

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: Agenda Item V. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, California Code of Regulations Section 1708.1, Notification of Temporary Closure, Including Consideration of Public Comments Received During 45-Day Comment Period

Background:

At the July 29, 2020 Board meeting, the Board approved proposed regulation text to add Section 1708.1 related to the notification of temporary closure. This proposal establishes the notification requirement for the temporary closure of licensed facilities.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on October 29, 2021, which ended on December 13, 2021. Several comments were received during the comment period. Attached following this memo are the following:

- 1. The proposed text released for 45-day public comment.
- 2. Board staff prepared summarized comments with recommendations
- 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 October 29, 2021 for 45-day comment.
- 2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses, approve the staff recommended modified regulation language, and initiate a 15-day public 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 1708.1 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.

Temporary Closure of Facilities 16 CCR § 1708.1

Title 16. Board of Pharmacy Proposed Text

Add Section 1708.1 to Title 16 of the California Code of Regulations, to read as follows:

§ 1708.1. Notification of Temporary Closure.

A permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4032 and 4312, Business and Professions Code.

Summarized Comments with Staff Recommendations Temporary Closure of Facilities



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Proposed Regulation to Add Title 16 CCR Section 1708.1, Temporary Closure of Facilities

<u>Summarized 45-day Comments Regarding Temporary Closure of Facilities with</u> Board Staff Recommendations:

Written Comments from Greg Doe, CA Correctional Health Care Services

Comment 1: The commenter expressed concern about the requirement for Correctional Pharmacies to report temporary closures exceeding three days. Commenter indicated that Correctional Pharmacies are closed over the Thanksgiving holiday (Thursday – Sunday) which would require the reporting of 40 closures yearly. Commenter indicated that patients continue to be served during these closures via ADDS machines. Additionally, the commenter indicated that Correctional Pharmacies do not serve the general public.

Response to Comment 1: Board staff have reviewed this comment and recommend changes to the text based thereon. Staff recommend amending the language to clarify holiday closures, routine short-term (four days or less) closures, and to exempt Correctional Pharmacies, as they do not serve the general public. This preserves the intent of the board in protecting the general public; Corrections has indicated that they jurisdictionally protect their inmate population.

Written Comments from Anthony Lorenzana, Clinicas del Camino Real

Comment 2: Commenter indicates that his pharmacy is closed over the Thanksgiving holiday (Thursday – Sunday) and he is unclear if he would need to report the closure to the Board. Commenter requested clarification on the definition of "temporary closure."

Response to Comment 2: Board staff have reviewed this comment and do not recommend any additional changes to the text based thereon, beyond the changes recommended in response to Comment 1. Staff believe the recommended modified text addresses the commenters' concern.

Written Comments from Lorri Walmsley, Walgreens

Comment 3: Commenter expressed concern about the requirement to report closures in the event of a natural disaster or when a pharmacy is closed on the

weekends and would need to report after one day as it poses a burden on the pharmacy.

Response to Comment 3: Board staff have reviewed this comment and do not recommend any changes to the text based thereon due to natural disasters, etc. Staff is proposing edits to clarify routine closures due to holidays, and to include routine closures of four days or less do not need to be reported. Board staff does not agree that reporting a closure is burdensome for a pharmacy as the report can be made by the pharmacist-in-charge via email to the board, which takes only a minute or two. As discussed at previous Committee and Board meetings (July 2021 Committee and Board meeting), the Board determined that the public needs to know whether their local pharmacy is open during a state of emergency or if they need to seek services elsewhere. As such, it is necessary for pharmacies to report closures during a state or federal emergency as not all locations may be closed.

Written Comments from Marie Cottman, Pharm.D.

Comment 4: Commenter indicates that, as a small business owner, she occasionally closes her pharmacy for more than three days. Commenter indicates that she plans these closures in the advance and coordinates with patient and providers. Commenter requests that the language be amended to specify "unplanned" closures.

Response to Comment 4: While this comment was received after the closure of the comment period, Board staff reviewed this comment and believe the recommended modified text addresses the commenters' request, as discussed above.

Board Staff Recommended Modified Text Temporary Closure of Facilities

Title 16. Board of Pharmacy Modified Text

Proposed modified changes are shown by single strikethrough for deleted text and single underline for added text.

Add Section 1708.1 to Title 16 of the California Code of Regulations, to read as follows:

§ 1708.1. Notification of Temporary Closure.

Except for Correctional Pharmacies, a A permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information. A temporary closure shall not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4032 and 4312, Business and Professions Code.

45-Day Public Comments Received Temporary Closure of Facilities

October 28, 2021

Lori Martinez California State Board of Pharmacy 2720 Gateway Oaks Drive, 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 §1708.1, Temporary Closure of Facilities. CCHCS operates approximately 40 licensed Correctional Pharmacies, 320 licensed Correctional Clinics and 480 Automated Drug Dispensing Systems servicing approximately 99,000 incarcerated patients and does not serve the general public.



The typical CCHCS Pharmacy is open Monday thru Friday for at least 8 hours each working day. However, the pharmacies are typically closed weekends and holidays. Since the Thanksgiving weekend is 4 calendar days, this would require 40 notifications to the Board annually. In addition, CCHCS Facility Planning and Activation Management has approximately 130 major construction projects either in process or scheduled over the next two years which may result in temporary closures to one or more locations.

