Subject: AMENDED WAIVER: Prescriber Dispensing of COVID-19 Antiviral Medication to an Emergency Room Patient

Date: Thursday, January 27, 2022 at 1:47:44 PM Eastern Standard Time

From: Board of Pharmacy News and Information on behalf of California State Board of Pharmacy

NOTE: The Pharmacy Law waiver regarding prescriber dispensing of COVID-19 medication to an emergency room patient is amended and reissued below. This waiver and all Pharmacy Law waivers are posted under COVID-19 Updates and Resources on the Board's website, www.pharmacy.ca.gov.

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, California State Board of Pharmacy President Seung Oh has authorized the following waiver of specific provisions of Pharmacy Law.

Prescriber Dispensing of COVID-19 Antiviral Medication to an Emergency Room Patient (including BPC sections 4068(a)(1), 4068(a)(5), 4068(a)(6), 4076.5, and 4427.2(a))

Waives the following provisions, including any regulation, related to the prohibition against a prescriber dispensing medications to an emergency room patient under the following conditions. All other provisions of Business and Professions Code (BPC) 4068 that are not explicitly waived (not listed below) are in effect.

- BPC 4068(a)(1) – The hospital pharmacy is closed and there is no pharmacist.
- BPC 4068(a)(5) – The prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.
- BPC 4068(a)(6) – The quantity of drugs dispensed to any patient … shall not exceed a 72-hour supply.
- BPC 4076.5 and CCR 1707.5 – Standardized patient-centered, prescription drug label
- BPC 4427.2(a) – Licensure requirement for ADDS

The conditions of the waiver are as follows:

1. The medication is a Food and Drug Administration (FDA) authorized or approved COVID-19 antiviral therapeutic medication, with the FDA label for the treatment of COVID-19, and is prescribed consistent with the conditions or limitations on use established in the FDA's approval or authorization, including any applicable conditions specified in any Emergency Use Authorization (EUA).
2. If the antiviral medication is packaged by the manufacturer in a ready to dispense container, the antiviral medication shall be dispensed in the original manufacturer's container.
3. Prior to prescribing and dispensing the medication, the prescriber reviews the patient's medication history to determine any drug interactions, contraindications, or potential for severe side effects.
4. The medication is labeled to include the patient's name; the drug name, strength, and manufacturer; directions for use; date of issuance; name of the prescriber; and hospital information.
5. Verbal consultation is provided by an authorized health care provider as specified in the conditions detailed in the FDA's approval or authorization for the drug that includes, at a minimum, information on directions for use, proper storage, the importance of compliance with directions, precautions, relevant warnings, common and severe side effects or adverse effects, and therapeutic contraindications.
6. The patient is advised that the COVID-19 antiviral medication is not packaged in a child-resistant container, when applicable.
7. Hospital inpatient pharmacies that are not closed and operate an automated unit dose system (AUDS) in the

emergency room will not be required to license the AUDS in the emergency room, provided the medications dispensed are limited to the COVID-19 antiviral therapeutic medications included in this waiver. The AUDS shall comply with all other requirements for an ADDS.

Amended and Reissue Effective: January 26, 2022

Expires: July 1, 2022

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