CALIFORNIA COMMUNITY PHARMACY COALITION
Patients. Access. Equity
PROJECT OF THE CALIFORNIA RETAILERS ASSOCIATION

December 2, 2024

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

Via Email: PharmacyRulemaking@dca.ca.gov

Re: Quality Assurance Program Proposed Regulation – Modified Text

Dear Ms. Martinez,

On behalf of the California Community Pharmacy Coalition (CCPC), I write to register the following comments and suggested modifications to the Board of Pharmacy's modified text to the proposed regulation related to quality assurance programs.

The CCPC recognizes the Board's mission to protect pharmacy consumers. CCPC members have implemented Quality Assurance (QA) programs as required by the Board to help prevent medication errors and improve pharmacy services for Californians. We understand that the goal of the proposed QA program regulation is to "ensure a more robust review of the circumstances surrounding each error and identification of possible contributing factors, including workload, to help prevent future medication errors." While we appreciate this goal, we are concerned about the ability of our members to comply with many of the proposed requirements, some of which are vague and overly broad, and the impact to the workforce upon which our members rely for delivering care to the citizens of California. However, we do acknowledge and appreciate the Board's acceptance of some of the suggestions outlined in our September 23 letter and we thank the board for obtaining a wide variety of perspectives on this topic through the public rulemaking process. We respectfully ask the board to review our concerns and proposed amendments as outlined below.

Recommendations Related to Modified Text

Delayed Implementation:

We request delayed implementation to allow our members sufficient time to develop IT solutions to automate some of the required information. Currently, this would be a very manual process, so we request additional time to update our systems in order to comply.

Define "Automation"

The modified text does not contain a definition of "automation." We request that the requirement to capture whether automation is involved be removed or defined because automation is utilized at some level of every prescription. It appears as though the Board is referring to large-scale automation used at central fill or mail order pharmacies. As written, "automation" could mean a counting machine or a pharmacy's operation software. At a minimum, if the Board chooses not to define "automation," we request an FAQ to delineate what type of automation the Board intends to capture with this regulation.

§ 1711. Quality Assurance Programs

We request that the Board provide clarity regarding the requirements for the timeframe of the investigation of an event and the submission of a quality assurance review to the Board. We feel that 2 business days is not a sufficient amount of time from the date of discovery of an event to complete its investigation. We feel the investigation should commence immediately, but additional time should be allotted for the completion of the quality assurance review. We also request clarity regarding when the information must be reported, e.g. after the investigation is completed?

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than ~~2 business days~~ **72 hours** from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

We also request the board to remove the requirement for the date, location, and participants in the quality assurance review, as this is often not systematically tracked and would require costly updates to currently used systems for recording and communicating the quality assurance review. Pharmacies do, however, currently ensure that all team members involved or responsible for an event, even if tangentially, participate in the quality assurance review. However, the additional information required is an unnecessary administrative burden that does not contribute to improved quality assurance outcomes.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
~~**(1) The date, location, and participants in the quality assurance review;**~~

Notification to the patient of an error and ensuring they are well informed on how to avoid injury or mitigate the error is an essential component to a CQI plan, however, pharmacies do not generally require the documentation of detailed information related to patient contact unless harm has actually occurred.

(2) The pertinent data and other information relating to the medication error(s) reviewed ~~**and documentation of any patient contact required by subdivision (c)…**~~

We support the board's intent to have standardization of error reporting, however, often the processes and procedures for error reporting may be proprietary and confidential, as well as specific to each pharmacy. We request this language is removed to ensure that each pharmacy may continue to utilize their current procedures and remain confidential for each organization.

(D) The type of error that occurred. ~~To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors.~~

We find this section of the rule to be especially concerning as written. The tracking of the workload as described is unattainable and impossible to comply with. Having a shared service process, the clinical functions are often completed by pharmacists tethered to other pharmacies whose work is being disseminated to various dispensing pharmacies. Their work also is not necessarily completed on the same day the medication is dispensed. If the error occurs on the front end, it does not seem appropriate to report the dispensing pharmacy volume and vice versa.

Not all pharmacy systems can differentiate between prescriptions sold that were processed at a central fill facility, how many consultations or clinical activities that were completed, or if the prescriptions dispensed were refills or new. There are several activities that are not tracked in any systems. For example, the number of calls made to physician's offices for clarifications/refills, outreach to a patient to discuss medication adherence, over-the-counter consultations, voicemails, phone call questions from a patient or prescriber. These items would need to be manually tracked by the pharmacy team and would increase workload and administrative burdens for the community pharmacist.

(E) The volume of workload completed by the pharmacy staff on the date of the error, ~~**including clinical functions**~~. If the date of the error is unknown, the average volume of workload completed daily shall be documented. ~~**For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.**~~

While recommended changes made by the pharmacy's patient safety organization, these changes are not specifically communicated back to the individual personnel in the pharmacies. Often changes are made broadly by the Patient Safety Organization to policies, procedures, the systems, or overall processes to reduce errors. However, the changes are not necessarily communicated for every change made as a result of recommendations from the quality assurance report. Additionally, if an individual pharmacy were to handle the changes it could result in de-standardization of the CQI process across the pharmacies.

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. ~~The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.~~ Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report.

Generally, the quality assurance records are retained and maintained by the pharmacy's patient safety organization and are protected from discovery. Additionally, many systems do not maintain these records for 3 years and costly system enhancements would be required if this language is implemented. It is also unclear what type of record this would be. Would there be a form that would be filled out and submitted to ISMP that could be downloaded and saved?

(e) shall be immediately retrievable in the pharmacy for at least ~~three years~~ **one year** from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

AB 1286 requires errors to be submitted to a board-approved patient safety organization, not directly to the Board. We request the following amendment to align with the law. And further consider changing the timeframe of retention back to one year as previously established in the prior comments.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one three~~ one year from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the **Board-approved patient safety organization (PSO)** within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the q

We also ask the board to provide clarity on this section as to what the intent of this language is and how the compliance with this section will be used as a mitigating factor. This language is ambiguous and may prevent the board from completing investigations and evaluations of medication errors in an unbiased and fair manner.

g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

The California Community Pharmacy Coalition is a project of the California Retailers Association and was formed to promote the positive impacts community pharmacies have within California's healthcare system by working on legislation and regulations that will expand access opportunities for community pharmacy services including in hard to reach, under-served areas where Californians often have very limited options for healthcare.

Thank you for taking our comments into consideration. Please do not hesitate to contact me at sarah@calretailers.com if you have any questions.

Sincerely,

Sarah Pollo
Policy Advocate
California Retailers Association

cc: Seung Oh, President, Board of Pharmacy
Anne Sodergren, Executive Officer, Board of Pharmacy
Julia Ansel, Deputy Executive Officer, Board of Pharmacy