TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Automatic Refill Programs

Section Affected: Title 16 California Code of Regulations (CCR) section 1717.5

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on July 17, 2020, and ended on August 31, 2020. The board's notice indicated that the board did not intend to hold a hearing on the matter unless requested. The board did not receive a request for a hearing during the comment period.

During the 45-day comment period, the board received several comments. At the September 17, 2020 board meeting, the board considered the comments and amended the regulation text to: (1) ensure a patient is notified of the patient's rights regarding removal of a prescription from the automatic refill program before enrolling in the program (informed consent); (2) include an option for electronic processes (notices and enrollment); (3) require proof be provided to a patient of withdrawal or disenrollment from the program; and (4) include an exemption for adult correctional facilities and juvenile detention facilities.

The board voted to initiate a 15-day public comment period, which commenced on September 25, 2020 and concluded on October 10, 2020. During the 15-day comment period, the board received several comments. At the October 27-28, 2020 board meeting, the board considered the comments submitted and determined that no additional modifications to the text were appropriate. The board voted to adopt the modified text as noticed for public comment on September 25, 2020.

First Modified Text

Subdivisions were renumbered as needed due to stricken text.

The board amended subdivision (a)(1) to remove the list of medications that may be refilled through the program. The board agreed with several comments received during the 45-day comment period and determined that maintaining the list of medications within the policies and procedures was not necessary. This will permit the pharmacy to establish the specific procedures for their pharmacy and their patients.

The board amended subdivision (a)(2). The board moved previous subdivision (a)(4) and combined it with subdivision (a)(2). Additionally, the board amended the language to change “when a patient enrolls” to “before a patient enrolls” to ensure the patient is provided the notice about the program prior to enrolling. Further, the board added the term “informed” to “consent” and added “for each prescription” at the end of the language.

The board determined that the program summary, including how to withdraw or disenroll from the program prior to enrolling, is necessary to ensure informed consent by the patient. Informed consent is necessary to ensure the patient has been educated about the auto-refill program and is making an informed decision about whether to enroll in the program or not. Additionally, this will ensure that a patient receives information about withdrawing or disenrolling should the patient change his or her mind in the future. The education of the patient or patient’s agent is important to reduce confusion and ensure the understanding that the prescription will be automatically refilled and the steps a patient needs to take in the event the patient no longer wishes the prescription be enrolled in the program. Further, the board determined that informed consent was required for each prescription enrolled in the program. A patient or the patient’s agent must have the option to enroll by prescription instead of a blanket enrollment. It may not be appropriate for all medications to be enrolled or the patient simply may not want all their prescriptions enrolled in the program. The board believes informed consent can be done on paper, by email, by SMS text messaging, or by other electronic means, as along as the pharmacy maintains a record. The board does not believe this process will pose an enrollment barrier due to the various technological options available.

The board amended subdivision (a)(3) to add “electronic informed” after “written.” The board added this phrase to align the record maintenance with the enrollment informed consent in subdivision (a)(2). The record can be maintained on paper, by email, by SMS text messaging, or by other electronic means. The board does not consider maintaining the records to be an administrative hurdle due to the various technological options available. The pharmacy can maintain the records that meets the needs of the pharmacy.

The board relocated subdivision (a)(4) with subdivision (a)(2) as explained above.

The board amended previous subdivision (a)(6), now subdivision (a)(5), to add “or electronic” to align the requirement with the electronic notice aspects of subdivisions (a)(2) and (a)(3). Due to the various technological options available, the board determined that the notification should not be limited to written notification. Adding the electronic option allows pharmacies to use other methods, including email, SMS text messaging, or other electronic means, that meet the needs of the pharmacy.

The board amended previous subdivision (a)(7), now subdivision (a)(6), to add the requirement for the pharmacy to document and maintain a patient or patient’s agent’s withdrawal or disenrollment for one year. Additionally, the pharmacy must provide confirmation to the patient or patient’s agent. The board has continued to receive

complaints from consumers stating they repeatedly request to disenroll from the program and are unable to do so. Therefore, the board decided to require pharmacies to retain documentation and provide a copy to stem consumer complaints.. This requirement will provide confirmation to the patient or patient's agent that they have been removed from the program. This confirmation to be patient can be as simple as a screen print, text, email, or other means determined by the pharmacy.

