December 12, 2022

The Honorable Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Re: Proposal to Add Business & Professions Code Sec. 4113.1 Related to Medication Error Reporting

Dear President Oh,

The California Retailers Association (CRA) is writing to express concerns with the Medication Error Reduction and Workforce Ad Hoc Committee's statutory proposal to add Section 4113.1 to the Business and Professions Code related to medication error reporting.

Our members appreciate the goals of the Medication Error Reduction and Workforce Ad Hoc Committee to reduce medication errors. While we are supportive of these goals, we do not believe that requiring medication errors to be reported to a single organization – in this case the Institute for Safe Medication Practices (ISMP) - is the appropriate solution. If the Board decides to mandate that pharmacies report medication errors to a third party, we believe pharmacies should have the option to report this information more broadly to any patient safety organization (PSOs).

PSOs were authorized over 15 years ago via the federal Patient Safety and Quality Improvement Act of 2005 as a way to improve patient safety and reduce incidences that put patients at risk. PSOs exist to allow healthcare providers, including pharmacy members, to report medication errors and share best practices associated with these errors with confidentiality. Participating pharmacy members can track and study patient safety data which can help identify patterns, which in turn helps them work toward prevention. This is a critical approach to ensuring patient safety and many community pharmacies already report medication error data to PSOs. According to a recent program evaluation by the Agency for Healthcare Research and Quality (AHRQ), the work of federally listed PSOs and healthcare providers to reduce medication errors is a successful and effective way to increase patient safety.

Requiring pharmacies to report medication error data to a single entity not only contradicts federal law, it could also result in a less robust, comprehensive depiction of the data. If pharmacies are permitted to report data to a PSO of their choice, they can report more detailed information, including sensitive data like the action taken by the pharmacy after the occurrence of the error. For these reasons, CRA recommends that the Board consider the approach adopted by the Virginia Board of Pharmacy, which allows pharmacies to report medication error information to the PSO of the pharmacy's choosing, as outlined below:

18VAC110-20-418. Continuous quality improvement programs.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with § 54.1-3434.03 of the Code of Virginia and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with § 54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on duty of the dispensing error.
b. A pharmacist on duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.
c. A pharmacist on duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error, that may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization, and analysis of the event.
b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18VAC110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.
c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.
d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.
e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:
(1) Dates the analysis was initiated and completed;
(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors; and
(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, online marketplaces, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware, and home stores. Our members include national chains as well as independent retailers from across California. California retail is the state's largest industry, operating in over 505,000 retail stores which accounts for over 25 percent of California's jobs with a combined $542 billion of the state's GDP.

Please do not hesitate to contact Jennifer Snyder or Lindsay Gullahorn with Capitol Advocacy at jsnyder@capitoladvocacy.com or lgullahorn@capitoladvocacy.com if you have any questions.

Sincerely,

Rachel Michelin
President & CEO
California Retailers Association

cc: Anne Sodergren, Executive Officer, Board of Pharmacy