Order of Adoption

Board of Pharmacy
California Code of Regulations
Change to Title 16, Division 17

Adopt Section 1713 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.

(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 delivery device to deliver previously dispensed prescription medications 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. A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.
3. The 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. 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. Any incident involving the 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 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 automated delivery device and the dangerous drugs within the device.
2. Determining and applying inclusion criteria regarding which medications are appropriate for placement in the 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 automated delivery device.
4. Describing the assignment of responsibilities to and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.
5. Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.
6. Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an 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, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia. Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

1. a patient med pak is reused only for the same patient;
2. no more than one-month supply is dispensed at one time; and
3. each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist preceptor before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) 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.
However, 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. The Board may in its sole discretion waive this application of the regulation for good cause shown.
(f) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1308.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.
(g) [f] The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

[Signature]
Virginia Herold
Interim Executive Officer

[Date]
12/22/06