The board amended previous subdivision (a)(8), now subdivision (a)(7), to change the word "is" to "was" and the word "and" to "or" with respect to refunds. The board determined that a patient, patient's agent, or payer for the prescription medication should receive a refund if the pharmacy filled/dispensed the prescription after the pharmacy was notified that the patient did not want the refill or the pharmacy was notified of withdrawal or disenrollment from the program. The word changes clarify that the pharmacy must be notified prior to refilling the prescription to qualify for a refund.

The board amended previous subdivision (a)(9), now subdivision (a)(8) to add "electronic" to the notification requirement. As in previous subdivisions, adding the electronic option allows pharmacies to use other methods, including email, SMS text messaging, or other electronic means, that meet the needs of the pharmacy.

Subdivision (c) was added to exempt adult correctional facilities and juvenile detention facilities from complying with the auto-refill provisions provided that they have written policies and procedures in place that detail the enrollment and refusal of the medication. This exemption is consistent with a similar exemption within CCR section 1707.2(b)(3) and is consistent with the Federal Receivership stipulation (included with the comments from commenter Gregory B. Doe, Pharm.D., California Correctional Health Care Services).

Second Modified Text

Subdivisions were renumbered as needed due to stricken text.

Subdivision (a)(2) was amended to clarify the term "each prescription." The term now reads "each new prescription wherein there is a change in the prescription medication, strength, dosage form, or directions for use." This is consistent with section CCR section 1717(b)(4). The board determined that the "prescriber" as listed in 1717(b)(4) should not be included in the auto refill consent requirement as the prescriber can frequently change within medical groups if a prescriber is out of the office and another prescriber is covering the office. As this prescriber change may be a temporary change, requiring another consent would not be necessary.

Subdivision (a)(3) has been added and reads "For each prescription to be refilled through the program, the pharmacy shall obtain annual renewal of each prescription from the patient or patient's agent no later than 12 months after the prescription was enrolled in the program." The board determined that annual renewal of consent is required for consistency with The Centers for Medicare and Medicaid Services (CMS)

Draft Calendar Year (CY) 2000 Call Letter, which allows mail order pharmacists to auto-ship refills under specified conditions. Such conditions included a requirement for members to confirm enrollment in the auto-ship program at least annually and requires plan sponsors to send two reminders to the beneficiary well in advance of shipments. With this Medicaid auto-ship program, members are permitted to choose to participate or not, and include all or a subset of their medications.

Finally, during the review of the regulation text, the board determined that the terms "prescription" and "prescription medication" should be amended within several subdivisions, specifically, (a)(8), (a)(9), (b), and (c), for clarity in the language to ensure that the terms were grammatically appropriate. The intent of the language is for the term "prescription" to reference the document issued by the prescriber for the prescription. The term "prescription medication" is the reference the actual medication dispensed to the patient.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the board does not have nor does it maintain data to define if any of its licensees are "small businesses" as defined in Government Code section 11342.610, the board determined that any adverse economic impact will not be significant. The proposed regulation establishes minimum standards for pharmacies offering the optional automatic refill programs. The pharmacy can use electronic or written documentation based on the needs of the pharmacy established by the pharmacy's policies and procedures.

Economic Impact Statement

The board does not anticipated large chain stores and pharmacies to incur additional costs because these facitilies already provide automatic refill services to consumers and currently have information technology (IT) systems in place to provide the notice and consent form, as specified, and currently have existing IT systems in operation to add a comment to a receipt or to send a text message/email to inform the consumer the prescription has been filled through an automatic refill process. As a result, no additional costs are anticipated for these pharmacies.

However, the board notes most small independent pharmacies do not currently provide automatic refill services. As a result, these pharmacies opting to provide automatic refill services may need to purchase IT systems or paper-based forms to comply with the regulations, as specified. The board estimates one-time IT costs of up to $5,000 and paper-based costs of up to $1,000 per year and ongoing for each location.

