# TITLE 16: BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS

#### **FINAL STATEMENT OF REASONS**

**Subject Matter of Proposed Regulations:** Discontinuance of Business

Sections Affected: Title 16, California Code of Regulations (CCR) section 1708.2

# **Updated Information**

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons is updated as follows:

The 45-day public comment period began on November 15, 2024 and ended on December 30, 2024. The Board's notice stated that the Board did not intend to hold a hearing on the matter unless requested. The Board did not receive a request for a hearing, and no hearing was held.

During the 45-day comment period, the Board received several comments. At the January 8, 2025 Board meeting, the Board reviewed the comments received and amended the draft regulation text to address concerns raised by stakeholders. The Board voted to initiate a 15-day public comment period, which commenced on February 10, 2025 and concluded on February 25, 2025.

Subsection (b) of the regulation text was amended to add statutory language from Business and Profession's Code (BPC) section 22949.92, that a pharmacy closure includes the cessation or substantial cessation of operations of a pharmacy. The Board added this clarification in response to public comment requesting clarification of requirements for temporary and permanent closure. (Existing CCR section 1708.1 includes requirements for temporary closures.)

Subsection (b)(1) of the regulation text was amended to change the number of days in advance of the closure a pharmacy shall notify patients of the closure, from 30 days to 45 days, so that it aligns with the requirement in BPC section 22949.92.1, which (was drafted and) went into effect after this rulemaking proposal's inception. The proposed regulation text was also amended to clarify that notification (about the closure) provided to patients shall be in a form of in which the pharmacy regularly communicates or advertises to its patients. The Board determined it is important for the pharmacy to use the same communication methods employed by the pharmacy for consistency, and to ensure the patients receive these communications.

Subsection (b)(4) of the regulation text was amended to add the owner as the responsible party for compliance with the requirements of the regulation section. The

owner shall certify compliance with the requirements, or the pharmacist-in-charge (PIC) shall certify compliance with the requirements if the PIC is available (as often, PICs move to other pharmacies before the closure occurs, either because they already happened to have another position lined up, or because they lined up another position upon finding out about the closure). The Board determined it is important for the owner to bear the responsibility of the requirements of the section given that a PIC might have already left before the pharmacy closed. The Board determined the owner to be the responsible party required to complete the requirements of the section, regardless of whether the PIC is available. BPC section 4113 requires the pharmacy designate the PIC or an interim pharmacist to act as and perform the functions of a PIC, and BPC section 4116 states only a licensed pharmacist, pharmacist intern, authorized officer of the law or person authorized to prescribe is permitted in the pharmacy licensed by the Board. Thus, a pharmacist—whether a PIC or an interim pharmacist retained to act as and perform the functions of a PIC—shall be among the possible certifiers of compliance with the section (either the PIC shall be an alternative to the owner if the PIC is still available, or an interim pharmacist retained to act as and perform the functions of a PIC shall certify along with the owner if an interim pharmacist is in the position). Ultimately though, the owner shall be responsible for compliance with the requirements of the section.

Subsection (b)(5) of the regulation text was amended to add a written notice posting requirement that mirrors the one in BPC section 22949.92.1(a)(2). The Board determined it was important to have this be included among the requirements of the regulation, as the statute only applies to covered pharmacies outlined in the statute. The Board, by its own authority, is establishing a requirement similar to the one in BPC section 22949.92.1(a)(2), and this requirement will apply to all pharmacies (unless exempted under proposed section (c) of the regulation) experiencing a closure.

Subsection (b)(6) of the regulation text was amended to add an exemption for general acute care hospital pharmacies owned by a health facility, as outlined in the requirement. The Board determined this change is necessary, as requirements for closure of a general acute care hospital pharmacy owned by a health care facility exist in Health and Safety Code section 1255.25.

During the (first) 15-day comment period from February 10, 2025 to February 25, 2025, the Board received one comment. At the March 6, 2025 Board meeting, the Board reviewed that comment, received from California Correctional Health Care Services (CCHCS), requesting subsection (b)(6) be amended to include the exemption of a "licensed correctional pharmacy dispensing only to patients of the California Department of Corrections and Rehabilitation" from the requirements in (b), in line with/in acknowledgement of BPC section (22949.92(a)(1)(B)), as CCHCS provides 60 days of medications to incarcerated persons upon release and does not continue to provide prescriptions after the person's release. Access to healthcare information, including prescription information, is available to the patient during incarceration and is available post-release through CCHCS' health information access policy. Additionally, all patients are informed of their ability to access this information in documents provided by CCHCS. The Board agreed with the staff recommendation to modify the proposed text in line with

