

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, Including Review of Comments Received During the Third 15-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 Requirements. This proposal amends the Board's regulations regarding discontinuance of business requirements at the time of 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 (APA), Board staff released the proposed text for the 45-day comment period on November 15, 2024, and the comment period ended on December 30, 2024. Several comments were received during the comment period. The Board reviewed the comments at the January 8, 2025 Board meeting and voted to amend the text in response to the comments received and Board staff recommendations.

Board staff released the revised text for a 15-day comment period on February 10, 2025, and the comment period ended on February 25, 2025. One comment was received during this comment period. The Board reviewed the comment at the March 6, 2025 Board meeting and voted to amend the text in response to the comment received.

Board staff released a revised text for a second 15-day comment period on March 11, 2025, and the comment period ended on March 26, 2025. 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 nonsubstantive changes to the regulation text, as well as one substantive change requiring a third modified text (with a respective 15-day comment period). 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.

At this Meeting:

The Board will have the opportunity to discuss the regulation, including the amendments requested by OAL, and adopt the text as noticed for the third 15-day comment period.

Possible Adoption Language:

Move to ratify the modifications to the regulation text published during the third 15-day comment period from October 6, 2025 through October 22, 2025. Additionally, direct Board staff to take all steps necessary to complete the rulemaking process.

Attached to this memo are:

- 1. The modified text that was released for the third 15-day public comment period.
- 2. The original noticed text and comments received during the 45-day comment period.
- 3. The first modified text, noticed for the first 15-day comment period and, comments received during that comment period.
- 4. The second modified text, noticed for the second 15-day comment period.

Department of Consumer Affairs Title 16. Board of Pharmacy

Third Modified Regulation Text Discontinuance of Business

Proposed changes made to the current regulation language are shown by strikethrough for deleted language and <u>underline</u> for added language.

Modified changes made to the proposed regulation language are shown by double strikethrough for deleted language and <u>double underline</u> for added language.

Second modified changes made to the proposed regulation language are shown by *italicized double strikethrough* for deleted language and *italicized double underline* for added language.

Third modified changes made to the proposed regulation language are shown with a **bold double strikethrough with dotted underline** for deleted language and a **bold dotted 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 <u>bB</u>oard prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (<u>individually or collectively referred to as a "closure"</u>) and shall follow official instructions given by the <u>bB</u>oard applicable to the transaction. For purposes of this section, a "closure" includes the cessation or substantial cessation of the business.
- (b) In addition to the requirements in **subsection** (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, in a form in which the pharmacy regularly communicates or advertises to its patients. 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 owner shall be responsible for compliance with the requirements of this section. The owner, or the pharmacist-in-charge; if available, 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) Post a written notice of the closure, which shall include with the planned closure date, in a conspicuous location at the pharmacy's entrance.
- (6) 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 meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), and a licensed correctional pharmacy dispensing only to patients of the California Department of Corrections and Rehabilitation, shall be exempt from the requirements of subdivision (b).
- (c) 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.

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.

15-Day Comment Period No Comments Received 3rd Modified Text

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 strikethrough for deleted language and <u>underline</u> 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 <u>bB</u>oard prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (<u>individually or collectively referred to as a "closure"</u>) and shall follow official instructions given by the <u>bB</u>oard 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, <u>4113</u>, 4332, and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.

45-Day Comment Period Comments Received



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,

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

Sheree Loure

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.

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 strikethrough for deleted language and <u>underline</u> for added language.

Modified changes made to the proposed regulation language are shown by double strikethrough for deleted language and <u>double underline</u> 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 <u>bB</u>oard prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (<u>individually or collectively referred to as a "closure"</u>) and shall follow official instructions given by the <u>bB</u>oard 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, in a form in which the pharmacy regularly communicates or advertises to its patients. 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 owner shall be responsible for compliance with the requirements of this section. The owner, the pharmacist-in-charge, if available, 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) Post a written notice of the closure with the planned closure date in a conspicuous location at the pharmacy's entrance.
 - (6) 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 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, <u>4113</u>, 4332, <u>and-4333</u>, <u>22949.92</u>, <u>and 22949.92.1</u>, 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,

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

Sheree Loure

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.

