California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1711 Related to Quality Assurance Programs and Review of Comments Received during the second 15-Day Comment Period

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Background:

At the February 7, 2023, Board meeting, the Board approved the proposed regulation text to amend Section 1711 related to Quality Assurance (QA) Programs. This proposal amends the board's regulations regarding quality assurance programs.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on August 9, 2024, which ended on September 23, 2024. Several comments were received during the comment period. The Board reviewed the comments at the November 2024 Board meeting and voted to amend the text in response to the comments received.

Board staff released the revised text for a 15-day comment period on November 15, 2024, which ended on December 2, 2024. One comment was received during this comment period. The Board reviewed the comment at the January 2025 Board meeting and voted to amend the text in response to the comment received.

Board staff released a revised text for a second 15-day comment period on January 27, 2025, which ended on February 11, 2025. Three comments were received during this comment period.

At the March 2025, Board meeting, Board members considered the comments received and the regulation text. During the meeting, members discussed the value of having a QA program that requires a systematic review of medication errors. Additionally, the discussion continued regarding the current QA regulation's purpose to advance error prevention by analyzing, both individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause(s) and any contributing factors, such as system or process failures. Members noted that most of the regulation focuses on reporting individual errors, and the need to encourage the collective system review approach further, potentially by requiring periodic system reviews.

The Board deferred a decision on the QA regulation to allow for staff to develop possible language to include this policy. The one-year timeframe to complete the Board's current QA rulemaking is August 8, 2025. With the one-year deadline approaching, Board staff recommend that the current rulemaking be withdrawn. This approach would enable the Board to continue its policy discussion on a collective review process and initiate a rulemaking with clear, regulatory language and policy.

Attached to this memo are:

1. The modified text that was released for the second 15-day public comment period.
2. Comments received during the 15-day comment period.

Department of Consumer Affairs
Title 16. Board of Pharmacy

Proposed Second Modifications to Regulation Text
Quality Assurance Programs

Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Modified regulation text to the proposed regulation text is indicated with a ~~double strikethrough~~ for deletions and a double underline for additions.

Second modified regulation text to the proposed regulation text is indicated with a ~~**bold double strikethrough**~~ for deletions and a **bold double wavy underline** for additions.

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 ~~S~~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:

(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.~~

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

(~~D~~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.

(~~E~~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.

(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.

(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 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.

(g) The pharmacy's compliance with this section will be considered by the ~~b~~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.

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.

1121 L Street, Suite 607 Sacramento, CA 95814 • P:916/443-1975• www.calretailers.com •
cra@calretailers.com

§ 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

RHS | PHARMACY ADVISORS

February 10, 2025

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

Re: Quality Assurance Program Proposed Regulations

Dear Honorable Members of the California State Board of Pharmacy,

Refined Health Solutions represents several pharmacy and digital health clients that are focused on providing patients with a better experience. We are writing on behalf of pharmacy clients to express our appreciation for the additional changes made to the second modified rule proposal for 16 CCR § 1711 regarding Quality Assurance Programs, and to respectfully raise additional concerns about the proposal. We recognize the efforts taken to address concerns and improve the regulatory framework related to medication error reporting and prevention, and look forward to continued collaboration with the Board to further enhance the proposal.

We respectfully bring to your attention that compliance with the proposed rule, particularly section (e)(2)(D) regarding workload data, will necessitate a significant overhaul of our clients' current quality programs. This includes revamping current quality software systems, standard operating procedures (SOPs), and staffing models to accurately capture and report the required data elements. Such comprehensive changes require substantial time and resources to ensure they are implemented correctly and effectively, minimizing disruption to patient care.

Specifically, the requirement to document the volume of workload completed by pharmacy staff on the date of the error, including vaccines, patient consultations, and other mandatory activities, as outlined in (e)(2)(D), represents a significant expansion of current data collection practices. Integrating this level of detail into existing systems

will require substantial modifications to pharmacy management software and workflows.

It is important to note the extensive requirements in this rule may unintentionally create a negative impact on small or innovative pharmacy models who cannot easily influence the technical priorities of their pharmacy management system vendor, and may have less resources to implement highly complex tracking and reporting mechanisms. Therefore, these pharmacies may need to implement extensive manual workflows to comply, impacting their capacity for performing patient care activities. With this said, we respectfully request that the Board clarify if section (e)(2)(D) applies to all outpatient pharmacies, including independents and chains, or solely chains.

