

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Discontinuance of Business**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under “Contact Person” in this Notice, must be received by the Board at its office by December 30, 2024.

Public Hearing

The Board has not scheduled a public hearing on this proposed action. The Board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or that person’s authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing, addressed to the individuals listed under “Contact Person” in this notice.

Written Comment Period

Written comments relevant to the action proposed, including those sent by mail, facsimile, or e-mail to the addresses listed under “Contact Person” in this notice, must be received by the Board at its office no later than December 30, 2024, or must be received by the Board at the hearing, should one be scheduled.

Authority and Reference: 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.

Informative Digest/Policy Statement Overview

The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (BPC section 4000, et seq.). The Board’s mandate and mission are to protect the public (BPC section 4001.1).

The Board’s current discontinuance of business regulations require a licensee to notify the Board and provide specified information; however, there are currently no provisions establishing requirements that help ensure continuity of patient care (though the Board’s Disciplinary Guidelines establish requirements that help ensure continuity of patient care in the event a premises license is surrendered or revoked).

The Board has received complaints from consumers and policy makers in two general areas: 1. A pharmacy has closed, and a patient cannot receive a refill because they are unable to contact the pharmacy to request a prescription transfer; and 2. A pharmacy has closed and transferred patient prescription refills to another pharmacy not of the

patient's choosing. In both such scenarios, patient care is impeded and many times, patients are required to seek a new prescription from their prescriber. The need to obtain a new prescription can delay treatment, which jeopardizes patient safety.

This proposal establishes requirements that a closing pharmacy must comply with to ensure arrangements are in place to facilitate the continuity of patient care. At minimum, the pharmacy must provide a written notice to ongoing patients that includes the name of the patient, name and address of the pharmacy, name of the pharmacy where the patients' records will be transferred, and information on how to request a prescription transfer prior to the closure of the pharmacy. Additionally, the pharmacy must reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients.

Anticipated Benefits of the Proposed Regulations

The Board has determined that this regulatory proposal will have the following benefits to health and welfare of California residents and will not impact worker safety or the state's environment.

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. For many communities, the closure of a local pharmacy and loss of the pharmacist means that healthcare services and medications are interrupted and hard to reach. The proposed amendments to the existing regulations will help ensure that patients have seamless and continued access to their medications and other healthcare services.

A notice of the discontinuance of a pharmacy will increase patient awareness of planned pharmacy closures and mitigate destabilization in patient's access to medications and healthcare services.

Evaluation of Consistency and Compatibility with Existing State Regulations

During the process of developing this regulatory proposal, the Board has conducted a search of any similar regulations on these topics and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. The proposed amendments expand upon existing regulations, which require a licensee or pharmacy to notify the Board and provide specified information upon discontinuance of a business. Furthermore, the Board's Disciplinary Guidelines establish requirements for continuity of patient care in the event a premises license is surrendered or revoked, but not in the event of discontinuance of business.

Disclosures Regarding This Proposed Action

Fiscal Impact and Related Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None. The proposed regulations do not result in a fiscal impact to the State. The Board does not anticipate additional workload or costs resulting from the proposed regulations, as the Board will be able to ensure compliance during the normal inspection process without additional workload or costs.

Nondiscretionary Costs/Savings to Local Agencies: None

Cost to any Local Agency or School District for which Government Code Sections 17500 - 17630 Require Reimbursement: None

Mandate Imposed on Local Agencies or School Districts: None

Significant Effect on Housing Costs: None

Business Impact Estimates:

The Board has made the initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. The proposed amendments expand on existing requirements, which provide clarity to consumers with respect to closure of pharmacies. Additionally, the proposal identifies the specific requirements for discontinuance of business. The estimated cost to the pharmacy is within existing parameters, and require a notice within normal business hours and the staff time spent to alert the consumer of the impending closure, arrange for the continuation of care for existing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating in the transfer of records or prescriptions for ongoing patients. The Board determined that the written notice could be provided via SMS text messaging, email, via a posted notice within the pharmacy, or another method as determined by the pharmacy based on the business practice of the pharmacy.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Small Business:

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a "small business", as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action may affect small businesses, but in a way that is extremely beneficial

to consumers, as staff time would be spent alerting the consumer of the impending closure, arranging for the continuation of care for existing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and cooperating (as may be necessary) in the transfer of records or prescriptions for ongoing patients. While their may be a minimal cost, the Board determined that the cost would not be substantial.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board concludes that this proposal will not:

- (1) create jobs within California;
- (2) eliminate jobs within California;
- (3) create new businesses within California;
- (4) eliminate existing businesses within California; and,
- (5) expand businesses currently doing business in the State of California.

The Board determined that this proposal will not create or eliminate jobs or businesses. The proposal identifies the specific requirements for discontinuance of business. The estimated cost to the pharmacy would be the staff time spent to alert the consumer of the impending closure, arrange for the continuation of care for existing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, as the proposed regulation provides clarity to consumers with respect to closure of pharmacies and will help ensure that patients have seamless and continued access to their medications and other healthcare services. The regulatory proposal will not impact worker safety or the state's environment.

Business Reporting Requirements

The regulatory action does not require businesses to file an additional report with the Board, as the existing regulations require businesses to report their closure to the Board.

Consideration of Alternatives

In accordance with Government Code section 11346.5(a)(13), the Board determined that no reasonable alternative that it considered to the regulation, or that has otherwise been identified and brought to its attention, would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less

burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments to the Board in writing relevant to the above determinations at the address listed for the “Contact Person” during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information on which this proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

Availability of Text of Proposal

Copies of the exact language of the proposed regulations, the Initial Statement of Reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy’s website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Availability and Location of the Final Statement of Reasons and Rulemaking File

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the Final Statement of Reasons, once it has been prepared, by making a written request to the Contact Person named below or by accessing the website listed below.

Contact Person

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Lori Martinez
Address: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 244-6648
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel
Address: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text, if any, can be accessed through the Board of Pharmacy's website: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.