



California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1708.2 Related to Discontinuance of Business and Review of Comments Received During the 45-Day Comment Period

Background:

At the April 24, 2024, Board meeting, the Board approved the proposed regulation text to amend Section 1708.2 related to Discontinuance of Business. This proposal amends the board's regulations regarding the closure of a pharmacy to ensure arrangements are in place to facilitate the continuity of patient care.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on November 15, 2024, which ended on December 30, 2024. Several comments were received during the comment period.

Attached to this memo are:

1. The proposed text that was released for the 45-day public comment period.
2. Board staff prepared summarized comments with recommended responses.
3. Board staff recommended modified text.
4. Comments received during the 45-day comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed on November 15, 2024.
2. Amend the regulation as recommended by Board staff and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff's recommended comment responses and modified text, and notice the modified text for a 15-day comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1708.2 as noticed. Further, 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.

**Department of Consumer Affairs
Title 16. Board of Pharmacy**

**Proposed Regulation Text
Discontinuance of Business**

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

Amend section 1708.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

- (a) Any permit holder shall contact the ~~the~~ Board prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (individually or collectively referred to as a "closure") and shall follow official instructions given by the ~~the~~ Board applicable to the transaction.
- (b) In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure shall complete the following:
- (1) At least 30 days in advance of the closure, provide written notice to patients that have received a prescription within the last year. At a minimum, this notice shall include:
- (A) the name of the patient and if one exists and is known to the pharmacy, the name of the legal representative of the patient,
- (B) the name and physical address of the pharmacy closure,
- (C) the name of the pharmacy where patient records will be transferred and maintained, and
- (D) information on how to request a prescription transfer prior to closure of the pharmacy.
- (2) Reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients,
- (3) Provide the Board with a copy of the notice specified in subsection (b)(1), and
- (4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance, along with a pharmacist retained to perform these functions.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332, and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.



Proposed Regulation to Amend Title 16 CCR Section 1708.2, Discontinuance of Business

Summarized 45-day Comments with Board Staff Recommendations:

Written Comments from Kaiser Permanente

Comment 1: Commenter recommends that subdivision (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: Board staff have reviewed the comment and seek guidance from the Board regarding whether to make changes to the text based on the comment. Board staff 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. Board staff notes that Board Policy was established prior to the introduction and passage of SB 1089 and Board policy discussions were specific that the notice be provided in written format. As the statutory language appears to allow different forms of communication in which the covered establishment regularly communicates with its patients, does the Board wish to allow for additional forms of communication with the regulation text? Board staff notes that under the provisions of the law, pharmacies must also post a written notice in a conspicuous location within the establishment. Written notification to patients is clear demonstration of compliance with the requirements; however, should the Board wish to provide additional flexibility, possible language that could be used is as follows: “(1) At least ~~30~~ 45 days in advance of the closure, provide written, including electronic, notice to patients that have received a prescription within the last year.”

Comment 2: Commenter recommends that subdivision (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: Board staff have reviewed the comment and do not recommend any changes to the text based on it. Board staff acknowledges that the Board provides a form that licensees can use to report a discontinuance of business; however, the form is not mandated. Board staff notes that the form will be updated to include the required certification; however, licensees are not

required to use the form and can submit the information in the format that meets the licensee's needs, provided all the necessary information is submitted.

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: Board staff have reviewed the comment and do not recommend any changes to the text based on it. Board staff note that 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. Board staff notes that the requirements established by SB 1089 went into effect on January 1, 2025.

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: Board staff have reviewed the comment and recommend that an inpatient pharmacy hospital that is owned by a health facility as defined in Section 1250 of the Health and Safety Code, and meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), be exempt from the requirements of subdivision (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: Board staff have reviewed the comment and recommend that the term "cessation or substantial cessation" be added to subdivision (b)(1) to include conforming language from the statute. Board staff notes that temporary closure is defined in California Code of Regulations section 1708.1. Additionally, under 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: Board staff have reviewed the comment and do not recommend any changes to the text based on it. Board staff 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.

**Department of Consumer Affairs
Title 16. Board of Pharmacy**

**Modified Regulation Text
Discontinuance of Business**

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

Modified changes made to the proposed regulation language are shown by ~~double strike through~~ for deleted language and double underline for added language.

