



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: Emergency Board Meeting Agenda Item III. Discussion and Consideration of Requests to Waive Provisions of Pharmacy Law Pursuant to Business and Professions Code section 4062

On September 28, 2020, Governor Newsom declared that a State of Emergency existed in Napa, Shasta and Sonoma counties due to the wildfires currently burning in those counties.

The Board received notification of the evacuation of Adventist Health St. Helena Hospital and a request for a waiver from Business and Professions Code section 4059.5(a) & (b) to allow the delivery of medications to an alternative care location. This request was being sought to ensure the continuity of patient care for cancer patients at the identified alternative care location.

Under the provisions of the Board's policy, President Lippe granted a waiver under the following conditions:

The waiver is limited to Cardinal Health, WLS 3434, and Adventist Health St Helena Hospital Pharmacy, HSP 3844, under the following conditions:

1. Cardinal Health will only deliver the dangerous drugs and dangerous devices ordered by Adventist Health St Helena Hospital Pharmacy to Adventist Health St Helena – Outpatient Services – Cardiology located at 999 Adams Street, Suite 106, St Helena, CA.
2. Dangerous drugs and dangerous devices delivered to Adventist Health St Helena – Outpatient Services – Cardiology located at 999 Adams Street, Suite 106, St Helena, CA by Cardinal Health, WLS 3434, must be signed for and received by a pharmacist, medical director, physician or duly authorized representative for Adventist Health St Helena Hospital Pharmacy.
3. All records or other documentation of acquisition and disposition of dangerous drugs and dangerous devices must be readily retrievable when requested by an authorized officer of the law and retained by Adventist Health St Helena Hospital Pharmacy and Cardinal Health for at least three (3) years from the date of making.

Effective: September 29, 2020

Expires: October 29, 2020, or when Adventist Health St Helena Hospital Pharmacy is able to resume pharmacy operations at 10 Woodland Road, Helena, CA 94574, whichever is sooner.

Board staff recently received a request for an extension of the waiver until December 1, 2020, or when the hospital is reopened.

Board staff recommend an extension of the waiver.

Following this memo is a copy of the emergency declaration and relevant law.

PROCLAMATION OF A STATE OF EMERGENCY

WHEREAS beginning on September 26, 2020, a weather system brought dangerous fire conditions to California, resulting in widespread red flag warnings; and

WHEREAS on September 27, 2020, the Glass Fire began burning in Napa County and has since spread into Sonoma County, and the Zogg Fire began burning in Shasta County; and

WHEREAS collectively, these fires have burned tens of thousands of acres, destroyed homes and other structures, forced the evacuation of tens of thousands of residents, and damaged or destroyed critical infrastructure; and

WHEREAS the Federal Emergency Management Agency approved a Fire Management Assistant Grant to assist with the mitigation, management, and control of the Glass Fire; and

WHEREAS strong winds, warm temperatures, dry fuels, and low humidity have caused these fires to spread rapidly; and

WHEREAS the number of fires actively burning statewide has resulted in a significant strain on California's mutual aid system, making it difficult for jurisdictions to obtain the necessary in-state and out-of-state firefighting resources to respond to these fires; and

WHEREAS under the provisions of Government Code section 8558(b), I find that conditions of extreme peril to the safety of persons and property exist due to the fires in Napa, Shasta, and Sonoma counties; and

WHEREAS under the provisions of Government Code section 8558(b), I find that the conditions caused by these fires, by reason of their magnitude, are or are likely to be beyond the control of the services, personnel, equipment, and facilities of any single local government and require the combined forces of a mutual aid region or regions to appropriately respond; and

WHEREAS under the provisions of Government Code section 8625(c), I find that local authority is inadequate to cope with the fires in Napa, Shasta, and Sonoma counties; and

WHEREAS under the provisions of Government Code section 8571, I find that strict compliance with various statutes and regulations specified in this proclamation would prevent, hinder, or delay the mitigation of the effects of these fires.

statutes, including the California Emergency Services Act, and in particular, Government Code section 8625, **HEREBY PROCLAIM A STATE OF EMERGENCY** to exist in Napa, Shasta, and Sonoma counties due to the wildfires currently burning in those counties.

IT IS HEREBY ORDERED THAT:

