

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Waiver Requirements for Off-Site Storage of Records

Section Affected: Amend Section 1707 of Article 2 of Division 17 of Title 16, California Code Regulations

Specific Purpose of the Proposed Changes/Problems Addressed

The Board of Pharmacy (Board) proposes to amend Section 1707 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of giving the Board discretion to grant a waiver of the requirement that records must be retained on the licensed premises, and to remove the blanket restriction requiring denial of a waiver if a licensed entity has failed to produce records or has falsified records pursuant to Section 4081 of the Business and Professions (B&P) Code.

Pharmacies are required to retain records of all acquisitions and dispositions of drugs for at least three years. Under the Board's current regulation, when requested, the Board must grant a waiver of the requirement to store such records on the licensed premises, unless the entity failed to produce or falsified records within the last five years. In other words, the Board cannot grant a waiver to an entity that failed to produce or falsified records in the last five years. Most pharmacies, however, have limited space, and storing volumes of records within the pharmacy can pose a safety risk to pharmacy personnel.

Separately, the current regulation requires the Board to grant a waiver in all cases, except when the entity failed to produce or falsified records. The primary purpose of maintaining records on the licensed premises is to ensure that they are readily available when needed for inspections and other law enforcement purposes. There is a greater potential for this purpose to be thwarted when records are stored off site. But even when the Board is aware of circumstances that would prevent a pharmacy from producing records promptly, it is powerless to deny a waiver in such cases under its current regulation.

This proposal will allow the board discretion when approving a waiver where a licensed entity is found in violation of section 4081 of the Business and Professions Code but lacks sufficient space within the licensed premises to store these records. It will also give the Board discretion to grant waivers when it is in the public interest to do so.

The Board's proposal makes the following specific changes to 16 CCR section 1707 subdivision (a):

- (1) Amend to change "shall" to "may, on a case-by-case basis," to give the Board discretion to approve a waiver. "Case-by-case-basis" was added to clarify that the Board would not be using set criteria to determine whether a waiver was appropriate, but rather

would evaluate each waiver request on its own merit. This is consistent with the terms of B&P sections 4105 and 4333.

- (2) Deletes “off-site” and replaces it with “outside the licensed area of the pharmacy” to clarify that the records will be stored outside the licensed premises.
- (3) Deletes “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,” to allow the Board discretion to approve a waiver even though a violation of B&P Section 4081 occurred.

Anticipated Benefits

Smaller pharmacies and high-volume pharmacies often do not have sufficient space to store prescription records within the pharmacy. This creates an unsafe environment because it creates a fire or tripping hazard. This proposal will benefit pharmacies that lack sufficient space to store records on the licensed premises by giving the Board the ability to allow them to store the records elsewhere. It will also benefit the public by giving the Board the ability to grant waivers in the public interest. The primary purpose of maintaining records on site is to ensure that they are readily available. Records stored off site are not always readily available, but the Board is powerless to deny a waiver in such cases under the Board’s current regulation. The public benefits from having the records readily available to the Board for inspection and other law enforcement purposes.

Factual Basis/Rationale

B&P section 4001.1 specifies that protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

B&P section 4081 generally specifies the record requirements for the manufacture, sale, acquisition, receipt, shipment, and disposition of dangerous drugs or dangerous devices. Additionally, this section generally specifies that a current inventory be kept by all licensees who maintain a stock of dangerous drugs or dangerous devices.

B&P section 4105 generally specifies the record requirements for the acquisition and disposition of dangerous drugs or dangerous devices.

B&P section 4333 specifies that all prescriptions filled by a pharmacy and all other records be maintained on the premises and available for inspection. This section also authorizes the Board to grant a waiver of the requirement that records be maintained on the licensed premises.

Pharmacies are required to retain records of all acquisitions and dispositions of drugs for at least three years. Most pharmacies have limited space available to store boxes of records and, therefore, storing records within the pharmacy can pose a health and safety risk to persons in the pharmacy.

This proposal would give the Board discretion to grant waivers to licensees on a case-by-case basis to store records outside the licensed pharmacy premises. It would specifically enable the board to grant waivers to licensees that failed to produce records or falsified records within the preceding five years.