Fiscal Impact Statement

The board currently ensures compliance with Pharmacy Law and regulations through robust inspection and enforcement programs. The board indicates the proposed regulations are not anticipated to increase workload or costs to the state.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The board considered not implementing this proposal, but as the board continues to receive consumer complaints regarding auto-refill programs, the board rejected this alternative.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period from July 17, 2020, to August 31, 2020, the board received several comments. The comments were provided in the meeting materials for the September 17, 2020 board meeting, and the board reviewed and considered them. The board amended the regulation text to address some of the concerns raised and voted to initiate a 15-day comment period.

Summary and Response to 45-day Comments:

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: The board accepted this comment in part; however, determined an alternative solution was appropriate. The board struck the language requiring a list of medications that may be refilled through the program. This will permit the pharmacy to establish the specific procedures for the pharmacy and its 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 the board takes a strong stance to protect patients.

Response to Comment 1: The board acknowledged 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board determined that they continue to receive complaints from patients that indicate 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. The board 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, the board 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, written consent is required for every prescription. The board amended 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board determined 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. The board does not believe this needs to be a time-consuming process.

Written Comments from Patricia Colburn

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: The board acknowledged the commenter's support of the regulation.

Written Comments from Clint Hopkins, PharmD., Pucci's Pharmacy

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 (section 1715.5(a)(6)) as this would allow email consent to avoid excessive paper waste of printing the notices.

Response to Comment 1: The board accepted this comment and amended the section 1715.5(a)(6) 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 considered this comment and determined that no changes were necessary in response to this comment. The board does not possess sufficient information to answer the commenters question based on the facts provided.

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: The board considered this comment and determined this comment be rejected in part as it is outside the scope of this regulation. This regulation is not addressing auto-delivery of medications. Further, the board amended the regulation text to address the second part of the comment with respect to requiring consent for enrollment of each prescription.

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: The board acknowledged 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 urged the board to abandon the rulemaking. The commenter indicated that if the regulation was going to continue, they recommended the amendments (see comments 2 – 6).

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon 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 section 1717.5(a)(1).

Response to Comment 2: The board considered this comment and amended the text to remove the requirement to maintain the list of drugs from the text. This will permit the pharmacy to establish 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 section 1717.5(a)(2).

Response to Comment 3: The board considered this comment and determined that no changes were necessary to the text based thereon. 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. The board 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, the board 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, fax, text, sign, or other form of communication, directs the patient to an electronic summary of the program"* be added to section 1715.5(a)(4).

Response to Comment 4: The board considered this comment and amended the text to address the concerns. The board moved subdivision (a)(4) to (a)(2) so the patient will receive the notice of the program prior to enrolling. Additionally, the board amended the text 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board does not agree that the requirement to conduct a drug regimen review conflicts with Title 16, section 1707.3. The board's policy decision with the development of the regulation is to ensure consumer protection. Performing drug therapy review will ensure issues like 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: The board considered this comment and amended the text to include electronic notification to address the concerns. The board 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.

Written Comments from Judith Wright

Comment 1: The commenter expresses support for the proposed regulation. The commenter states 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: The board acknowledged 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: The board considered this comment and determined that no changes were necessary. The board determined that the problems with auto-refill programs continue to exist as the board continues to receive complaints from patients about auto-refill 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 section 1717.5(a)(1) to read ".... a list of medication classes that are ineligible to be refilled...."

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. The board determined that the requirement to maintain 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board 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: The board considered this comment and amended the language to address the concerns. The board determined that the requirement to maintain 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 electronic notices be permitted via SMS, phone, digital dashboards, online messages, and smartphone apps.

Response to Comment 2: The board considered this comment and amended the language to address the concerns. The board amended the regulation text to add "or electronic" where appropriate to allow 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: The board considered this comment and deleted the the requirement to maintain the list of drugs from the text. This will permit the pharmacy to establish the specific procedures for the pharmacy and its 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 section 1717.5(a)(2) to increase communication options.

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. The board determined 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. The board believes this can be done on paper, by email, by SMS text messaging, or by other electronic means, as along as the pharmacy maintains a record. Additionally, the board 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: The board considered this comment and amended the language to read “written or electronic informed consent...” This will allow the consent to be stored electronically which would be accessible to the pharmacy and board inspectors if the board receives an auto-refill complaint.

Comment 4: Ms. Michelin expressed concern about the requirement for written notification in subdivisions (a)(4) and (a)(6). She states 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 a pharmacy.

