



Instructions for Completing an Application for Waiver To Store Records Offsite

NOTE TO APPLICANT: *If waiver is approved, store approved waiver in the pharmacy with the self-assessment form.*

California law requires pharmacies and other licensed facilities to maintain records and other documentation of the acquisition and distribution of dangerous drugs and dangerous devices for three years. Additional requirements exist in federal law. California law requires that these records be retained in readily retrievable form. Specific provisions regarding the storage and maintenance of records are found in various California laws, including:

Business and Professions Code sections 4081, 4105, 4333
Health and Safety Code sections 11159, 11164, 11179, 11205
Code of Regulations, Division 17, Title 16, sections 1707, 1707.1, 1717.4, 1718

The Board of Pharmacy is authorized to grant waivers to allow offsite storage of records under specific provisions provided in California Code of Regulations section 1707. The attached form is the application for the waiver for offsite storage of pharmacy records. Other board-licensed facilities may obtain waiver applications by contacting the board. A copy of the regulation is attached for your information.

All records stored offsite must be kept in a secure area to prevent unauthorized access. Examples of reasonable storage areas are at records maintenance facilities or commercial storage centers. The licensee must be able to produce the records within two business days upon the request of the board or another authorized officer of the law. The board requests that the waiver, if approved, be kept in the pharmacy.

All prescription records for non-controlled substances must be kept in the pharmacy for one year from the date of dispensing. All prescription records for controlled substances must be kept in the pharmacy for two years from the date of dispensing.

A waiver for offsite storage of records is not needed if the records will be kept in a storage area at the same address or adjoining the licensed premises.

The Board of Pharmacy will review the information you provide on the attached form. If the waiver for offsite storage of records is approved, a signed copy of the form will be returned to you within 30 days. However, until you receive a board-signed copy of the form, offsite storage of records is not authorized.

A new waiver for offsite storage of records is needed if the records are moved to a different offsite location.

1707 **Waiver Requirements for Offsite 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 shall be granted to any entity licensed by the board for offsite storage of the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.
- (b) An entity that is granted a waiver pursuant to subdivision (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 (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 (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 (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 exemptee) 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.

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