The proposed action echoes the Board's discretionary authority in B&P sections 4105 and 4333 to grant waivers to licensees of the requirement that records must be kept on the licensed premises. It is necessary to adopt the discretionary standard in regulation to keep the criteria governing waivers in one place.

The proposed action is also necessary because the Board's existing regulation is unduly restrictive. By prohibiting the Board from granting waivers to licensees that previously failed to produce records or falsified records, the Board is prevented from addressing the practical reality that pharmacies often lack the physical storage space to maintain records on site. The current regulation forces such licensees to keep records on site, even if they will be kept in an unsafe manner. Under the proposed regulation, the Board may still deny a waiver if the licensee previously failed to produce records or falsified records, but the proposed regulation gives the Board much-needed flexibility in those circumstances.

Similarly, the Board proposes to amend the regulation in order to have discretion over granting waivers. Licensees may request a waiver of the on-site storage requirement for safety, cost, space, convenience, or other reasons that the Board does not presently anticipate. For this reason, the Board did not attempt to catalog the various grounds for granting a waiver in the regulation. However, the main purpose of the on-site record retention requirement is for the records to be readily accessible to the Board and others. (See, e.g., Bus. & Prof. Code, §§ 4081 [records shall be "open to inspection by authorized officers of the law"], 4105 [records maintained on site to be "readily retrievable"], 4333 [records maintained on site and "available for inspection by authorized officers of the law"].) The Board is cognizant that its decision-making is grounded in this statutory purpose, and that its case-by-case determinations must not be arbitrary, capricious or entirely lacking in evidentiary support. (See, e.g., *McGill v. Regents of Univ. of Cal.* (1996) 44 Cal. App. 4th 1776, 1786.)

Under the current regulation, this purpose can be thwarted when records are stored off site. Indeed, even when the Board is aware of circumstances that would prevent a pharmacy from producing records promptly, it is powerless to deny a waiver in such cases under its current regulation. Accordingly, the proposed amendment is necessary to give the Board discretion to deny a waiver in cases where the statutory purpose would be thwarted by granting a waiver.

Clarifying the regulation to "outside of the licensed area of the pharmacy," rather than "off-site," is necessary to clarify the scope of the regulation and better align it with the statutes.

B&P sections 4105 and 4333 authorize the Board to waive the requirement that records be kept “on the licensed premises.” The proposed amendment better aligns with the Board’s statutory authority. Separately, the term “off-site” is ambiguous and confusing. On this point, the Board does not envision that the proposed change will result in a substantive change to the regulation, but it will help clarify that the Board would be granting licensees permission to store records off of the licensed premises.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held January 4, 2017 (Meeting Materials Pages 1, 6-7, and Attachment 7, Minutes Pages 1, 13-15).
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 24, 2017 (Meeting Materials Pages 1, 7-8 and Attachment 5, Minutes Pages 1, 22-23).

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This includes the ability of California businesses to compete with businesses in other states. This proposal will allow some pharmacies to store their records outside of the licensed premises. Some pharmacies may choose to rent secure storage for the records, and in those cases, there would be a small monthly fee. Additionally, the proposed regulation does not require the use of a specific computer software.

Economic Impact Assessment

This regulatory proposal will have the following effects:

It will not create or eliminate jobs, will not create new businesses or eliminate businesses, and will not affect the expansion of businesses currently doing business within the State of California because this regulation is related to the storage of records and not jobs.

This regulatory proposal will have no impact on the health and welfare of California residents because this regulation is related to the storage of records and not the health and welfare of California residents.

This regulatory proposal benefits worker safety because the proposed regulation will allow pharmacies to minimize clutter by storing records outside of the licensed area of the pharmacy.

The proposal will have no impact on the benefits to state’s environment because this regulation is related to the storage of records and not the state’s environment.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected licensees and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. By not implementing this proposal, the Board would not have the ability to grant waivers when a pharmacy has been found in violation of Section 4081 of the Business and Professions Code. This would result in a pharmacy having to store records on-site, which may create an unsafe work environment.