TITLE 16. BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing scheduled.

Subject Matter of Proposed Regulation: Quality Assurance Programs

Section Affected: Amend Title 16, California Code of Regulations (CCR) section 1711

Background and Statement of the Problem

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

Medication errors complaints are among the most common consumer complaints received by the Board. In fiscal year 2020/21, the Board initiated 521 investigations alleging a prescription error, with 367 indicating patient harm. In the first six months of fiscal year 2021/22, the Board initiated 282 prescription error investigations, with 190 indicating patient harm. Medication errors vary in severity, including serious patient harm and death.

CCR section 1711 establishes requirements for each pharmacy to establish 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.

Originally effective in January 2002, the QA regulation provisions have remained largely unchanged, with the exception of minor changes in 2004 and recent amendments in 2021 as part of the implementation of Automated Drug Delivery Systems (ADDS), including provisions to clarify the QA program regarding the uses of ADDS. 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.

As part of the Board's evaluation of medication errors, and in response to information at the national level, suggesting that workforce issues may be a contributing factor to these types of errors, the Board conducted a workforce survey which focused on the community pharmacy setting. As reported in the media, in survey results, and in public comments received by the Board, workforce strains are a contributing factor to medication errors; however, the Board received public comment that pharmacy staff are prohibited from including staffing and other workforce issues in QA reporting.

Furthermore, as part of the Board's evaluation of medication errors and workforce issues, it considered whether the current QA program requirements are thorough, or if changes to the regulation were necessary to advance error prevention. As part of its discussion, the Board considered numerous questions regarding potential changes to the QA program and reporting requirements, including:

1. Should the date the error occurred be required?
2. Should the staff involved in the error be documented?
3. Should the type of error be required? (e.g., wrong patient, wrong directions, relevant drug information, etc.)
4. Should the volume of workload completed on the date the error occurred be required?
5. Are there standardized items that should be captured, e.g., prescription volume (new and refill), immunizations provided, MTM, etc.?
6. Should the number of staff and classifications on the date of the error be required?
7. Should requirements be updated to require documentation of the actions taken (as well as recommended changes) and the date those actions occurred?
8. Should the Board standardize a QA form?
9. Should a threshold be established after which a specified number of medication errors occur (i.e., 12 in a one-month period) that the pharmacy is required to take additional action? (i.e., complete the ISMP self-assessment tool, engage with a consultant that specializes in medication error reduction, etc.)
10. The current records retention schedule is one year. Should this be extended to allow for assessment of process improvements implemented or should aggregate year end data be required before removal of the QA records?
11. Does the Committee believe the proposed requirements established in section 1711(e)(2)(A)-(E) are necessary for reporting of incidents involving the use of an ADDS, or should incidents be exempt from including these additional elements of the QA report?

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 from this regulatory action:

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.

Specific purpose of, and rationale for, proposed changes

The Board's proposal makes the following changes:

The Board proposes capitalizing the "B" in "Board" and lowercasing the "s" in "section" throughout the section. This change is non-substantive because it is a grammatical change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency throughout the regulations. Inconsistent capitalization/lowercasing may result in misinterpretation and confusion.

The Board proposes grammatical/punctuation edits to add or remove commas throughout the section. This change is nonsubstantive because it is part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for clarity and grammatical correctness.

Subsection (e)(2) is amended to add the term "including" due to the addition of new subsections within (e)(2) that follow. The purpose of this addition is to introduce the required pertinent data/information to be reviewed and documented. The addition is necessary for proper formatting of the regulation text, and to introduce the list that follows.

Subsection (e)(2)(A) through (e)(2)(E) adds the following:

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

(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.
(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."

The Board determined that the date and approximate time or date range, if known, shall be documented to clearly identify when the error occurred. The purpose of this addition is to establish the requirement that medication error reports include the date and time (when known) of each error reported. This information is necessary for an accurate QA review in order to identify what was happening within the facility that could be contributing factors to each medication error. If the pharmacy is unable to determine when the error occurred, the pharmacy shall notate "unknown" in the record to denote the pharmacy attempted to (but could not) ascertain the possible date and time the error occurred.

The Board determined that error reports should include the names of staff involved in a medication error. The purpose of this inclusion is to establish the requirement that medication error reports include the names of staff involved in any medication error. This inclusion is necessary to determining the root cause of the error and identifying if additional training was needed. If repeated medication errors occur and the same staff are involved each time, the pharmacy may need to investigate further and take additional steps to correct the underlying cause.

