

California Language

CA Business and Professions Code Section 4125:

4125. (a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication

errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program

shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the

pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be

considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as

provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records

maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by

a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient

from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records

not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

Cal. Code of Regulations Section 1711:

§1711. Quality Assurance Programs. [Effective October 22, 2004]

(a) Each pharmacy shall establish or participate in an established quality assurance program which 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 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);
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.

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(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.

(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) 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.