the statutory requirement and this public comment and voted to initiate a second 15-day public comment period, which commenced on March 11, 2025 and concluded on March 26, 2025. Additionally, the Board voted that, if no adverse comments were received during the second 15-day comment period, the Board authorized the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at CCR section 1708.2 as noticed. Further, the Board voted to delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Subsection (b)(6) of the regulation text was amended to add an exemption for a licensed correctional pharmacy dispensing only to patients of the California Department of Corrections and Rehabilitation. The Board determined this change is necessary because correctional pharmacies dispensing only to patients of the California Department of Corrections and Rehabilitation are exempt from the recently-enacted statutory requirement being implemented in the regulation and would (therefore) be exempt from the regulation's requirements. The change was made in response to the recently-enacted statute and the public comment.

During the second 15-day public comment period, which commenced on March 11, 2025 and concluded on March 26, 2026, no public comments were received.

The final rulemaking package was submitted to the Office of Administrative Law (OAL) for review on August 14, 2025. Following their review, OAL requested one substantive change to the regulation text, which required the release of a third modified text (with a respective 15-day comment period), as well as additional nonsubstantive changes. The modified text was released (with OAL's requested changes) for a third 15-day comment period on October 6, 2025, and the comment period ended on October 22, 2025. No public comments were received.

#### Subsections (a) and (b)

Subsection (a) is amended to relocate a provision from proposed section (b)to become a second sentence in (a), to read "For purposes of this section, a 'closure' includes the cessation or substantial cessation of the business." Subsection (b) is therefore amended to remove "(cessation or substantial cessation)". This change is a non-substantive change without regulatory effect because it is part of an effort to "renumber[], reorder[], or relocat[e] a regulatory provision" within the meaning of Title 1, CCR section 100(a)(4).

#### Subsection (b)

Subsection (b) is amended to add the word "subsection" before "(a), a pharmacy that . . ." in the first sentence, for consistency throughout the section and the Board's regulations generally. This change is a non-substantive changes without regulatory effect because it is cross-reference change that is part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

## Subsection (b)(4)

The second sentence of subsection (b)(4) is amended to add "or" between "The owner," and "the pharmacist-in-charge", and remove the comma after "pharmacist-in-charge". The Board determined it was important to have the owner, or the pharmacist-in-charge (PIC) if available, responsible for certifying compliance with the requirements of the section.

The Board, in discussing and drafting the proposed regulations, made a point to be mindful of the realities facing licensees, especially PICs and pharmacy staff, which apply generally but especially at the time of closures, that would impact implementation and compliance: 1) PICs and pharmacy staff are often already extremely overworked and overburdened, especially leading up to and during closures, and therefore the Board did not want to add to their workload and create additional burdens and pressures; 2) PICs often do not have control over many/any of the mechanisms that impact compliance with these particular proposed regulations, so would it be reasonable or practical to always require the PIC to be responsible for ensuring, and (solely) certifying, compliance; and 3) along the same lines (as in 2), the Board did not want to create problems for PICs by requiring them to certify when they might not even be working for the closing pharmacy at the time leading up to and/or during the closure, as they might have already started in a position at another pharmacy (for various reasons—coincidentally timed move to another pharmacy, a move in anticipation/as a result of the upcoming closure, etc.). The Board's intention was to provide flexibility, by allowing certification of compliance by the owner or PIC if the PIC is available, so that the PIC is not especially burdened by the compliance requirements, and so that, in an already stressful time, the PIC does not feel their license could be in jeopardy if they cannot ensure, and therefore certify, compliance.

## Subsection (b)(5)

Subsection (b)(5) is amended to add ", which shall include", remove "with", and add a comma after the word "date". These changes are non-substantive changes without regulatory effect, as they are structure, grammar, and punctuation changes that are part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). The resulting language mirrors the language in BPC section 22949.92.1.

## Subsection (b)(6)

Subsection (b)(6) is amended to be subsection (c), which is a non-substantive change without regulatory effect because it is part of an effort to "renumber[], reorder[], or relocat[e] a regulatory provision" within the meaning of Title 1, CCR section 100(a)(4).