Notwithstanding each of the closures identified, CCHCS is obligated to provide medications to its patients twenty-four hours a day, seven days a week. The 320 Correctional Clinics, with the 480 ADDS machines located within, maintain this medication availability. All patients receiving services from CCHCS can be serviced from any correctional clinic location across their institution utilizing the organization's enterprise based Electronic Health Record.

With patient care continually provided, since CCHCS doesn't provide services to the general public and temporary closures are not limited to emergency or unforeseen occurrences, requiring notification would be a significant investment of time and effort for both CCHCS and the Board, without bringing additional benefit to the patients. CCHCS is therefore respectfully requesting an exemption from CCR §1708.1, Temporary Closure of Facilities.

Respectfully,

Grey Doc.

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Greg Doe, Pharm.D.

Statewide Chief of Pharmacy Services

California Correctional Health Care Service



Lorri Walmsley, RPh, FAzPA
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November 16, 2021

Dr. Seung Oh President California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

RE: Proposed Regulations to Add Section 1708.1 Notification of Temporary Closure

Dear President Oh:

On behalf of all Walgreens owned pharmacies in California, Walgreens thanks the Board for the opportunity to submit comments on the proposed regulations to add Section 1708.1 to Article 2 of Division 17 of Title 16 of the California Code of Regulations related to Notification of Temporary Closure.

While the majority of our pharmacies would rarely reach a closure of greater than 3 consecutive days, there are circumstances; natural disasters for example, where this requirement would be extremely burdensome for pharmacies to comply with. Additionally, some pharmacies are closed on weekends and the requirement to notify if those pharmacies close for one day is again burdensome to pharmacies. We respectfully request the following amendments as indicated below.

§ 1708.1. Notification of Temporary Closure.

A permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive <u>business</u> days, <u>unless the closure is caused by a declared state or federal declaration of emergency</u>. Closure dates will be public information.

Walgreens thanks the Board for the opportunity to provide feedback on these proposed regulations. Please do not hesitate to contact me with any questions or for further information.

Sincerely,

Lorri Walmsley, RPh, FAzPA Director, Pharmacy Affairs Walgreen Co.

Loui Walmsley

From: ALorenzana@clinicas.org <ALorenzana@clinicas.org>

Sent: Tuesday, November 30, 2021 11:02 AM

To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>

Subject: Comments to Proposed Rule - Notification of Temporary Closure -Title 16, California Code of

Regulations

[EXTERNAL]: alorenzana@clinicas.org

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Hello Ms. Lori Marinez

I would like to submit comment regarding the Proposed Rule Re: Notification of Temporary Closure - Title 16, California Code of Regulations

The text of the proposed regulation states that " temporary closure of a facility as soon as any closure exceeds three consecutive calendar days", however there is no definition given in the proposed regulation of a 'temporary closure'.

In the case of my pharmacy we typically are closed for the Thanksgiving Holiday and the Friday following Thanksgiving, we are not open on Saturdays and Sundays, normal business hours are Mon-Friday only. We provide notice to our patients by telephone messaging and physical postings of our holiday closures at least 7 days before they occur.

Under the current proposed rule, it is unclear if I would be require notify the Board of my pharmacy's closure, as in the example above I am closed for more than three calendar days.

I urge the Board to consider language in the regulation to define the term 'temporary closure' to assist all licensees with compliance.

In this definition, days outside of normal business hours, state and federal holidays, and other scheduled closures the pharmacy has provided the public proper notice of such closures be excluded from the "three consecutive calendar days" calculation.

Clarification of this rule is needed for licensees, and to implement the Boards original intention as stated within the Initial Statement of Reasons, so the public can "allow patients and healthcare practitioners to make informed decisions about the availability of prescription medications "when a pharmacy experiences a temporary closure for natural disaster, construction problems or vandalism/destruction.

Thank you for considering my recommendation and request

Anthony Lorenzana, Pharm.D.

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From: Marie Cottman <marie@pacificcompound.com>

Sent: Monday, January 3, 2022 1:46 PM

To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>

Subject: Re:NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: NOTIFICATION OF TEMPORARY

CLOSURE

Lori, I received the email that you are out of town so I thought I would draft this. If it can be considered, I would appreciate it. Thanks, Marie

Dear Board of Pharmacy,

I apologize for being tardy with my comments. I hope that you will still consider them regarding the Notification of Temporary Closure.

There have been occasions, as a small business owner, that I have needed to close the pharmacy for more than 3 days. These have all been planned in advance and patients and providers were notified by us several weeks in advance. We coordinated refill timing and even provided contact information for another compounding pharmacy in the case of an emergency so that patients and providers knew who to call.

I respectfully request that you modify the language to include "unplanned closure." --- A permit holder shall notify the board of any <u>unplanned</u> temporary closure of a facility as soon as any closure <u>it</u> exceeds three consecutive calendar days. Closure dates will be public information.

Thank you for your consideration.

Sincerely, Marie Cottman

Marie Cottman, Pharm.D.

Clinical Pharmacist/ Co-Owner
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