

## Important Information for Licensees Related to COVID-19 Emergency – 3/24/20

As the nation faces this public health crisis, the California State Board of Pharmacy (Board) extends its gratitude for your individual and collective response to the health care needs of Californians. To assist licensees, the Board is providing a summary of important news and information related to the COVID-19 emergency.

### Declared State of Emergency

In response to the declared state of emergency, the Board reminds licensees of key state laws and other important information intended to help provide prescription drugs – including controlled substances – for consumers during a declared state of emergency. Summaries are provided. Please click on the links to read the full text of each statute to understand all the conditions and requirements.

- California Business and Professions Code (BPC) [section 4062](#) establishes various authorities for the board and its licensees during a federal, state or local emergency under specified conditions.
- BPC [section 4064](#) authorizes a pharmacist to refill a prescription for a dangerous drug or device if the prescriber is unavailable and if, in the pharmacist’s professional judgment, failure to refill the prescription might interrupt ongoing care or have a significant adverse impact on the patient’s well-being.
- BPC [section 4064.5](#) allows pharmacists under conditions specified in the law to dispense up to a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount.
- During a declared emergency, Health and Safety Code (HSC) [section 11159.3](#) authorizes a pharmacist to fill a prescription for a controlled substance that does not conform to the controlled substances security form requirements under specific conditions.

### Waivers to Pharmacy Law and Regulations

The president of the Board has authorized [waivers to specific provisions of Pharmacy Law](#) or regulations adopted pursuant to it in response to the COVID-19 emergency. Waivers granted by the Board president are limited to 30 days.

Information about [Pharmacy Law waivers](#) is updated regularly and can be found under “COVID-19 Information” on the Board’s website, [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). Updates also are emailed as [subscriber alerts](#).

The Board president has granted waivers to the following provisions under specific conditions:

**Sterile Compounding Renewal Requirements for Facilities Located within a Hospital (BPC sections 4127.1(c) & (d) and 4127.15(b) – 3/21/20**

A sterile compounding pharmacy whose license expires on or before May 1, 2020, may have its license renewed without being subject to the renewal requirements in BPC sections 4127.1(c) and (d) and 4127.15(b) under the following conditions:

1. The sterile compounding facility is located within a hospital or satellite location regulated by the California Department of Public Health and issued a General Acute Care Hospital License.
2. The compounding facility complies with all other provisions of Pharmacy Law as applicable, unless otherwise waived by the Board during this declared emergency.

**Prohibited Acts Involving Dangerous Drugs or Devices (BPC sections 4169(a)(1) and 4161(b)) – 3/21/20**

A California-licensed pharmacy may receive dangerous drugs and dangerous devices from an unlicensed pharmacy, wholesaler, or third-party logistics provider located in another state to alleviate a temporary shortage of a dangerous drug or device that could result in the denial of health care under the following conditions:

1. The unlicensed location is appropriately licensed in its home state, and documentation of the license verification is maintained by the California pharmacy.
2. The pharmacy maintains documentation of the temporary shortage of any dangerous drug or device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
3. The pharmacy complies with all record-keeping requirements for each dangerous drug and device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
4. All documentation and records required above shall be maintained and readily retrievable for three years following the end of the declared emergency.
5. The dangerous drug or device was produced by an authorized FDA registered drug manufacturer.

**Staffing Ratio Provisions (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations, section 1793.7) – 3/19/20**

The ratio of pharmacists to pharmacy technicians may increase to allow for one additional pharmacy technician for each supervising pharmacist under the following conditions:

1. The pharmacy documents the need for the ratio modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume, limitation on staff availability because of quarantine.
2. The supervising pharmacist, exercising their professional judgment, may refuse to supervise the additional pharmacy technician and provide the pharmacist-in-charge of their determination. When making such a determination, the supervising pharmacist must specify the circumstances of concern with respect to the pharmacy and patient care implications. Under such circumstances, the ratio may not increase.

The pharmacy must maintain a readily retrievable record, documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver and the staff operating under the waiver, and justification of the need. Records must be maintained for one year following the end of the declared emergency.

#### **Remote Processing Provisions (BPC section 4071.1(a)) – 3/18/20**

For the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy as defined in Business and Professions Code (BPC) sections 4029 and 4037.

In addition to the provisions of BPC section 4071.1(a), pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under this waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The waiver does not include the dispensing of a drug or final product verification by remote processing.

Further, this waiver expands the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

#### **Pharmacy and Pharmacist Remote Processing Waiver Conditions**

Pharmacists are permitted to conduct remote processing as permitted by this waiver if in compliance with the following:

- The pharmacist must be a California-licensed pharmacist who either processes medication orders or prescriptions from a remote site or on the premises of a California licensed-pharmacy.
- A California-licensed pharmacy may allow staff to engage in remote processing provided the pharmacy has policies and procedures that outline the authorized functions to be performed. Policies and procedures must include methods for protecting the confidentiality and integrity of patient information and must expressly prohibit the printing or storage of protected health information on a device that is outside of the licensed pharmacy. Such policies must be readily retrievable and provided to the board upon request (i.e. be able to be produced within three business days of request).
- A pharmacy utilizing remote processing shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order, prescription processing, and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a

pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

- A pharmacy must ensure that any pharmacist performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site pharmacist has access to when the pharmacy is open.
- Each remote entry record must comply with all record keeping requirements for pharmacies, including capturing the positive identification of the pharmacist involved in the remote review and verification of a medication order or prescription.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