The language and meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), is removed from new subsection (c), a non-substantive change without regulatory effect, as this change is removing language the Board does not have discretion to add, as that type of hospital does not exist. The requirement in Business and Professions Code section 22949.92(a)(1)(B)(iii) states that The pharmacy is not owned

by a health facility as defined in Section 1250 of the Health and Safety Code." Therefore, the full sentence in the proposed regulation would read: "A general acute care hospital pharmacy that is not owned by a health facility as defined in Section 1250 of the Health and Safety Code." However, it is not possible for there to be a general acute care hospital pharmacy that is not owned by a health facility as defined in Health and Safety Code (HSC) section 1250. Under HSC section 1250, a "general acute care hospital" is, and is therefore owned by, a health facility. Every hospital must be licensed by the California Department of Public Health (CDPH). CDPH certification requires the hospital to provide basic services which includes pharmacy services. The license of the pharmacy and the drugs contained within the pharmacy must be owned by the CDPH licensed health facility. BPC section 22949.92 (SB 1089 (Smallwood-Cuevas, Chapter 625, Statutes of 2024)) was enacted during the promulgation of these proposed regulations, and in an effort to mirror some of the language of that statute in the proposed regulations, the Board added the citation to the statute to this regulation subsection, inadvertently resulting in language exempting a type of hospital that simply does not and cannot exist. Therefore, this change (removing this language) is a non-substantive change without regulatory effect.

Additionally, the structure and grammar of the language remaining in new subsection (c) are amended so new subsection (c) reads in its entirety "The following pharmacies shall be exempt from the requirements of subsection (b): (1) A general acute care hospital pharmacy that is owned by a health facility as defined in Section 1250 of the Health and Safety Code; and (2) A licensed correctional pharmacy dispensing only to patients of the California Department of Corrections and Rehabilitation." These changes are non-substantive changes without regulatory effect that are part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

The rest of the changes to the subsection are structure, syntax, and grammar changes, nonsubstantive changes that are part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

#### NOTE

The NOTE is amended to remove "22949.92, and 22949.92.1" from the "Reference" section. This change is a non-substantive change without regulatory effect, as it is part of an effort to "chang[e] an 'authority' or 'reference' citation for a regulation" within the meaning of Title 1, CCR section 100(a)(5). The citations to these BPC sections are being removed because they were included in error. The Board's regulations are not further implementing BPC sections 22949.92 and 22949.92.1, but rather the Board is using its own authority to promulgate regulations that mirror the language of BPC sections 22949.92 and 22949.92.1. These BPC sections were enacted (SB 1089 (Smallwood-Cuevas, Chapter 625, Statutes of 2024)) during the promulgation of these proposed regulations, and the Board determined it would mirror some aspects of the statutes in these regulations, under its own authority, and that the regulatory requirements would apply to a larger set of licensee pharmacies than the pharmacies covered by the statutes.

At the November 6, 2025 Board meeting, the Board ratified the modifications to the regulation text published during the third 15-day comment period from October 6, 2025 through October 22, 2025. Additionally, the Board directed staff to take all steps necessary to complete the rulemaking process.

## **Local Mandate**

A mandate is not imposed on local agencies or school districts.

## **Small Business Impact**

The Board determined that the proposed regulatory action will not have any adverse economic impact on small businesses. Although the proposed regulation will directly affect businesses statewide when a pharmacy closes and this may include small businesses, the Board does not anticipate any adverse economic impact. The Board notes that the discontinuance of business requirement as amended in the proposed regulation requires minimal cost to implement, and any cost would be born as a result of the statute this proposed regulation section implements.

## **Consideration of Alternatives**

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, as effective and less burdensome to affected private persons than the adopted regulation, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board considered not adopting the proposed regulation; however, the Board determined that alternative was not reasonable, as it is necessary to implement and make specific the statutory requirements.

# Objections or Recommendations/Responses to Comments

#### **45-Day Comment Period**

During the 45-day comment period, which began on November 15, 2024 and ended on December 30, 2024, the Board received several comments. At the January 8, 2025 Board meeting, the Board reviewed the comments received and amended the draft regulation text to address issues to clarify defintions and provide additional guidance to the regulationed public within the draft regulation text. The Board voted to initiate a 15-day public comment period.

# **Summary and Response to 45-day Comments:**

#### **Written Comments from Kaiser Permanente**

**Comment 1:** Commenter recommends that subsection (b)(1) be amended to add "or electronic" to allow for electronic notice to be sent to patients, as mailing a written notice would be wasteful, and some patients elect to have all communications made electronically.

**Response to Comment 1:** The Board reviewed the comment and voted to amend the text based on the comment. Subsection (b)(1) was amended to add "in a form in which the pharmacy regularly communicates or advertises to its patients." The Board noted this allowed the pharmacy to notify their patients electronically if already communicating with or advertising to patients electronically, allowing for continuity.