Response to Comment 4: The board considered this comment and determined that no changes were necessary to the text based thereon. The board 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, the board 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board does not agree that the requirement to conduct a drug regimen review conflicts with Title 16, section 1707.3. The board's policy decision with the development of the regulation is to ensure consumer protection. Performing drug therapy review will ensure issues with duplication in therapy, drug interactions, 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: The board considered this comment and determined that no changes were necessary to the text based thereon. 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., 16 CCR Section 1707.6.

Written Comments from Lori Hensic, PharmD., Scripps

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 section 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: The board considered this comment and determined that no changes were necessary to the text based thereon. 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, by email, by SMS text messaging, or by other electronic means, as along as the pharmacy maintains a record. 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 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board determined that verbal enrollment should not be permitted due to the ongoing complaints the board receives 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: The board considered this comment and determined that no changes were necessary to the text based thereon. Again, the board determined that verbal enrollment should not be permitted due to the ongoing complaints the Board receives about unauthorized enrollment. Additionally, the board determined that consumers need 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 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: The board considered this comment and amended the regulation to allow for withdraw or disenrollment from the auto-refill to be completed via written, online, or electronic means with a confirmation being provided to the patient. The board continues to receive complaints that patients have been unable to disenroll from the program after repeated requests. This requirement will provide confirmation to the patient or patient's agent that they have been removed from the program. The board believes 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 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board 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 was 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 within the board's Initial Statement of Reasons (ISR).

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. The board stated in the ISR that the Federal Centers for Medicare & Medicaid Services proposed new regulations in 2013 resulting in new rules for Medicaid consumers enrolled in auto-refill, which is correct. The board was unable to locate any other reference to the Federal Auto-ship policy within the ISR or Notice of Proposed Action. The Centers for Medicare and Medicaid Services (CMS) released a Draft Calendar Year (CY) 2000 Call Letter to allow mail order pharmacists to auto-ship refills under specified conditions. Such conditions included a requirement for members to confirm enrollment in the auto-ship program at least annually and requires plan sponsors to send two reminders to the beneficiary well in advance of shipments. With this Medicaid auto-ship program, members are permitted to choose to participate or not, and include all or a subset of their medications.

Comment 2: Dr. O'Brien states that the Board's auto-refill regulation conflicts 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: The board considered this comment and determined that no changes were necessary to the text based thereon. The board determined that DHCS has not formally adopted any policy related to auto-refill programs Further, as Dr. O'Brien states in his comment, DUR recommends annual consent to automatically refill medications and the board's regulation also requires annual consent.

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 benefit.

Response to Comment 3: The board considered this comment and determined that no changes were necessary to the text based thereon. This regulation sets forth the parameters for auto-refill programs. Additionally, the board continues to receive complaints from patients about auto-refill programs and this shows an ongoing need for these regulations.

Written Comments from Lorri Walmsley, RPh, Walgreens.

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:

(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: The board considered this comment and determined that no changes were necessary to the text based thereon. 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 and education of a patient about the program prior to enrollment. Further, the recommended language is extremely broad with little to no documentation required to be 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.

Written Comments from Gregory B. Doe, PharmD., California Correctional Health Care Services

Comment 1: Dr. Doe indicated that a federal receivership regarding correctional healthcare stipulates that automatic refills are "not to be dependent on patient requests." Dr. Doe requested an exemption be added to the board's auto-refill regulation for inmates of an adult correctional facility or a juvenile detention facility. Specifically, he proposed: "Automatically refilling prescription medications for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section consistent with the policies and procedures of the facility."

Response to Comment 1: The board considered this comment and amended the language to address the concerns. The board added new subdivision (c) to exempt adult correctional facilities and juvenile detention facilities.

First 15-Day Public Comment Period

During the public comment period from September 25, 2020, to October 10, 2020, the board received several comments. The comments were provided in the meeting materials for the October 27-28, 2020 board meeting, and the board reviewed and considered them.

Summary and Response to 15-day Comments:

Written Comments from Anthony Lorenzana, PharmD.

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

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. As authorized by section 1717.5(a)(2), prescribers may serve as the patients' agent should the patient authorize the prescriber to do so.