Amend section 1708.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

- (a) Any permit holder shall contact the ~~b~~Board prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (individually or collectively referred to as a "closure") and shall follow official instructions given by the ~~b~~Board applicable to the transaction.
- (b) In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure (cessation or substantial cessation) shall complete the following:
- (1) At least ~~30~~45 days in advance of the closure, provide written notice to patients that have received a prescription within the last year. At a minimum, this notice shall include:
- (A) the name of the patient and if one exists and is known to the pharmacy, the name of the legal representative of the patient,
- (B) the name and physical address of the pharmacy closure,
- (C) the name of the pharmacy where patient records will be transferred and maintained, and
- (D) information on how to request a prescription transfer prior to closure of the pharmacy.
- (2) Reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients,
- (3) Provide the Board with a copy of the notice specified in subsection (b)(1), and
- (4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance, along with a pharmacist retained to perform these functions.
- (5) An inpatient hospital pharmacy that is owned by a health facility as defined in Section 1250 of the Health and Safety Code, and meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), shall be exempt from the requirements of subdivision (b).

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332, ~~and 4333~~, 22949.92, and 22949.92.1, Business and Professions Code; and Section 11205, Health and Safety Code.



December 10, 2024

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: *Proposal to Amend Section 1708.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations*

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed amendments to the Board's regulations pertaining to discontinuance of business of a licensed pharmacy. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

The proposed regulation requires a pharmacy that plans to cease operations due to closure to send a written notice to patients that have received a prescription from the pharmacy within the last year. Many patients have elected to receive communications from their pharmacy in an electronic format. Mailing a written notice to a patient who prefers to receive electronic communications would be wasteful and inconsistent with their stated preference. Therefore, we encourage the Board to clarify the regulation to specify that the required notice of pharmacy closure may be provided electronically; please see the suggested change to the regulation text below (modified text in **red font**).

(1) At least 30 days in advance of the closure, provide written **or electronic** notice to patients that have received a prescription within the last year. At a minimum, this notice shall include:

The proposed regulation requires the pharmacist-in-charge of a pharmacy that plans to cease operations due to closure to certify compliance with the requirements of this regulation. If it is left to the pharmacist-in-charge to devise the content and format of the certification, we anticipate that the certifications that the Board receives will be highly variable in quality. To promote consistency in the manner in which the required certification is provided to the Board, we suggest that the Board update its existing Discontinuance of Business form (17M-8) to include certification of compliance with this regulation and amend the regulation accordingly.

(4) **The Board shall publish a certification form upon which** the pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance, along with a pharmacist retained to perform these functions.

Finally, the rulemaking package did not include information about when the Board intends for the proposed regulation to take effect. We expect that it will take most organizations some time to develop an application to facilitate obtaining the information about patients who have filled prescriptions at the



closing pharmacy and generating a form letter with the required information. Therefore, we encourage the Board to set an effective date for the regulations that will provide the regulated public with ample time to come into compliance with these new requirements. We suggest that at least three months from the date that the regulation is filed with the Secretary of State would be a reasonable effective date.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board's regulations pertaining to discontinuance of business of a licensed pharmacy. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully,

A handwritten signature in black ink, appearing to read "J. Gray", with a long, sweeping horizontal line extending to the right.

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente



December 30, 2024

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833

Submitted via email to Lori.Martinez@dca.ca.gov

SUBJECT: Board of Pharmacy Proposed Regulations: Discontinuance of Business

Dear Ms. Martinez,

On behalf of more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Board of Pharmacy's (BoP) proposed regulations for discontinuance of business.

The BoP is a key partner with hospitals and their pharmacies to promote quality, safety, and continuity of care for patients. CHA recognizes efforts by the board to establish stronger discontinuance of business regulations for community retail pharmacies. However, in the hospital environment, the proposed regulations are unnecessary, costly, and duplicative.

Unlike retail pharmacies, hospitals are licensed and certified by both the California Department of Public Health (CDPH) and the federal Centers for Medicare & Medicaid Services. Both entities have extensive pharmacy compliance requirements and under California state law, Health and Safety Code 1255.25 already requires prescribed activities a hospital must comply with prior to closing. Most notable of these prescribed activities is a 120-day public notice, which is a notice posted at the entrance to all affected facilities, as well as a notice to CDPH and the board of supervisors of the county in which the health facility is located in. Additionally, hospitals are required to provide the public with a description of the three nearest available comparable services in the community.

In the BoP Initial Statement of Reason, the "underlying data" used to justify the necessity for these proposed regulations reference the following:

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held February 6, 2023 (Meeting Materials Agenda Item XII, Agenda)
2. Relevant Meeting Materials and Minutes from Licensing Committee Meeting held January 24, 2023 (Meeting Materials Agenda Item VII, Meeting Minutes)

Both the written materials and the recordings of these two meetings (including comments from the public) clearly indicate that the discussion of “necessity” for these proposed regulations was driven by concerns related to closures of retail/community pharmacies and not hospital pharmacies.

Compliance with these proposed regulations will require hospitals to develop new capacity to generate a written letter for all patients served within the last year. Currently, hospitals experience over 57 million patient encounters annually. Technological interfaces with patients’ electronic health records are extremely costly, may cause confusion for the public, and will require development and testing time. As a result, CHA recommends a one-year implementation delay after promulgation of the regulations.

