NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

September 23, 2024

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833

Via email: PharmacyRulemaking@dca.ca.gov

Re: Quality Assurance Programs – Amending section 1711 of Title 16, Division 17, Article 2 of the California Code of Regulations

Dear Ms. Martinez,

On behalf of our members operating chain pharmacies in the state of California, NACDS thanks the Board of Pharmacy for the opportunity to submit comments on the Quality Assurance Programs proposed regulations amending section 1711 of Title 16, Division 17, Article 2 of the California Code of Regulations. Although NACDS appreciates the Board of Pharmacy's commitment to improving patient safety through pharmacy quality assurance programs designed to reduce medication errors, NACDS has a number of concerns with the proposed regulations.

Adoption 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 requiring pharmacies to submit PSWP to the Board could be considered an inappropriate disclosure.

Comments and Proposed Changes

We offer the following comments and proposed changes to the proposed regulation:

Proposed changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language. Amend section 1711 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows: § 1711.

Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(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 from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(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;

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

(c)~~;~~, including: Board of Pharmacy Proposed Text Page 2 of 2 16 CCR § 1711 Quality Assurance Programs 4/6/2024

(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.

(B) The names of staff involved in the error.

We recommend replacing the word “involved” with the word “responsible” because “involved” is too broad. Also, we recommend the Board further analyze this amendment to determine whether or not it may conflict the federal Patient Safety Act of 2005 which is built on the premise that a reported incident and the protected information should not be tied back to a healthcare provider to ensure the provider feels comfortable reporting incidents in the future.

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

We recommend the Board define the “use of automation” as this term count be interpreted to be ambiguous.

(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.

This requirement 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.

> (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, pharmacies may be unable to comply with this requirement. It is incredibly broad, and pharmacies do not specifically measure all activities conducted within the pharmacy. The increased administrative burden of collecting these additional data points to measure all activities conducted within the pharmacy is counterintuitive to the objective. We respectfully request that this section be removed.

(3) The findings and determinations generated by the quality assurance review; and,

(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.

We recommend the Board further analyze this amendment to determine whether or not it may conflict the federal Patient Safety Act of 2005. The "documentation" may be designated as Patient Safety Work Product (PSWP).

(f) The record of the quality assurance review, as provided in subdivision

(e) shall be immediately retrievable in the pharmacy for at least three 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 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 pharmacies to invest in significant system updates. Also, we recommend the Board further analyze this amendment to determine whether or not it may conflict with the federal Patient Safety Act of 2005, specifically the role of the Patient Safety Organization (PSO).

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.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section. NOTE: Authority cited: Sections 4005 and 4125, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125 and 4427.7, Business and Professions Code.

We support the Board's efforts to protect patient safety and encourage the Board to consider our comments in support of quality assurance efforts by licensees through patient safety organizations. In addition to the concerns and recommendations outlined above, we request a one-year delayed implementation of this regulation to allow pharmacies sufficient time to update their policies and system to comply. If you have any questions or need additional information, please contact Sandra Guckian, RPh, MS, IOM, Vice President, State Pharmacy & Advocacy, at sguckian@nacds.org or 703-774-4801.

Sincerely,

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President and Chief Executive Officer
National Association of Chain Drug Stores

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

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.