### **Pharmacy Intern and Pharmacy Technician Remote Processing Waiver Conditions**

Pharmacy interns and pharmacy technicians are permitted to conduct **nondiscretionary tasks** related to remote processing as permitted by the waiver if in compliance with the following:

- The pharmacy intern or pharmacy technician who either enters medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy must be licensed by the Board.
- A pharmacy utilizing remote processing shall ensure that all pharmacy interns and pharmacy technicians providing such services have been trained on the pharmacy's policies and procedures relating to medication order or prescription processing and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy shall ensure that any pharmacy intern or pharmacy technician performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems to which an on-site pharmacy intern or pharmacy technician has access when the pharmacy is open.
- Each remote entry record must comply with all record keeping requirements for pharmacies.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

### **Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5) – 3/17/20**

Waive the signature requirement for the receipt of the delivery of drugs as required in BPC section 4059.5 under the following conditions:

1. The delivery personnel confirm that the employee accepting the delivery is a pharmacist.
2. The delivery personnel input the pharmacist's name and license number conveyed to them by the pharmacist directly into their signature capture device in lieu of the pharmacist physically signing the tablet as part of the delivery process.

**Note:** This waiver applies only to the **signature** requirement for the pharmacist accepting delivery.

**Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6)) – 3/17/20**

Waive provisions related to the prohibition against a prescriber to dispensing medications to an emergency room patient if the medication dispensed is a short-acting or long-acting bronchodilator.

**Requirement for Consulting Pharmacist to Perform Visits to Clinic (BPC section 4182(a) & (b) and section 4192(a) & (b)) – 3/17/20**

Waive the requirement for a consulting pharmacist to perform quarterly visits to a clinic under the following conditions:

1. The consulting pharmacist, using his or her professional judgment, determines that the quarterly inspection is not required during the declared emergency.
2. When making such a determination, it may be appropriate to consider prior consultation report findings, potential impact to patients receiving care in the clinic, etc.
3. A consulting pharmacist performs a desk audit of the clinic's procedures and records in lieu of the visit.
4. A consulting pharmacist generates a report outlining any findings resulting from the desk audit and provides that report to the professional director or his or her designee.
5. The consultant receives confirmation to his or her satisfaction, that the corrections outlined in the findings of the audit have been made.

**USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8) – 3/17/20**

Waive USP <797> requirements related to the use of personal protective equipment (PPE) as related to Business and Professions Code section 4126.8, in that a PPE masks and gowns may be reused by staff performing sterile compounding under the following conditions:

1. The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain the single-use provisions established in <USP 797>.
2. The pharmacy has developed a policy that details the conditions under which PPE may be reused. Such policies shall be consistent with standards of practice used during emergency situations.
3. Documented training on the policy is provided to all staff.
4. Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.
5. Surface sampling schedule was reviewed for the possible need to increase the frequency.
6. Documentation is maintained indicating the duration of time the pharmacy is operating under the waiver approval.

### **Use of Hand Sanitizer Before Donning Sterile Gloves (Title 16, California Code of Regulations, section 1751.5(a)(5)) – 3/17/20**

Waive Title 16, C.C.R., section 1751.5(a)(5) to allow for hand cleaning with the use of non-persistent activity alcohol sanitizer prior to donning sterile gloves.

Information about [Pharmacy Law waivers](#) is updated regularly and can be found under “COVID-19 Information” on the Board’s website, [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). Updates also are emailed as [subscriber alerts](#).

### **How to Request a Pharmacy Law Waiver**

If you would like to request a waiver of a provision that has not already been granted to all licensees by the Board, please include the following information in your request:

1. License number(s).
2. A brief statement regarding the extent of the waiver sought.
3. A brief statement describing how the declared emergency has caused a need for the waiver.
4. Relevant laws that you are requesting be waived.
5. An authorized contact person – Any owner, officer, member, pharmacist-in-charge, or other individual authorized to act on behalf of the licensee.

Send your waiver request to [compounding.waivers@dca.ca.gov](mailto:compounding.waivers@dca.ca.gov). (Note: This address is for waiver requests regarding any provisions of Pharmacy Law or regulations, not just compounding.) The Board will respond to the authorized contact person by email.

In addition, the Board is set to discuss and consider waivers to Pharmacy Law provisions during a teleconference meeting at 2 p.m. March 27. The [meeting agenda](#) is posted under “Meetings” on [the Board’s website](#).

The public may provide written comments in advance of the meeting. The Board requests that written comments state the item to which they are addressed and be provided by 5 p.m. March 26 to allow time to post the comments on the website and provide the comments to members. As noted on the agenda, the meeting will not be webcast, and written comments received in advance will not receive any personal response.

### **Additional Information**

The Board encourages licensees to go online to [covid19.ca.gov](http://covid19.ca.gov) for the latest information on the coronavirus emergency in California from the Governor’s Office. The website includes links to other sources of important health care information, including the [California Department of Public Health](#) (CDPH). Important information also is available online from the federal [Centers for Disease Control and Prevention](#) (CDC) and the [Food and Drug Administration](#) (FDA).

For additional updates and information from the California State Board of Pharmacy, visit [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) and [submit your email address to receive subscriber alerts](#) from the Board.

###