15-Day Comment Period Comments Received Modified Text

February 19, 2025

Lori Martinez California State Board of Pharmacy 2720 Gateway Oaks Dr Suite 100 Sacramento, CA 95833

Members of the Board,

California Correctional Health Care Services (CCHCS) appreciates the opportunity to provide comment in response to proposed California Code of Regulations §1708.2, Discontinuance of Business. CCHCS operates approximately 40 licensed Correctional Pharmacies, 615 licensed Correctional Clinics, and 460 Automated Drug Dispensing Systems (ADDS), servicing approximately 90,000 incarcerated patients.

CCHCS does not provide pharmacy services to the general public. CCHCS provides continuity of care for incarcerated persons within our institutions, and in the rare instance that one of CCHCS' licensed correctional pharmacies ceases operations, pharmacy services will continue to be provided from our other institutional pharmacies or Central Fill Pharmacy. All records will continue to be maintained by CCHCS.

CCHCS provides a 60-day of medications to incarcerated persons upon release and does not continue to provide prescriptions once they have released to the community. Access to healthcare information, including prescription information, is available to our population during incarceration and 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 in Addendum I below.

CCHCS is requesting that "licensed correctional pharmacy" be added to "subsection (6)" so that it reads as follows:

(6) 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 meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), and a licensed correctional pharmacy dispensing only to patients of the California Department of Corrections and Rehabilitation, shall be exempt from the requirements of subdivision (b).



Page 2

Respectfully,



Greg Doe, PharmD
Statewide Chief of Pharmacy Services
California Correctional Health Care Services

Greg.Doe@cdcr.ca.gov Cell: 916-658-3823

Page 3

Addendum I: Information provided to the incarcerated persons in the Patient Orientation to Health Care Services handbook given to all incarcerated persons upon entry.

Release of Health Care Information

If you or someone else wants to look at your health record, you need to:

- Fill out a CDCR 7385, Authorization for Release of Protected Health Information form.
- Turn it in to the Health Information Management (Health Records) Department.

The CDCR 7385 must:

- · Be signed by you or your authorized legal representative.
- · List the information (type of health records) you want released.
- · Say who receives the information and their address.
- · Say why they need the information.
- · Say when the authorization expires (up to a year).
- Choose a time for the information to be ready.

Health care information and records, including treatment for substance use disorder, are confidential and shared only with the treatment team except under certain situations including but not limited to:

- During medical emergencies.
- · If required by legal proceedings such as, but not limited to, Board of Parole Hearings.
- Purposes of audit or program evaluation.
- If permitted by law.

Department of Consumer Affairs Title 16. Board of Pharmacy

Second Modified Regulation Text Discontinuance of Business

Proposed changes made to the current regulation language are shown by strikethrough for deleted language and <u>underline</u> for added language.

Modified changes made to the proposed regulation language are shown by double strikethrough for deleted language and <u>double underline</u> for added language.

Second modified changes made to the proposed regulation language are shown by *italicized double strikethrough* for deleted language and *italicized 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 <u>bB</u>oard prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings (<u>individually or collectively referred to as a "closure"</u>) and shall follow official instructions given by the <u>bB</u>oard 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, in a form in which the pharmacy regularly communicates or advertises to its patients. 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 owner shall be responsible for compliance with the requirements of this section. The owner, the pharmacist-in-charge, if available, 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) Post a written notice of the closure with the planned closure date in a conspicuous location at the pharmacy's entrance.

(6) 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 meets the requirements of Business and Professions Code section 22949.92(a)(1)(B)(iii), and a licensed correctional pharmacy dispensing only to patients of the California Department of Corrections and Rehabilitation, 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.

15-Day Comment Period No Comments Received 2nd Modified Text