Title 16. Board of Pharmacy
Proposed Regulation

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1711 of Article 2 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 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.) t The date, location, and participants in the quality assurance review;
(2.) t The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
(3.) t The findings and determinations generated by the quality assurance review; and,
(4.) r 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.

(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. Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.

(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.

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.

Amend section 1713 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated patient dispensing system (APDS) delivery device to deliver previously dispensed prescription medications to patients provided:

~~(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.~~

~~(2)~~(1) A pharmacist has determined that each patient using the ~~device~~ APDS meets inclusion criteria for use of the APDS ~~device~~ established by the pharmacy prior to delivery of prescription medication to that patient.

~~(3)~~(2) The APDS ~~device~~ has a means to identify each patient and only release that patient's prescription medications.

~~(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).~~

~~(5)~~(3) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

~~(6) The device is located adjacent to the secure pharmacy area.~~

~~(7) The device is secure from access and removal by unauthorized individuals.~~

~~(8) The pharmacy is responsible for the prescription medications stored in the device.~~

~~(9)~~(4) Any incident involving the APDS ~~device~~ where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

~~(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).~~

(e) Any pharmacy making use of an APDS ~~automated delivery device as permitted by subdivision (d)~~ shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the APDS ~~automated delivery device~~ and the dangerous drugs within the APDS ~~device~~.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS ~~device~~ and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS ~~automated delivery device~~.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS ~~automated delivery device~~.

(5) Orienting participating patients on use of the APDS ~~automated delivery device~~**,** notifying patients when expected prescription medications are not available in the APDS ~~device~~**,** and ensuring that patient use of the APDS ~~device~~ does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the APDS ~~device~~ is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS ~~automated delivery device~~.

~~(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been~~

~~previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.~~

Note: Authority cited: Sections 4005, 4075, and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, ~~and~~ 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7, and 4427.8, Business and Professions Code

Add section 1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  (1) A new automated drug delivery system license has been issued.
  (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.
  (3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system’s compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18) entitled “Automated Drug Delivery System Self-Assessment”. Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
  (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
    (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
    (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
    (C) DEA registration number, expiration date, and date of most recent DEA inventory;
    (D) Hours of operation of the pharmacy; and
    (E) ADDS license number, address, and hours of operation.
  (2) The pharmacist-in-charge shall respond “yes”, “no”, or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(3) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink on the self-assessment form.
(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink on the self-assessment form.
(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system’s license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, and 4427.5, Business and Professions Code.