1. All agencies of the state government are to utilize and employ state personnel, equipment, and facilities for the performance of any and all activities consistent with the direction of the Governor's Office of Emergency Services and the State Emergency Plan. Also, to protect their safety, all residents are to obey the direction of emergency officials with regard to this emergency in order to protect their safety.
2. The Governor's Office of Emergency Services shall provide assistance to local governments, if appropriate, under the authority of the California Disaster Assistance Act, Government Code section 8680 et seq., and California Code of Regulations, Title 19, section 2900 et seq.
3. As necessary to assist local governments and for the protection of public health and the environment, state agencies shall enter into contracts to arrange for the procurement of materials, goods, and services necessary to quickly assist with the response to and recovery from the impacts of these fires. Applicable provisions of the Government Code and the Public Contract Code, including but not limited to travel, advertising, and competitive bidding requirements, are suspended to the extent necessary to address the effects of the fires.
4. The California National Guard is hereby mobilized under Military and Veterans Code section 146 to support disaster response and relief efforts, as directed by the Governor's Office of Emergency Services, and to coordinate with all relevant state agencies and state and local emergency responders and law enforcement within the impacted areas. Sections 147 and 188 of the Military and Veterans Code are applicable during the period of participation in this mission, exempting the California Military Department from applicable procurement rules for specified emergency purchases, and those rules are hereby suspended.
5. The provisions of Unemployment Insurance Code section 1253 imposing a one-week waiting period for unemployment insurance applicants are suspended as to all applicants who are unemployed as a direct result of these fires who applied for unemployment insurance benefits during the time period beginning September 27, 2020, and ending on the close of business on March 27, 2021, who are otherwise eligible for unemployment insurance benefits.
6. Vehicle Code sections 9265(a), 9867, 14901, 14902, and 15255.2, requiring the imposition of certain fees, are suspended with regard to

7. The provisions of Vehicle Code sections 4602 and 5902, requiring the timely registration or transfer of title, are suspended with regard to any registration or transfer of title by any resident who is unable to comply with those requirements as a result of the fires. The time covered by this suspension shall not be included in calculating any late penalty pursuant to Vehicle Code section 9554.
8. Health and Safety Code sections 103525.5 and 103625, and Penal Code section 14251, requiring the imposition of fees, are hereby suspended with regard to any request for copies of certificates of birth, death, and marriage, and dissolution of marriage records, by any individual who lost such records as a result of the fires. Such copies shall be provided without charge.
9. In order to directly respond to the needs of impacted assisted living facilities, adult residential facilities, child care facilities, children's residential facilities, resource family homes, and other similar facilities within the State Department of Social Services' jurisdiction, the Director of the State Department of Social Services may waive any provisions of the Health and Safety Code or Welfare and Institutions Code, and accompanying regulations or written directives, with respect to the use, licensing, or approval of facilities or homes within the Department's jurisdiction set forth in the California Community Care Facilities Act (Health and Safety Code section 1500 et seq.), the California Child Day Care Facilities Act (Health and Safety Code section 1596.70 et seq.), and the California Residential Care Facilities for the Elderly Act (Health and Safety Code section 1569 et seq.). Any waivers granted pursuant to this paragraph shall be posted on the Department's website and shall only be in effect so long as necessary to address the direct impacts of the fires identified in this proclamation.
10. In order to ensure hospitals, clinics, and other health facilities remain open, the Director of the Department of Public Health may waive any of the licensing requirements of Chapters 1 and 2 of Division 2 of the Health and Safety Code and accompanying regulations with respect to any hospital, clinic or health facility identified in Health and Safety Code sections 1200 and 1250 that is impacted by the fires. Any waiver shall include alternative measures that, under the circumstances, will allow the facilities to remain open while protecting public health and safety. Any facilities being granted a waiver shall be established and operated in accordance with their disaster and mass casualty plan. Any waivers granted pursuant to this paragraph shall be posted on the Department's website and shall only be in effect so long as necessary to address the direct impacts of the fires identified in this proclamation.
11. The operative provisions in numbered paragraphs of Executive Order N-81-20 hereby apply in addition to Napa, Shasta, and Sonoma counties as if incorporated herein, as applicable to the fires identified in the State of Emergency declared in this Proclamation.

notice be given of this proclamation.

IN WITNESS WHEREOF I have hereunto set my hand and caused the Great Seal of the State of California to be affixed this 28th day of September 2020.

GAVIN NEWSOM
Governor of California

ATTEST:

ALEX PADILLA
Secretary of State

BUSINESS AND PROFESSIONS CODE - BPC
DIVISION 2. HEALING ARTS [500 - 4999.129]
(Division 2 enacted by Stats. 1937, Ch. 399.)

CHAPTER 9. Pharmacy [4000 - 4427.8]
(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

ARTICLE 3. Scope of Practice and Exemptions [4050 - 4068]
(Article 3 added by Stats. 1996, Ch. 890, Sec. 3.)

4062.

(a) Notwithstanding Section 4059 or any other law, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy or clinic in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy or clinic.

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

(d) Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board's opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.

(e) (1) A pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, may be relocated. The relocation shall not be considered a transfer of ownership or location under Section 4110, if no changes are made to the management and control, or ownership, of the pharmacy and all applicable laws and regulations are followed. Notification of the relocation shall be provided to the board immediately upon identification of the new location.

(2) For purposes of this section, "severely damaged" means damage that renders the premises unsafe or unfit for entry or occupation.

(Amended by Stats. 2019, Ch. 679, Sec. 1. (AB 690) Effective October 9, 2019.)

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4059.5.

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the

dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

(Amended by Stats. 2017, Ch. 598, Sec. 5.5. (SB 752) Effective January 1, 2018.)