



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item XI. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code section 4062

Background

Beginning in March 2020, the Board has been granting waivers of Pharmacy Law and its regulations consistent with the authority of Business and Professions Code (BPC) section 4062. During the pandemic the Board has delegated authority to the Board President to approve waivers. As part of the December 10, 2021 meeting, members delegated to the President the authority to use discretion on waivers included in the meeting materials through August 31 or sooner at the President's direction. As part of the discussion, members clarified that new waivers would follow the current delegated authority which provides the President with the authority to issue a waiver for up to 90-days and extend waivers for two additional 90-day periods.

For Discussion and Consideration

Consistent with the authority, the Board President has continued to issue and extend waivers. Provided below is information on current broad waivers that will otherwise expire as detailed consistent with the current delegated authority. Members will have the opportunity to review the waivers and determine if additional extensions are appropriate.

a. Consideration of Broad Waivers

Provided below is a summary of the waiver, the effective date, expiration, and data on the use of the waivers based on pharmacy inspections conducted within the last 60 days.

i. [Pharmacists Initiating and Administering Vaccines \(CCR Section 1746.4\(d\)\)](#)

Summary: Waives the requirement for a pharmacist to notify each patient's primary care provider of a COVID-19 vaccine administration under specified conditions.

Effective: December 17, 2020

Expiration: August 27, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.

- Frequency of Use:** Eight percent of pharmacies report using this waiver. Staff note that the waiver may also be used outside of pharmacies as pharmacists may be providing vaccinations in other locations.
- ii. [Duty to Consult \(Title 16, California Code of Regulations, section 1707.2\(a\)\)](#)
Summary: Waives the requirement for in-person consultation under specified conditions.
Effective: April 1, 2020
Expires: August 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner
Frequency of Use: 10 percent of pharmacies report using this waiver.
 - iii. [Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System \(ADDS\) - Business and Professions Code sections 4119.11\(a\)\(9\) and BPC 4427.2\(e\)](#)
Summary: Waives the inspection requirement a condition of licensure of an ADDS under specified conditions.
Effective: April 13, 2020
Expires: August 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
Frequency of Use: Fifty-two percent of ADDS locations required a waiver of the in-person inspection.
 - iv. [Prescriber Dispensing Medication to Emergency Room Patient \(BPC sections 4068\(a\)\(1\), 4068\(a\)\(5\), and 4068\(a\)\(6\)\)](#)
Summary: Waives the prohibition against a prescriber dispensing medications to an emergency room patient under specified conditions.
Effective: March 27, 2020
Expires: August 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
Frequency of Use: Board staff are not aware of any hospitals currently using this waiver.
 - v. [Staff Ratio of Pharmacists to Intern Pharmacists and General Supervision – Immunizations – BPC 4114](#)
Summary: Increases the pharmacist to intern pharmacist ratio to allow for one additional intern for each supervising pharmacist, if the additional intern is administering immunizations. Further, changes the level of supervision of this additional intern pharmacist to general supervision at the discretion of the supervising pharmacist.
Effective: December 16, 2020
Expiration: August 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
Frequency of Use: No use reported.

**b. Consideration of Site-Specific Waiver
University of California, Student Health Pharmacies**

Background

On November 17, 2020, President Lippe approved a waiver request received from the University of California seeking a waiver to CCR Section 1707.2(b)(1)(C)(ii) to allow a pharmacist to be available no less than five days per week as specified locations. The waiver was initially approved for 90 days and was subsequently extended for two additional 90-day periods.

Provided below is the approved waiver.

In response to the Governor's emergency declaration and consistent with the authority of the board to waive statutory requirements in the event of a declared disaster, the board president, through his delegated authority, grants an extension of limited waiver to the provisions of Title 16, California Code of Regulations section 1707.2 (b)(1)(C)(ii), in that a pharmacist is available no less than five days per week to the following pharmacies:

- UC Santa Cruz, PHE 36033
- UC Davis, PHE 36229
- UC Irvine, PHE 35938
- UC Los Angeles, PHE 54650
- UC Riverside, PHE 45578
- UC Santa Barbara, PHY 46043
- UC San Diego, PHY 35957

This waiver is granted effective 11/17/2020 through 8/31/2021. We respectfully request that you provide the board with subsequent notification if you anticipate the need of the waiver beyond the additional 90-day period granted herein. Please be advised that should a further extension of this waiver be sought, the matter will require consideration by the full Board during its July Board Meeting. The Board respectfully requests that any such request be submitted no later than July 2, 2021.

Please retain a copy of the extension approval.

Following this memo is a copy of the waiver request received seeking to extend the current site-specific waiver.



UC Health
1111 Franklin
Oakland, Ca 94607
www.ucop.edu/uc-health

July 20, 2021

Anne Sodergren
Executive Officer
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Request for a Waiver of Title 16, section 1707.2(b)(1)(C)(ii)

Dear Ms. Sodergren:

I am writing on behalf of seven of the University of California's student health services pharmacies, located on the campuses in Davis, Santa Cruz, Santa Barbara, Los Angeles, Irvine, Riverside, San Diego, to request a Pharmacy regulation waiver due to the COVID-19 pandemic, pursuant to Governor Newsom's declaration of a state of emergency on March 4, 2020 and Section 4062 of the Business & Professions Code, in order to aid in the protection of public health and the provision of patient care to University of California students.¹ The student health services pharmacies appreciate the flexibility permitted by the current waiver of Section 1707.2(a) of Title 16 of the California Code of Regulations with respect to in-person oral consultation, and hope that the Board of Pharmacy will consider extending that waiver again beyond August 31, 2021, particularly as data indicate that the COVID-19 Delta variant is quickly spreading in California.² In addition, the student health services pharmacies respectfully request that the Board of Pharmacy grant a limited waiver of one of the requirements added to Section 1707.2(b) with respect to mail pharmacy services, in that a pharmacist is only required to be available no less than five days per week (instead of six days per week), in order to allow student health pharmacies to continue to provide mail pharmacy services to University of California students.³

Please see below for a brief statement regarding the relevant regulation, the extent of the waiver requested, and our need for such a waiver.

