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

Proposed Regulation to Amend Title 16 CCR Section 1711, Quality Assurance Programs

---

Summarized 15-day Comments Regarding Quality Assurance (QA) Programs with Board Staff Recommendations:

Written Comments from Sarah Pollo, California Retailers Association

Comment 1: The commenter requests a one-year delayed implementation period to allow pharmacies to update their policies and procedures and systems.

Response to Comment 1: Board staff note that this comment was previously submitted during the 45-day comment period and already reviewed and considered by the Board. The Board accepted staff's recommendation that the Board establish a January 1, 2026 effective date.

Comment 2: Commenter requests that the term "automation" be defined because automation is involved in nearly every prescription.

Response to Comment 2: Board staff note that this comment was previously submitted during the 45-day comment period and already reviewed and considered by the Board. Board staff does not recommend any changes to the text based upon the comment. Board staff note that the term "automation" is specific to the dispensing process, and staff do not believe a definition is required as in the text, the term is specifically linked to its use in dispensing.

Comment 3: Commenter requests that subdivision (d) be amended to change the review time from 2 business days to 72 hours as two business days is not sufficient time from the date of discovery of an event to complete its investigation.

Response to Comment 3: Board staff note that this comment is outside the scope of this regulatory action and comment period, as subdivision (d) is existing regulation text and is not being amended in this rulemaking. Additionally, Board staff does not recommend any changes to the text based upon the comment. Board staff note that subdivision (d) requires that the investigation "commence" with 2 business days and does not require that the investigation be completed within 2 business days.

Comment 4: Commenter requests that the Board remove the requirement for the date, location, and participants in the quality assurance review to be

documented in the record (subdivision (e)(1)), as this is often not systematically tracked and would require costly updates to currently used systems for recording and communicating the quality assurance review. Commenter states that the additional information required is an unnecessary administrative burden that does not contribute to improved quality assurance outcomes.

Response to Comment 4: Board staff have reviewed the comment and do not recommend a change to the text. Board staff note the commenter is referencing a current legal requirement, making this comment outside the scope of the comment period. Board staff direct the commenter to the existing regulation text in subdivision (e)(1) which is not being amended in this rulemaking. Compliance with these elements of the record is already required.

Comment 5: Commenter requested that the Board remove the requirement for documentation of any patient contact information as required in subdivision (e)(2). Commenter indicates that notification to the patient of an error is an essential component to a CQI plan; however, pharmacies do not generally require the documentation.

Response to Comment 5: Board staff have reviewed the comment and do not recommend a change to the text. Board staff note the commenter is referencing a current legal requirement, making this comment outside the scope of the comment period. Board staff direct the commenter to the existing regulation text in subdivision (e)(2) which is not being amended in this rulemaking.

Comment 6: Commenter requests that the requirement to include the pharmacy's categories for identifying the types of errors in the pharmacies' policies and procedures (subdivision (e)(2)(D)) be removed because they are proprietary and their inclusion could jeopardize confidentiality.

Response to Comment 6: Board staff have reviewed the comment and believe the commenter is referencing subdivision (e)(2)(C) of the modified text. Board staff note that this comment was previously submitted during the 45-day comment period and has already been reviewed and considered by the Board. The Board determined no changes should be made based on those comments. The comment is outside the scope of the 15-day comment. Consistent with the Board's prior determination, staff does not recommend any changes to the text. Board staff notes that QA reports are confidential and would not be discoverable.

Comment 7: Commenter indicates that tracking of the workload as described in subdivision (e)(2)(E) is unattainable and impossible to comply with. Having a shared service process, the clinical functions are often completed by pharmacists tethered to other pharmacies whose work is disseminated to various dispensing pharmacies.

Response to Comment 7: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to understand the workload of the pharmacy, regardless of setting, on the day of the error in order to conduct a detailed analysis into the error and possible fatigue of the individuals involved. According to ISMP, part of Just Culture includes coaching the staff involved in the error. The Board's QA program is generally consistent with Just Culture, which encourages a systematic review of a medication error, including environmental factors, workflow, use of devices, and staffing patterns. Further, Board staff note that the requirements are specific; however, licensees can determine how to collect the data based on their business practice. Board staff note that the Board previously discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml)

Comment 8: The commenter indicated that it is impossible to track central fill prescriptions separately as the workload is a shared responsibility across a single prescription. The commenter requests that the requirement be removed. Additionally, the commenter states that consultations and phone calls must be manually tracked, increasing workload.

Response to Comment 8: Board staff note that this comment was previously submitted during the 45-day comment period and already reviewed and considered by the Board. Board staff does not recommend any changes to the text based upon the comment. Board staff note that the commenter appears to be misinterpreting the regulation text. The regulation text requires that prescriptions filled by a central fill location be documented separately from prescriptions volume filled at the pharmacy when documenting the total volume of prescriptions dispensed at the pharmacy on the day of the error, where applicable. The regulation does not require that the documentation be split into two documents. Additionally, the pharmacy can determine a tracking method that works best for the business processes within the pharmacy.

Comment 9: Commenter requests that the documentation requirement added to subdivision (e)(4) be removed as changes may be made to systems, workflow, and policies and procedures that may not be reported back to the specific individual in the field and stores cannot make changes in isolation from other stores.

Response to Comment 9: Board staff note that this comment was previously submitted during the 45-day comment period and already reviewed and considered by the Board. The Board determined no changes should be made based on those comments. The comment is outside the scope of the 15-day comment. Consistent with the Board's prior determination, staff does not

recommend any changes to the textIt appears the commenter may be misinterpreting the proposed change, which will establish a requirement to maintain documentation of the steps taken as part of the quality assurance report. Board staff note that current law already requires the pharmacy to inform pharmacy personnel of the changes to pharmacy policy, procedure, systems, or processes make as a result of recommendations.

Comment 10: Commenter requests that the QA record retention period remain at one year instead of three because the change would require significant system updates. Additionally, the commenter requests that the quality assurance records for Automated Drug Delivery Systems be reported to the PSO and not the Board.

Response to Comment 10: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to maintain the records for a longer period to allow for pharmacy personnel to examine for patterns that can assist in error reduction and prevention. Further, Board staff notes that records can be stored electronically and can be electronically archived or purged following the end of the retention period. Additionally, the Board previous discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml). Finally, Board staff notes that the records related to Automated Drug Delivery Systems are necessary to monitor the use of technology for medication dispensing on an ongoing basis.

Comment 11: The commenter requests clarification on subdivision (g) and the intent of this language and how compliance with this section will be used as a mitigating factor.

Response to Comment 11: Board staff note that this comment is outside the scope of this regulatory action and comment period as subdivision (g) is existing regulation text and is not being amended in this rulemaking.