The Board determined that the use of automation in the dispensing process should be documented as automation errors, including a wrong drug error and medications being administered to patients with a documented allergy, that were dispensed via automation. The purpose of this inclusion is to establish the requirement that medication error reports include whether automation was used in the dispensing process. It is necessary that this information be included because, while the pharmacist is responsible for medication errors, this information will help the pharmacy understand the underlying cause of the error and whether it was a result of relying on automated systems, or if reliance on automated systems was a contributing factor.

The Board determined that the type of error should be included in the documentation. The purpose of this inclusion is to establish the requirement that the type of error be included in error reports. This inclusion is necessary because the type of error is important to understand the full picture of the situation and the severity of error. Additionally, it will allow for patterns to be identified, which may point to a larger systematic problem. The pharmacy's policies and procedures must include the category

the pharmacy uses for identifying the types of errors to ensure that all pharmacy staff are reporting the errors in the standardized format. The Board determined that the pharmacy should determine the category standards that are appropriate for their facility and their business model.

Finally, the Board determined that the scope of workload should be documented in error reports. The purpose of this inclusion is to establish the requirement that scope of workload be included in medication error reports. This inclusion is necessary, as this information must be taken into consideration with other factors—such as practice setting (e.g., central fill, community, inpatient, long-term care, etc.); if the pharmacist was working alone; robotics used; number of pharmacists/pharmacy technicians working; and the point in the shift that the error occurred—when determining the cause of the error. Contributing clinical and non-clinical services provided may play a role in the underlying conditions at the time of the error. Additionally, the Board has received feedback with respect to immunizations and sufficient space and time needs to be allocated to account for all workload. This information can help pharmacies understand what was happening within the facility, and whether there were distractions, to determine possible root causes of medication errors.

Subsection (e)(4) is amended to add "Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report." The purpose of this addition is to establish the requirement that pharmacies maintain documentation of steps taken to prevent future errors. This addition is necessary for pharmacy accountability. The facility must take steps to prevent future errors and not simply complete the QA reports with no further action, as this will not prevent future errors.

Subsection (f) is amended to change the length of time that the QA record must be immediately retrievable in the pharmacy from one year to three years. The purpose of this change is to extend the length of time the QA record must be immediately retrievable in the pharmacy. The extension of the records retention is necessary to allow for assessment of the process improvements implemented following evaluation of a QA report. The Board determined that three years would provide more clarity to the regulated public, as the other pharmacy records must be maintained for three years pursuant to BPC section 4105, and having pharmacies maintain all records for the same length of time (when possible) reduces confusion and ensures that the records are not inadvertently destroyed.

BPC Section 4125 is added to Authority cited (with the letter "s" added to the end of the word "Section" for grammatical correctness) and "and Section 2 of Chapter 677, Statutes of 2000" has been removed. The purpose of this addition is to ensure the inclusion of the authorizing statute. This change is necessary because that Chapter establishes the statute and the statute specifically requires pharmacies to have a QA program, so identifying the BPC section is more appropriate.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board Meeting held February 6-7, 2023 (Meeting Materials Agenda Item IX, Meeting Minutes (Pages 1, 15-19))

2. Relevant Meeting Materials and Minutes from Medication Error Reduction and Workforce Committee Meeting held November 16, 2022 (Meeting Materials Agenda Item V, Meeting Minutes)
3. Relevant Meeting Materials and Minutes from Board Meeting held October 25-26, 2022 (Meeting Materials Agenda Item IX, Meeting Minutes (Pages 1, 16-17))
4. Relevant Meeting Materials and Minutes from Medication Error Reduction and Workforce Committee Meeting held September 14, 2022 (Meeting Materials Agenda Item IV, Meeting Minutes)

Business Impact

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 assessment and documentation of medication errors. Any workload or costs to comply with the proposed regulations are anticipated to be incurred within normal business operations.

Economic Impact Assessment

The Board has determined 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;
(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. The proposed regulation ensures 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, which will not create or eliminate jobs or businesses.

This regulatory proposal benefits the health and welfare of California residents. This proposal requires thorough review and documentation of medication errors to prevent future errors, which is a benefit to the health and welfare of California residents and employee safety. This proposal will not impact the state's environment.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The Board considered not adopting the proposed regulation; however, the Board determined that alternative was not reasonable, as existing QA programs requirements are broad and do not reflect the current practice of pharmacy.

Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business

No such alternatives have been proposed, however, the Board welcomes comments from the public.