DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Quality Assurance Programs

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments, relevant to the action proposed, in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Persons in this Notice, must be received by the Board at its office by September 23, 2024.

PUBLIC HEARING
The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under "Contact Persons" in this notice.

WRITTEN COMMENT PERIOD
Written comments relevant to the action proposed, including those sent by mail, facsimile, or e-mail to the addresses listed under "Contact Persons" in this Notice, must be received by the Board at its office no later than September 23, 2024, or must be received by the Board at the hearing, should one be scheduled.

The Board may, after holding a hearing if requested and considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Business and Professions Code (BPC) sections 4005 and 4125, the Board proposes amending section 1711 in Division 17 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (BPC section 4000, et seq.). The Board's mandate and mission are to protect the public (BPC section 4001.1).

Existing regulation at CCR section 1711 requires each pharmacy to institute or

participate in an established Quality Assurance (QA) program that assesses and documents medication errors to determine the cause and an appropriate response as part of a mission to help prevent medication errors and improve the quality of pharmacy services provided to California consumers. This section also defines a medication error as “any variation from a prescription or drug order not authorized by the prescriber” but “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.” As required by this section, an investigation of each medication error shall commence as soon as reasonably possible, but no later than two business days from the date the medication error is discovered.

Generally, a QA program is intended to advance medication error prevention by analyzing, individually and collectively, investigative and other pertinent data to address the cause and contributing factors. Required elements include:

1. Date, location, and participants in the QA review,
2. Pertinent data and other information relating to the medication error reviewed and documentation of any patient contact,
3. Findings and determinations generated by the QA review, and
4. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

Workforce strains are a contributing factor to medication errors; however, the Board has received public comment that staff are prohibited from including staffing and other workforce issues in QA reporting. This proposal will directly address this problem.

This proposal will amend section 1711 of Article 2 of Division 17 of Title 16 of the CCR to ensure that QA programs capture the approximate date of the error, the staff involved, any use of automation, the type of error, and workload volume. Additionally, the proposal will require thorough review and documentation to prevent future errors. These amendments will 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.

Anticipated Benefits of Proposal

Protection of the public is the Board’s highest priority in exercising its licensing, regulatory, and disciplinary functions. The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents and employee safety.

This proposal updates the requirements for the QA program. These requirements have been in place, unchanged, for 20 years and are quite broad. The amendments will ensure the QA program is up to date with the current practice of pharmacy and that pharmacies thoroughly assess and document medication errors. This will help in determining the cause of medication errors and appropriate responses to take to help prevent future errors, thereby improving the quality of pharmacy services and helping prevent future medication errors, which benefits the health and welfare of California residents and employee safety.

This regulatory proposal does not affect the state's environment.

Evaluation of Consistency and Compatibility with Existing State Regulations

During the process of developing this regulatory proposal, the Board conducted a search of any similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The regulations do not result in a fiscal impact to the state in the form of federal funding or any cost or savings to any state agency. The Board already ensures licensees comply with current laws and regulations related to QA programs through inspections. As a result, the Board does not anticipate any increase in workload or costs resulting from the proposed regulations. Any workload and costs of implementation are a result of current law.

Nondiscretionary Costs/Savings to Local Agencies: None

Cost to any Local Agency or School District for which Government Code Sections 17500 - 17630 Require Reimbursement: None

Mandate Imposed on Local Agencies or School Districts: None

Significant Effect on Housing Costs: None

Business Impact Estimates:
The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The proposed amendments expand on existing requirements for QA programs which will ensure thorough documentation and assessment of medication errors. Any workload or costs to comply with the proposed regulations are anticipated to be incurred within normal business operations.

Cost Impact on Representative Private Person or Business:
The Board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The Board concludes that this proposal will not:

(1) create jobs within California;
(2) eliminate jobs within California;
(3) create new businesses within California;
(4) eliminate existing businesses within California; and
(5) expand businesses currently doing business in the State of California.

The Board determined that this proposal will not create or eliminate jobs or businesses. This proposal will require thorough review and documentation of medication errors to prevent future errors. These amendments will ensure a more robust review of the circumstances surrounding each error and identification of possible contributing factors, including workload, in order to prevent future medication errors and improve the quality of pharmacy service, which benefits the welfare of California residents and employee safety. This proposal will not impact the state's environment.

Benefits of Regulation:

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents and employee safety.

This proposal updates the requirements for QA program. These requirements have been in place, unchanged, for 20 years and are quite broad. The amendments will ensure the QA program is up to date with the current practice of pharmacy, and ensure that pharmacies thoroughly assess and document medication errors. This will help in determining the cause of medication errors and appropriate responses to take to help prevent future errors and improve the quality of pharmacy services, which benefits the health and welfare of California residents and employee safety.

This regulatory proposal does not affect the state's environment.

Business Reporting Requirements

This regulatory proposal does not require businesses to file a report with the Board.

Effect on Small Business:

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a "small business", as defined in Government Code section 11342.610, the Board has determined that the proposed regulatory action may affect small businesses. However, the proposed changes are necessary to protect the public, and any workload or costs to comply with the proposed regulations are anticipated to be incurred within normal business operations.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board must determine that no reasonable alternative it considered to the regulation, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposal described in this Notice, or more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments—relevant to the above determinations—in writing, at the address listed below for the Contact Persons, during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, the Initial Statement of Reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the person named below.

You may obtain a copy of the Final Statement of Reasons, once it has been prepared, by making a written request to the Contact Person named below or by accessing the website listed below.

Contact Persons

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Lori Martinez
Address:	Board of Pharmacy 2720 Gateway Oaks Drive, Ste. 100 Sacramento, CA 95833
Phone No.:	(916) 518-3100
Fax No.:	(916) 574-8618
E-Mail Address:	PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name:	Julie Ansel
Address:	Board of Pharmacy 2720 Gateway Oaks Drive, Ste. 100 Sacramento, CA 95833
Phone No.:	(916) 518-3100
Fax No.:	(916) 574-8618
E-Mail Address:	PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text ,if any, can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.