February 11, 2025

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 – Second Modified Text

Dear Ms. Martinez,

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

The CCPC has commented on the last two drafts – back in December 2024 and in September 2024 – and wanted to also acknowledge and appreciate the Board's acceptance of some of the suggestions outlined in our September letter and many of our requests we included in the December letter. We thank the board for obtaining a wide variety of perspectives on this topic through the public rulemaking process and appreciate and support the Board's efforts to improving patient safety through pharmacy quality assurance programs designed to reduce medication errors and improve the overall quality of medication dispensing through monitoring and improvement strategies.

We respectfully ask the board to review our additional concerns and proposed amendments on the current draft regulatory text.

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§ 1711. Quality Assurance Programs

The CCPC requests that the Board reconsider and remove the requirement to record date and location of the quality assurance review. This requirement poses significant challenges, as this information is often not systematically tracked within existing systems, and updating these systems to accommodate such detailed data would incur substantial costs and administrative burden. Pharmacies, however, already ensure that all relevant team members—whether directly or tangentially involved in an event—are included in the quality assurance review process and record their participation in the review. The inclusion of additional, non-essential details like date and location adds an unnecessary layer of complexity without demonstrable improvements to the quality assurance outcomes. Removing this requirement would streamline the process, reduce administrative overhead, and allow pharmacies to focus more effectively on the core objectives of quality assurance, namely improving patient safety.

(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;

The CCPC also respectfully requests that the Board reconsider the requirement to document whether automation is involved in the dispensing process. Automation is integrated at some level into nearly every prescription, whether through systems for data entry, drug dispensing, inventory management, or prescription delivery tracking. The current definition of 'automation' is overly broad and imprecise, which may lead to confusion and potential misinterpretation of the Board's intent. It is unclear whether the Board seeks to track specific forms of automation, such as automated counting or dispensing machines, or whether it aims to capture all automated systems involved in the process. Given the pervasive role of automation in modern pharmacy practice, mandating documentation of this factor would not yield meaningful insights and could impose unnecessary administrative burdens. Moreover, the mere use of automation does not inherently suggest a causal relationship with dispensing errors. While collecting additional data points can be valuable in identifying areas for quality improvement, capturing excessive or irrelevant data is often counterproductive and does not necessarily contribute to more effective analysis. We recommend that the Board clarify its objectives and focus on more targeted and actionable data points, ensuring that reporting requirements are both relevant and conducive to improving the quality of care.

~~(B) The use of automation, if any, in the dispensing process.~~

The CCPC fully supports the Board's intent to promote standardization in error reporting, as it is crucial for improving patient safety and fostering continuous improvement. However, we respectfully request that the language requiring standardized reporting processes be removed, as the specific procedures and processes used for error reporting in each pharmacy are often proprietary, confidential, and tailored to the unique needs of the organization. These processes are developed to ensure that the pharmacy can effectively manage and address errors in a way that aligns with its operational structure. Requiring a one-size-fits-all approach may compromise the confidentiality of sensitive operational procedures and potentially disrupt established practices that are proven to work within the organization. We urge the Board to allow pharmacies the flexibility to continue utilizing their own, confidential error reporting processes while still meeting overarching goals for transparency and patient safety.

(C) 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.~~

The CCPC is concerned by the current form of this rule, particularly the requirement to report the volume or average volume of workload on the date of the error. This is an unrealistic expectation and, in many cases, impossible to integrate into existing pharmacy CQI programs and systems. These limitations make compliance with the proposed requirements not just difficult, but infeasible.

Additionally, numerous essential pharmacy activities are not tracked by any existing systems. Many pharmacy management systems are simply not equipped to differentiate between prescriptions processed at central fill facilities, track the specific number of consultations or clinical activities performed outside of vaccinations, or categorize prescriptions as refills versus new ones. For example, tasks such as phone calls to medical offices for clarifications or refills, outreach to patients regarding medication adherence, over-the-counter (OTC) consultations, voicemail follow-ups, and phone inquiries from patients or prescribers are vital components of patient care, yet are not captured in current pharmacy software. Attempting to manually track these activities would place an overwhelming administrative burden on pharmacies, particularly in high-volume environments where pharmacists are already stretched thin. This additional workload would divert time and resources away from direct patient care, ultimately undermining the quality of service provided to patients. The notion that such extensive tracking can be integrated into continuous quality improvement (CQI) programs is not realistic.

CQI efforts are most effective when they focus on targeted, actionable data points that directly impact patient outcomes and operational efficiency. The broad and arbitrary nature of the proposed reporting of workload would result in an overabundance of data—much of which would be irrelevant to the true drivers of quality improvement. In practice, this would lead to data overload, making it even harder to derive meaningful insights or actionable improvements. We urge the Board to reconsider these requirements and explore more feasible, system-supported methods for monitoring relevant activities. The focus should be on capturing data that reflects the actual demands of modern pharmacy practice, without overwhelming staff or detracting from the primary goal of delivering high-quality, patient-centered care.

~~D) An outpatient pharmacy report must also document the The volume of workload completed by the pharmacy staff on the date of the error, if known, 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, and number of patient consultations given (or an estimate if the exact number of patient consultations is not available), 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.

Request for Clarity on Definitions

Additionally, with regard to (2)(ED) in the second modified text for Quality Assurance Programs, the California Community Pharmacy Coalition would like clarity from the board on the definitions of "outpatient pharmacy", which is not defined in the California rule book and neither is "community pharmacy". Sec. 4001 has a definition of change community pharmacy – 75+ locations and independent community pharmacy for 4 or less locations. We are unclear what a pharmacy is considered under these definitions if a pharmacy has 5-74 locations. If the answer is "community" or "outpatient" that would be a helpful clarification.

Delayed Implementation

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

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 Moo
Policy Advocate
California Retailers Association

cc: Seung Oh, PharmD, President Board of Pharmacy
Anne Sodergren, Executive Officer, Board of Pharmacy
Julie Ansel, Assistant Executive Officer