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

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. The regulation is silent on how the records are stored by the pharmacy. Therefore, the pharmacy can establish the specific procedures that meet the needs of their pharmacy and patients.

Written Comments from Emily Haugh, PharmD., PillPack

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

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. As the term "medication" is overly broad, the term would not be appropriate here. As with the duty to consult (16 CCR section 1707.2), if a new prescription is issued for a medication already enrolled in automatic refill and the medication is the same dosage form, strength, written instructions, and within the same year, a new consent for automatic refill would not be required. To avoid duplicative drug therapy, a patient needs to give consent to enroll annually and if there is a change in dosage form, strength, or written instructions.

Written Comments from Rachel Michelin, California Retailers Association

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

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. The regulation will not become effective until after it is approved by the Office of Administrative Law. Further, the board determined that a delayed effective date of January 1, 2022 is appropriate to ensure pharmacies are compliant upon the effective date of the regulation. A pharmacy may opt to but is not required to proactively make changes to meet the regulation requirements prior to its effective date.

Comment 2: Ms. Michelin requests clarification on section 1715(a)(2), specifically, regarding the phrase "each prescription" and whether the phrase means each

"medication." Ms. Michelin states that managing automatic refill medications by prescription number will be confusing to patients and could lead to errors.

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. As the term "medication" is overly broad, the term would not be appropriate here. As with the duty to consult regulation (16 CCR section 1707.2), if a new prescription is issued for a medication already enrolled in automatic refill and the medication is the same dosage form, strength, written instructions, and within the same year, a new consent for automatic refill would not be required. To avoid duplicative drug therapy, a patient needs to give consent to enroll annually and if there is a change in dosage form, strength, or written instructions. The regulation does not require management of automatic refills by prescription number.

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

Response to Comment 3: The board considered this comment and determined that no changes were necessary to the text based thereon. The board previously reviewed and considered this issue during the 45-day comment period. The board continues to receive complaints that patients have been unable to disenroll from the program after repeated requests. This requirement will provide confirmation to the patient or patient's agent that they have been removed from the program. The board believes this confirmation to be patient can be as simple as screen print, text, email, or other means determined by the pharmacy.

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

Response to Comment 4: The board considered this comment and determined that no changes were necessary to the text based thereon. As the regulation states, if the pharmacy was notified that the patient did not want the medication and the pharmacy still filled the prescription, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription, the patient should receive a refund as the pharmacy was notified prior to the filling/dispensing and should not have filled/dispensed the prescription. A detailed explanation of the refund requirement is available is contained in the Initial Statement of Reasons (page 5).

Written Comments from Lorri Walmsley, RPh, Walgreens.

Comment 1: Ms. Walmsley expresses concern about the written or electronic notice required to be provided to the patient before enrolling in an automatic refill program. Ms. Walmsley states that Walgreens allows patients to enroll by phone via their interactive

voice response (IVR) refill system. Ms. Walmsley recommends the language be amended to read “Before a prescription is dispensed to the patient for the first time using an automated refill program,” replacing “Before a patient enrolls[.]”

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. As enrollment through the IVR would be considered electronic, it appears that IVR messaging could be modified to provide a description of the program and the process to withdraw or disenroll to the patient or patient’s agency before the patient or patient’s agent selects the option to enroll. If the patient listens to the recording about the program and opts to enroll, that would be considered electronic consent.

Written Comments from Rob Geddes, PharmD., Albertsons

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

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. The board previously reviewed and consideration of this topic during the 45-day comment period. Additionally, the data provided at the previous board meeting was a sample of data and was not the totality of the complaints the board continues to receive. The previous review and consideration of this issue is available in the September 2020 Board’s meeting materials (agenda item VII.b.), and webcast, which can be found on the Board’s website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

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

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. The regulation will not become effective until after it is approved by the Office of Administrative Law. Further, the board determined that a delayed effective date of January 1, 2022 was appropriate to ensure pharmacies are compliant upon the effective date of the regulation. A pharmacy may opt to but is not required to proactively make changes to meet the regulation requirements prior to its effective date.

