September 20, 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

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 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.

In addition, passage of these amendments could potentially put pharmacies who are members of Patient Safety Organizations (PSOs) at odds with the requirements set forth in the Patient Safety and Quality Improvement Act of 2005 (PSQIA). PSOs have been established to achieve many of the same goals as the Board is trying to accomplish with these amendments. Reports made to a PSO are designated as Patient Safety Work Product (PSWP), and while each PSO participant can designate which elements of a report are PSWP, they typically include contributing factors, root cause analysis, and corrective action recommendations. Items designated as PSWP cannot be shared by PSO members and inappropriate disclosure could result in fines. Requiring pharmacies to make PSWP available for inspection or submitted to the Board could be considered an inappropriate disclosure.

Our primary and most significant concern relates to new Section 1711(e)(2)(E), which reads as follows:

> (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.

As written, our members would be unable to comply with this requirement. It is incredibly broad, and our member pharmacies do not specifically measure all data elements that are ascertainable in the provision as drafted. Further, it does not provide sufficient notice as to what the Board considers a "mandatory activity". For example, it could capture a task such as taking out the garbage since that is a "mandatory" activity. Collection of this data would also result in an increased administrative burden which is counterintuitive to the goal of this proposal.

Additionally, the separate tracking of central fill prescriptions is not possible. The split processing based on the shared nature of the work does not make local sense; the local community pharmacy and the central fill pharmacy both have shared responsibility and tasks that will be completed on a single prescription. We respectfully request that this section be removed.

The CCPC has additional concerns/suggestions with the proposed regulation as follows:

> Section 1711(e): 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;
>
> (2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c), <u>including</u>
> <u>(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record.</u>
> <u>(B) The names of staff involved in the error.</u>
> <u>(C) The use of automation, if any, in the dispensing process.</u>
> <u>(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.</u>

We recommend replacing the phrase "involved in the error" in (B) to "performing the step(s) in the dispensing process where the error originated and was not caught" because "involved" is overly broad. We also request that the word "automation" in (C) be defined because nearly every prescription has automation involved. Further, the requirement in (D) that the pharmacies' policies and procedures include the category the pharmacy uses for identifying the types of errors could jeopardize pharmacies' confidentiality. The categories pharmacies use for identifying the types of errors are proprietary and specific to each company, so we request that this requirement be removed.

> Section 1711(e)(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. <u>Documentation of the steps taken to prevent future</u> errors <u>shall be maintained as part of the quality assurance report.</u>

Although many of our members contract with Patient Safety Organizations and make changes to systems, workflow, policies and processes, they do not necessarily communicate all steps specifically back to the specific individual in the field. This would be very costly to implement and if the stores were to make process changes in isolation, it could lead to destandardization. Where standardized workflows have built-in safeguards that drive patient safety, de-standardization could actually pose risks to patient safety. For this reason, we request that the documentation requirement be removed.

> Section 1711(f): The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ <u>three</u> years 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 ~~b~~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.

Requiring the record of the quality assurance review to be immediately retrievable in the pharmacy for at least three years would require our members to invest in significant system updates. We request that the timeframe remain one year.

In addition to the concerns and suggested revisions outlined above, we request a one-year delayed implementation of this regulation to allow pharmacies sufficient time to update their policies - and their systems - 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 or Lindsay Gullahorn with Capitol Advocacy at lgullahorn@capitoladvocacy.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