**Comment 2:** Commenter recommends that subsection (b)(4) be amended to require the Board to publish a certification form that a pharmacist-in-charge shall use to certify compliance.

**Response to Comment 2:** The Board reviewed the comment and voted to amend the text based in part on the comment. Subsection (b)(4) was updated to include that the owner is responsible, and the owner, or the pharmacist-in-charge if still available, shall certify compliance. The Board noted there is already a form available that licensees *can* use to report a discontinuance of business; however, the form is not mandated.

**Comment 3**: The commenter encourages the Board to set an effective date for the regulations to allow the regulated public ample time to comply with these new requirements. The commenter requests a three-month delay in the effective date.

**Response to Comment 3:** The Board reviewed the comment and did not make any changes to the text based on the comment. The regulation's effective date is determined by the date of filing with the Secretary of State, consistent with Government Code Section 11343.4, which establishes regulation effective dates based on a rolling quarterly basis.

#### **Written Comments from California Hospital Association**

**Comment 4:** Commenter expressed concern that hospitals have extensive pharmacy compliance requirements, and "in the hospital environment, the proposed regulations are unnecessary, costly, and duplicative". Further, Health and Safety Code 1255.25 establishes requirements that a hospital must comply with before closing, with the most notable being a required 120-day public notice posted at the entrance to all affected facilities. Additionally, hospitals must provide the public with a description of the three nearest available comparable services in the community.

**Response to Comment 4:** The Board reviewed the comment and voted to amend the text based on the comment. Subsection (b)(5) was amended to change "inpatient hospital pharmacy" to "general acute care hospital pharmacy." The Board agreed an inpatient pharmacy hospital that is owned by a health facility as defined in Section 1250 of the Health and Safety Code will be exempt from the requirements of subsection (b).

**Comment 5:** Commenter requested clarity on the difference between permanent and temporary closures. For a hospital, a temporary closure could occur due to a disaster or the need for a hospital to relocate its pharmacy during construction to meet seismic retrofitting requirements or expand to meet its communities' needs.

Response to Comment 5: The Board reviewed the comment and voted to amend the text based on the comment. The term "cessation or substantial cessation" was added to subsection (b)(1) to include conforming language from the statute. The Board noted that temporary closure is defined in California Code of Regulations section 1708.1. Additionally, under BPC section 22949.92.1(b), "a covered establishment shall not be required to provide [the closure notice required by the] section if either of the following circumstances applies: (1) A closure is necessitated by a physical calamity or act of war. (2) The closure is caused by business circumstances that were not reasonably foreseeable at the time that notice would have been required."

## **Written Comments from PJ Nachman**

**Comment 6:** The commenter opposes the proposed changes, as they pose additional administrative burdens during business discontinuance. The commenter indicates that these changes disproportionately target pharmacies, particularly independently owned and operated pharmacies, a sector already under immense financial strain. The commenter states that the regulation does not account for the economic impact on Pharmacies (administrative burden), existing onerous requirements (finding a pharmacy to accept records), and the wider impact on stakeholders (will force pharmacies to close), and notes misplaced priorities (the Board should focus on the problems created by PBMs and wholesalers).

Response to Comment 6: The Board reviewed the comment and did not make any changes to the text based upon the comment. The Board notes that Business and Professions Code section 22949.92.1 (SB 1089, Smallwood-Cuevas, Chapter 625, Statutes of 2024), requires that pharmacies, as specified, provide written notice of the closure to specified persons or entities no later than 45 days before a closure. The Board's language provides flexibility to reduce the economic impact to pharmacies to determine how to operationalize the requirements, consistent with the recently enacted legislation and the Board's policy goals. The commenter referenced unfair business practices, including by PBMs, and the Board is currently raising these issues as part of its report to the Legislature as part of its Sunset Review Process.

#### **Summary and Response to 15-day Comments:**

Written Comment by Greg Doe, PharmD, Statewide Chief of Pharmacy Services, California Correctional Health Care Services (CCHCS)

**Comment 7:** The commenter requests subsection (b)(6) be amended to include the exemption of a "licensed correctional pharmacy dispensing only to patients of the

California Department of Corrections and Rehabilitation" from the requirements in subsection (b). Commenter indicates that CCHCS provides 60 days of medications to incarcerated persons upon release and does not continue to provide prescriptions after the person's release. Access to healthcare information, including prescription information, is available to the patient during incarceration and is available post-release through CCHCS' health information access policy. Additionally, all patients are informed of their ability to access this information in the Patient Orientation to Health Care Services handbook.

**Response to Comment 7:** The Board reviewed the comment and voted to incorporate such an exemption into the proposed text.