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

Response to Comment 3: The board considered this comment and determined that no changes were necessary to the text based thereon. The board previously reviewed and consideration of this issue during the 45-day comment period. This requirement will provide confirmation to the patient or patient's agent that they have been removed from the program and does not have to require programming enhancements. The confirmation can be as simple as screen print, text, email, or other means determined by the pharmacy that meets the needs of their practice. The previous review and consideration of this issue is available in the September 2020 Board's meeting materials (agenda item VII.b.), and webcast, which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

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

Response to Comment 4: The board considered this comment and determined that no changes were necessary to the text based thereon. As the regulation states, if the pharmacy was notified that the patient did not want the medication and the pharmacy still filled the prescription, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription, the patient should receive a refund, as the pharmacy was notified prior to the filling/dispensing and should not have filled/dispensed the prescription. A detailed explanation of the refund requirement is available is contained in the Initial Statement of Reasons (page 5).

Second 15-Day Public Comment Period

During the public comment period from May 28, 2021, to June 12, 2021, the board received several comments. The comments were provided in the meeting materials for the June 17, 2021 board meeting, and the board reviewed and considered them.

Summary and Response to Second 15-day Comments:

Written Comments from Thomas Finch, PharmD., Save Mart

Comment 1: Dr. Finch believes that that requirement for annual consent for auto refill required by (a)(3) creates an unnecessary burden on pharmacies and patients as prescribers already have to confirm the prescription every 12-months. Dr. Finch believes that the add language will result in reams of additional paperwork when the prescriber has already confirmed it in necessary.

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. The board refers the commenter to the board's response regarding annual consent in the comments made by Dr. John Michael O'Brien during the 45-day comment period. The previous review and consideration for this topic is available with the September 2020 Board's meeting

materials (agenda item Vii(a) – comments 1 and 2), and webcast, which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Comment 2: Dr. Finch indicates that changing the terms "and" for "or" in subsection (a)(8) creates unnecessary ambiguity in the language and will burden pharmacies with by requiring refunds be issued when notice was not provided.

Response to Comment 2: This comment is outside of the scope of the text the Board proposed to modify during this comment period. The board refers the commenter to the board's response to the comment made by Ms. Michelin during the first 15-day comment period. The previous review and consideration for this topic is available with the October 2020 Board's meeting materials (agenda item X – comment number 4), and webcast, which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Written Comments from Rob Geddes, PharmD., Albertsons

Comment 1: Dr. Geddes has requested that the implementation date be moved from January 1, 2022 to July 1, 2022 to allow additional time for implementation.

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. The board agreed to modify the effective date to July 1, 2022.

Comment 2: Dr. Geddes requests that (a)(7) be amended to remove the requirement to provide confirmation of disenrollment from the auto refill program to the patient as it would require programming changes.

Response to Comment 2: This comment is outside of the scope of the text the board proposed to modify during this comment period. The board refers the commenter to the board's response to the comment made by Dr. Hensic's comment during the 45-day comment period. The previous review and consideration for this topic is available with the September 2020 Board's meeting materials (agenda item Vii(a) – comment number 4), and webcast, which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Comment 3: Dr. Geddes requests that (a)(8) be amended to remove the requirement to provide a refund to the patient if the pharmacy was notified that the patient did not want the refill.

Response to Comment 3: This comment is outside of the scope of the text the Board proposed to modify during this comment period. The board refers the commenter to the board's response to Dr. Geddes previous comment during the first 15-day comment period. The previous review and consideration for this topic is available with the October 2020 Board's meeting materials (agenda item X – comment number 4), and webcast,

which can be found on the Board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Written Comments from Rachel Michelin, California Retailers Association

Comment 1: Ms. Michelin has requested that the implementation date be moved from January 1, 2022 to July 1, 2022 to allow additional time for implementation.

Response to Comment 1: This comment is duplicative of a comment from Dr. Geddes, during this 15-day comment period. The Board incorporates its response to that comment herein by reference.

At its June 17, 2021 meeting, after reviewing and considering all comments in the record, the board voted to adopt the regulation text as noticed for public comment on May 28, 2021. The Board voted to approve all comment responses, and voted to modify the effective date of the regulation to July 1, 2022. Additionally, the board delegated to the Executive Officer the authority to make technical and nonsubstantive changes as necessary to complete the rulemaking file.