

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

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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 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. 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. The Board reviewed the comments at the January 2025 Board meeting and voted to amend the text in response to the comments received and Board staff recommendations.

Board staff released revised text for a 15-day comment period on February 10, 2025, which ended on February 25, 2025. One comment was received during this comment period from the California Correctional Health Care Services (CCHCS). The commenter indicates that CCHCS provides 60 days of medications to incarcerated persons upon release and does not continue to provide prescriptions once they have been 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. CCHCS requests the following amendment to subsection (6):

(b)(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).

Board staff have reviewed the comment and recommend that it be accepted and that the recommended language be incorporated into subsection (b)(6).

This memo includes the modified text released for the 15-day public comment period and the comments received during that period. A second modified text, which includes the language amendment recommended by CCHCS, is also provided.

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 February 10, 2025.
- 2. Amend the regulation as recommended by Board staff and notice the modified text for a second 15-day comment period.

Possible Motion:

Accept the Board staff's recommended comment response and modified text, and notice the second modified text for a second 15-day comment period. Additionally, if no adverse comments are received during the second 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

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.

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).



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Respectfully,



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

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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.