

## Department of Consumer Affairs

### Title 16. Board of Pharmacy

#### Proposed Regulation Text

Proposed changes made to the current regulation language are shown by ~~strike through~~ for deleted language and underline for added language.

Amend Section 1707 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707. Waiver Requirements for Off-Site Storage of Records.

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver may, on a case-by-case basis, be granted to any entity licensed by the board for storage of the records outside the licensed ~~area of the~~ pharmacy premises described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code. The board may consider space limitations within the pharmacy premises, cost, previous compliance with records requirements, ease of access to records stored outside of the licensed ~~area premises~~, and any other factor presented by the licensee in making its determination.

(b) An entity that is granted a waiver pursuant to ~~subdivision~~ section (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in ~~subdivision~~ section (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision section (a), all prescription records for non-controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision section (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, ~~or~~ designated representative, responsible manager or professional director) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

(h) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver may, on a case-by-case basis, be granted to any entity that has previously been licensed by the board, for storage of the records outside the licensed premises described in subdivision (c) of Section 4105 of the Business and Professions Code if the board determines at a minimum that the following conditions are met:

(1) The storage area must be secured, located inside an enclosed building identified with an address, with access limited to the owner(s) of the entity. The records must be open for inspection by the board and authorized officers of the law, Monday through Friday from 8:00AM to 5:00PM.

(2) All records are maintained for at least three years from the date that the license was canceled, revoked, surrendered or otherwise terminated and no longer current and active, in a readily accessible and retrievable format.

(3) All records are secured so that the confidentiality of any patient-related information is maintained.

(4) Records that shall be maintained include records of manufacture and of sale, acquisition, receipt, shipment or disposition of dangerous drugs and dangerous devices, and policies and procedures related to pharmacy personnel and pharmacy operations.

(5) Records maintained electronically shall be maintained in a readily retrievable format and be produceable in a hardcopy, digitized copy, or electronic copy.

(6) Any paper records converted into a digital format shall be maintained only in a noneditable format.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.