Clarity is also necessary to differentiate between a permanent closure and a temporary closure. For a hospital, a temporary closure could occur due to a disaster or the need for a hospital to relocate their pharmacy during construction to meet seismic retrofitting requirements or expansion to meet the needs of their communities.

The California Legislature and the California Department of Health Care Access and Information are working diligently to lower health care costs. Every additional requirement a hospital must fulfill raises costs, which runs counter to this shared goal. These competing considerations must be balanced when updating regulations.

For the reasons stated above, CHA recommends that hospitals licensed under the Health and Safety Code; section 1250 be exempt from these requirements.

CHA appreciates the opportunity to discuss these perspectives. If you have questions, please contact me at slowe@calhospital.org or 916-240-8277.

Sincerely,



Sheree Lowe
Vice President, State Policy

From: PJ Nachman <pnachman@tinrx.com>

Sent: Friday, November 15, 2024 2:47 PM

To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>

Subject: RESPONSE Notice of Proposed Action - Discontinuance of Business

Response to Proposed Regulatory Action: 16 CCR § 1708.2 - Discontinuance of Business

Dear California State Board of Pharmacy,

I am writing in strong opposition to the proposed changes under 16 CCR § 1708.2, which would require pharmacies to bear additional administrative burdens in the event of business discontinuance. While continuity of care for patients is paramount, these changes disproportionately target pharmacies, significantly independently owned and operated pharmacies, a sector already under immense financial strain, without addressing the root causes of the crisis.

Pharmacies, particularly independent pharmacies, operate in a systematically flawed business model dominated by Pharmacy Benefit Managers (PBMs), Wholesalers and their PSAO's. These entities extract significant profits, leaving pharmacies with razor-thin margins, if any at all, or outright losses on many prescriptions. The proposed regulation, while well-intentioned, fails to account for the following realities:

1. Economic Impact on Pharmacies:

- o The additional administrative costs of notifying patients, reversing claims, and coordinating prescription transfers demand time, staff, and resources that many pharmacies simply cannot afford.
- o Pharmacies already hemorrhage funds due to unfair PBM practices, including predatory clawbacks, retroactive fees, and below-cost reimbursement rates. Adding this regulatory burden only accelerates the rate of closures.

2. Already Onerous Requirements:

- o It is already painful enough that pharmacies are required to find another failing pharmacy to take on years of paper documents, a requirement that adds significant logistical and financial strain.
- o Adding these proposed requirements on top of existing obligations only worsens an already untenable situation.

3. Wider Impact on Stakeholders:

- o Forcing more pharmacies to close because of onerous regulations does not protect patients—it harms them. Each closure leaves communities, especially underserved areas, with fewer options for care.
- o Pharmacy owners and employees are also victims of this flawed system. As businesses shut their doors, jobs are lost, livelihoods are destroyed, and access to healthcare becomes a casualty.

4. Misplaced Priorities:

- o Instead of targeting pharmacies already struggling to survive, the Board should use its authority to challenge the monopolistic practices of PBMs and wholesalers. These entities exploit their position, taking advantage of both pharmacies and patients daily.
- o Where is the Board's concern for patients when PBMs and wholesalers impose unreasonable costs that delay or deny care?
- o Where is the urgency to stop Goliaths in the industry from perpetuating these systemic inequities?

This regulation reflects a lack of understanding of the current pharmacy business model and places an undue burden on an industry already teetering on the brink of collapse. The Board should focus its efforts on tackling the upstream problems created by PBMs and wholesalers, which are the true threats to patient care continuity.

In closing, I urge the Board to reconsider this proposal and shift its focus to policies that address the systemic inequities harming pharmacies, patients, and healthcare workers alike. Instead of layering additional hardships on pharmacies, the Board should be fighting alongside them to dismantle the structures perpetuated by PBMs and ensure equitable, sustainable care for all Californians.

Thank you,

PJ Nachman

COO of former TIN Rx Pharmacies

From: Board of Pharmacy News and Information <PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy

Sent: Friday, November 15, 2024 4:00 PM

To: PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV

Subject: Notice of Proposed Action - Discontinuance of Business

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed modifications to Title 16 CCR § 1708.2, related to the Discontinuance of Business. Any person who wishes to comment on the proposed modifications may do so by submitting written comments beginning November 15, 2024, and ending on December 30, 2024, to the following:

Contact Person: Lori Martinez

Agency Name: California State Board of Pharmacy

Address: 2720 Gateway Oaks Drive, Ste 100

Sacramento, CA 95834

Email: PharmacyRulemaking@dca.ca.gov

Fax: (916)574-8618

Any responses to comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons.

All documents related to this regulatory action are available on the Board's website:
https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.