Furthermore, we have been informed that the proposed vendor for data submission is not yet ready to launch, which poses an additional challenge. Without clear technical specifications and a functional platform for submitting quality assurance records, pharmacies will face significant difficulties in implementing these changes in a timely and compliant manner. Understanding the vendor's reporting requirements is critical for ensuring our clients' systems are properly configured and that data is transmitted accurately and securely.

In light of these challenges, we respectfully request that the Board consider further edits to the rule to align with standards in other states, such as those previously referenced in Ohio. The Ohio rules offer a clear and robust quality reporting framework, particularly in the area of workload data collection and reporting.

Alternatively, we propose that the Board allow an 18-month period of enforcement discretion, commencing once the vendor is fully prepared to receive data and has provided comprehensive technical specifications. This grace period would provide pharmacies with the necessary time to:

- Develop and implement revised SOPs and training programs for pharmacy staff.
- Modify existing pharmacy management systems to accurately capture and report the required data elements.
- Integrate with the vendor's data submission platform and ensure data integrity.
- Validate the effectiveness of updated quality assurance programs.

We believe that this approach would not only facilitate a smoother and more effective implementation of the new regulations but also enhance the overall quality of pharmacy services and, ultimately, benefit the health and welfare of California residents.

Thank you for your time in reviewing our recommendations for the proposal. We welcome the opportunity to discuss these concerns further and offer the Board our support in revising the proposed language to allow for easier implementation while achieving the goal of improved patient safety.

Sincerely,

Emily Haugh, PharmD
Founder, Principal Consultant
Refined Health Solutions
emily@refined.health

February 6, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95834

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Proposal to amend section 1711 of Article 2 of Division 17 of Title 16 of the California Code of Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed amendments to the Board's regulations pertaining to quality assurance programs. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

In the Initial Statement of Reasons for the proposed modifications to the regulation, the Board claims that pharmacy workload statistics need to be included in quality assurance reports because "this information must be taken into consideration… when determining the cause of the error."[1] However, the Board is ignoring the fact that the regulation in its current and modified form already requires the quality assurance report to include "the findings and determinations generated by the quality assurance review," which by definition includes the "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."[2] Therefore, to the extent that the individuals performing the quality assurance review determine that the workload in the pharmacy might have contributed to a medication error, that information is already required to be included in the quality assurance report. Requiring the pharmacy's workload statistics to be documented on every quality assurance report, even when the reviewers determine that workload was not a contributing factor to the error, will be administratively burdensome for Pharmacists-in-Charge and will provide no discernible benefits to the public.

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[1] California Board of Pharmacy, *Initial Statement of Reasons Quality Assurance Programs*, https://www.pharmacy.ca.gov/laws_regs/1711_isor.pdf (last visited Feb. 3, 2025).
[2] Cal. Code Regs. tit. 16, § 1711(e).

Moreover, if these workload statistics are genuinely necessary because "this information must be taken into consideration… when determining the cause of the error," we wonder why the Board is willing to include numerous carve-outs to this requirement in the proposed regulation.[3] Specifically, in response to valid public comments, the proposed regulation text in CCR 1711(e)(2)(D) has been modified with various caveats to the point that it is virtually indecipherable. Based on our reading of the proposed regulation, there are at least three different scenarios that could occur related to documenting workload statistics as part of a quality assurance report:

1. If both the date of the error and workload statistics are unknown, then the average daily workload statistics would need to be documented on the quality assurance report.
2. If the date of the error is known and the workload statistics are unknown, then the estimated number of consultations provided—but no other workload statistics—would need to be documented on the quality assurance report.
3. If both the date of the error and the workload statistics are known, then the actual known workload statistics would need to be documented on the quality assurance report.

Based on the second modified text of the proposed regulations, a pharmacy might be incentivized to be ignorant to the workload statistics for the pharmacy so that, in most cases, the quality assurance report would only need to include an estimate of the number of consultations provided. Given these factors, we encourage the Board to delete section 1711(e)(2)(D) from the proposed regulation.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board's regulations pertaining to quality assurance programs. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully,

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

[3] Initial Statement of Reasons, *supra*.