



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VIII. Discussion and Consideration of Adoption of Board Approved Regulations, Comments Pending Review by the Board

d. Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage

Background:

At the January 2017 Board meeting, the Board approved proposed text to amend Section 1707 of Title 16, CCR, related to off-site storage of records. This proposal amends the board's regulations regarding the waiver requirements for off-site storage of records to allow Board discretion to grant those cited for a records violation to receive a waiver to store records off-site.

As required by the Administrative Procedure Act, board staff released the proposed text for the 45-day comment period on February 7, 2020, which ended on March 23, 2020. One comment was received during the comment period and is attached following this memo.

The comment, from Elizabeth Marley, PharmD., requested clarification if nonresident pharmacies need to apply for off-site storage waivers or if the requirements only apply to resident pharmacies. Board staff recommends the comment be rejected. Board staff notes that the off-site storage requirements apply to non-resident pharmacies pursuant to Precedential Decision No. 2019-01 [In the matter of the Citation Against: ESI Mail Pharmacy, Inc. dba Express Scripts, (Case No. CI 2009 44657; OAH Case No. 2011060384)]. Board staff believes that to include additional language expressly applying this regulation to non-resident pharmacies would risk creating a negative implication that other regulations of the Board without similar express language do not apply to non-resident pharmacies.

During pre-review, a possible clarity issue was identified with respect to the case-by-case basis for approving record storage waivers. To correct this, Board staff has proposed modified text to include some of the factors the Board would consider as part of its case-by-case analysis. Such factors include space limitations within the pharmacy, cost, previous compliance with records requirements, ease of access to records stored outside of the licensed area, and any other factor presented by the licensee.

In addition to the comment received during the comment period, the initial proposed text and the staff recommended modified text are attached following this memo.

STAFF RECOMMENDED MOTION:

Approve the staff modified language provided for a 15-day public comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to adopt the modified text and make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Offsite Storage

16 CCR § 1707

**Title 16. Board of Pharmacy
Proposed Text**

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 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 ~~shall~~ may, on a case-by-case basis, be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy 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 designated representative) 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.

Off-Site Storage
16 CCR § 1707
45- Day Comment

From: Elizabeth Marley
Sent: Monday, February 10, 2020 9:40 AM
To: phystatus@dca.ca.gov <phystatus@dca.ca.gov>
Subject: Nonresident pharmacy question....

Not certain if this is the correct email for this question, so please forward to the appropriate place or let me know to whom I should speak.

My question concerns ***“off site record storage”*** as it is explained ***§ 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations.***

We are a nonresident pharmacy located in North Carolina. Permit NRP 1940. NC regulations require us to keep 2 years records on site, then we can store records off site.

Do we need to request a waiver according to California law? Is this mainly for resident pharmacies??

Elizabeth Marley, PharmD
Marley Drug Compliance Coordinator
5008 Peters Creek Parkway
Winston-Salem, NC 27127
(336) 771-7672

Off-Site Storage
16 CCR § 1707
Staff Recommended
Modified Text

**Title 16. Board of Pharmacy
Modified Text**

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

Proposed changes to the initial proposed text are shown by double underline for added language.

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 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 ~~shall~~ may, on a case-by-case basis, be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy 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.~~ The board may consider space limitations within the pharmacy, cost, previous compliance with records requirements, ease of access to records stored outside of the licensed area, and any other factor presented by the licensee in making its determination.
- (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 designated representative) 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.