Regulations Requested to Be Waived

The recently amended "Duty to Consult" regulations set forth in Title 16, Section 1707.2(b) of the California Code of Regulations establish several new requirements effective October 1, 2020

¹ Cal. Bus. & Prof. Code § 4062(b).

² <https://www.sfgate.com/bayarea/article/California-COVID-delta-variant-mask-mandate-rules-16318047.php>

³ The President of the Board of Pharmacy previously granted a 90-day waiver of this requirement to certain UC student health pharmacies effective November 17, 2020 through August 31, 2021 pursuant to the authority delegated to him by the Board.

regarding mail order pharmacy services.⁴ Specifically, subsection (b)(1)(C)(ii) requires that when a patient or a patient’s agent is not present, “including, but not limited to, a prescription drug that was shipped by mail or delivery,” a pharmacist must be available with ready access to the patient’s record to speak to the patient or the patient’s agent “for no less than six days per week.”⁵

Extent of the Waiver Requested

The seven University of California student health pharmacies identified in this letter request a waiver of Section 1707.2(b)(1)(C)(ii), but only as to the provision requiring a pharmacist to be available for consultation for no less than six days per week.⁶ As explained below, the student health pharmacies are able to comply with all other aspects of the amendments to Section 1707.2(b). The student health pharmacies also have appreciated the flexibility permitted by the current waiver of Section 1707.2(a) with respect to in-person oral consultation, and hope that the Board of Pharmacy will consider extending that waiver again beyond August 31, 2021, particularly as data indicate that the COVID-19 Delta variant is quickly spreading in California.

Statement of Need

Many University of California students are covered under the UC Student Health Insurance Plan (UC SHIP) and depend on University student health services providers for medical and behavioral health services. As a result of the ongoing COVID-19 public health emergency, UC student health pharmacies began mailing prescription drugs to student patients to ensure continuity of care for students who are not present on campus. Both the UC student health pharmacists and student patients have found mail order prescriptions essential to maintaining patient care throughout this crisis. Although UC campuses anticipate offering in-person instruction in the fall term, we believe that it will be critical to maintain the flexibility to offer pharmaceutical services by mail as well as in-person. In light of data indicating that the COVID-19 Delta variant is spreading in California, as well as across the nation, UC campuses may need to adjust or limit to their in-person operations in order to respond to changes in the pandemic, and want to be able to do so without jeopardizing continuing of care for our students.

However, the UC student health pharmacies’ normal hours of operation are forty hours and five days (Monday through Friday) per week. The student health centers and their pharmacies are not open during the weekends. As a result, the UC student health pharmacies are concerned that the requirement that a pharmacist must be available for consultation no less than six days per week may preclude our student health centers from continuing to provide this important service to our students.

The student health pharmacies are able to comply with all of the other aspects of the new requirements in Section 1707.2(b) and generally are very proactive when it comes to patient consultation. Moreover, our pharmacists make sure to encourage the student to make contact again if they have further questions.

Consistent with Section 1707.2(b)(1), the UC student health pharmacies send students a secure email message that notifies the patient of his or her right to request consultation, the hours of availability and the telephone number from which a patient may obtain oral consultation from a pharmacist who has ready access to the patient’s record. This written information is also included in the patient’s mailed package along with the drug. During a recent routine inspection

⁴ 16 CCR § 1707.2.

⁵ 16 CCR § 1707.2 (b)(1)(C)(ii).

⁶ The UC Berkeley University Health Services, Tang Center pharmacy (PHE 38890) also supports this request but maintains operations seven days per week and does not require a waiver of the regulation at this time.

at one of the UC student health pharmacies, the Board of Pharmacy inspector reviewed and approved the language of the written notice provided to patients. Finally, as noted above, UC student health pharmacists are available for oral consultation forty hours and five days per week, during the regular hours of operation of the student health pharmacies.

For these reasons, UC student health pharmacies respectfully request a limited waiver of the requirement for a pharmacist to be available for consultation for no less than six days per week, which will allow UC student health pharmacies to continue to provide services to student patients during the COVID-19 emergency. Without this exemption, our student health centers may be forced to discontinue mail delivery of prescriptions altogether due to the added cost of making a pharmacist available on a weekend day when the pharmacy is not open.

Please let us know if there is any additional information that you require. Should you have any questions regarding this request, please do not hesitate to contact Sarah Huchel, Legislative Director, UC Health, UC State Government Relations, UC Office of the President, at Sarah.Huchel@ucop.edu or Brad Buchman, Chief Medical Officer, UC Student Health and Counseling, UC Office of the President, at Brad.Buchman@ucop.edu. Thank you in advance for your time and attention to this matter.

Licensees:

UC Santa Cruz PHE 36033

UC Davis PHE 36229

UC Irvine PHE 35938

UC Los Angeles PHE 54650

UC Riverside PHE 45578

UC Santa Barbara PHE 46043

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