DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS

PROPOSED REGULATORY LANGUAGE
Quality Assurance Programs

Legend:	Added text is indicated with an underline. Omitted text is indicated by (* * * *) Deleted text is indicated by ~~strikeout~~.

Amend section 1711 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. The program shall, at a minimum, include the following:

(1) All medication errors discovered shall be subject to a quality assurance review.

(2) Assessment and documentation of each medication error to determine the potential causes, contributing factors and appropriate responses to minimize and mitigate future errors.

(3) Aggregate and analyze medication errors identified pursuant to paragraph (1) to prepare reports that assess medication error trends, causes and contributing factors, and establish pharmacy systems or workflow processes that minimize or mitigate future errors.

Nothing in this section shall supersede, or be construed as a substitution for, the requirement that community pharmacies report medication errors to an entity approved by the Board pursuant to Business and Professions Code section 4113.1.

(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.~~ has the same meaning as set forth in Business and Professions Code section 4113.1.

(c) Policies and procedures: the pharmacy shall establish policies and procedures that define the quality assurance program requirements. At a minimum, the policies and procedures must establish the following:

(1) ~~Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.~~ The time frame within which a medication error review must commence. An investigation of each medication error shall commence as soon as is reasonably possible after discovery, but in no case later than 2 business days from the date the medication error is discovered.

(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.~~

The provisions for notification of impacted parties (including the patient or the patient's agent, and the prescriber) of the medication error and at minimum, how to avoid injury or mitigate the error.

(3) ~~The~~ Documentation of communication ~~requirement~~ to impacted parties as required 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.~~ The information required to be documented in an individual medication error report and aggregate medication error report, including factual findings and actions taken in response.

(5) The frequency with which aggregate medication error reports are created.

(6) The frequency with which the pharmacist-in-charge (PIC) is required to review individual and aggregated medication error reports. At a minimum, the PIC shall review and sign each aggregated medication error report annually.

(7) The process the pharmacy will use to communicate all aspects of its quality assurance program to pharmacy personnel, including communication of process improvements, and how to minimize or mitigate medication errors.

(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.~~ Records:

(1) Individual and aggregate medication error reports shall be retained and immediately retrievable for at least three years from the date created.

(2) Any medication error report related to the use of a licensed automated drug delivery system must also be submitted to the Board within 30 days of creation of the report.

(3) Medication errors related to the use of an unlicensed automated drug delivery system must also be submitted as an aggregate medication error report upon annual renewal of the facility license.

(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);~~

~~(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.~~ Mitigation:

~~(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least 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.~~

~~(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~~f) Contracting: 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. Pharmacies located in the state and operated under common ownership may satisfy the requirements of this section pursuant to policy and procedures that allow for joint and collaborative review, analysis and communication.

Credits

NOTE: Authority cited: Section 4005, Business and Professions Code~~; and Section 2 of Chapter 677, Statutes of 2000~~. Reference: Sections 4125 and 4427.7, Business and Professions Code.