unable to locate any other reference within the rulemaking to the Federal Auto-ship policy within the Initial Statement of Reasons or Notice of Proposed Action. Staff notes that CMS released a Draft CY 2000 Call Letter to allow mail order pharmacist to auto-ship refills under specified conditions. Such conditions included a require for members to confirm enrollment in the auto-ship program at least annually and also requires plan sponsors to sent two reminders to the beneficiary well in advance of shipments. With this program, members are permitted to choose to participate or none, all or a subset of their medications.

Comment 2: Dr. O'Brien states that the Board's auto-refill regulation conflict with the Global Medi-Cal DUR Board recommendations and the California Department of Health Care Services (DHCS) is considering following the DUR Board's recommendations.

Response to Comment 2: Board staff recommend that this comment be rejected. Board staff notes that DHCS has not adopted any policy.

Comment 3: Dr. O'Brien states that the Board's auto-refill regulation is in response to over 100 consumer complaints; however, 330 million prescriptions were filled in California. Dr. O'Brien states that the proposed regulation will impact medication adherence without a fiscal impact benefit.

Response to Comment 3: Board staff recommend that this comment be rejected. This regulation sets forth the parameters for auto refill program.

<u>Written Comments from Lorri Walmsley, RPh, Walgreens.</u>

Comment 1: Ms. Walmsley identified the benefits of auto-refill programs as medication adherence and better workflow management in the pharmacy. Ms. Walmsley does not agree that auto-refill programs increase the amount of unused pharmaceutical waste and recommends that the Board consider the Texas Board of Pharmacy regulation text (provided in original comment). Further, Ms. Walmsley recommended the following changes to the Board's regulation:

1715.5

(a)(2) ~~The patient or patient's agent shall enroll by written, online, or electronic consent to participate in the program.~~ The patient or the patient's agent must affirmatively indicate that they wish to enroll in such program.

(3) ~~The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.~~ The pharmacy shall discontinue the automatic refill program when requested by the patient or the patient's agent.

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

~~(6) 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.~~

~~(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.~~

(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 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.

~~(9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.~~

Response to Comment 1: Board staff recommend that this comment be rejected. The regulation language used in Texas does not provide many of the consumer protections included in the Board's proposal, including its lack of requirements for documentation, education of a patient about the prior to enrollment. Further, the recommended language also offered by the commenter is extremely broad with little to no documentation retained for consumer protection or enforcement purposes. Additionally, the commenter's recommended language does not address the continued problem of patients being enrolled in auto-refill without their consent and being unable to disenroll in the program.

4. Board staff recommended modified text

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

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(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.

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.

5. The proposed text released for 45-day public comment.

Title 16. BOARD OF PHARMACY
Proposed Text

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) The patient or patient's agent shall enroll by written, online, or electronic consent to participate in the program.

(3) The pharmacy shall keep a copy of the written 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) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

(6) 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.

(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.

(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 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.

(9) A pharmacy shall make available any written 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.

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.