



Alerts

California Board of Pharmacy COVID-19 Waivers

April 9, 2020

Health Care Alert

In response to the federal and state declarations of public health emergencies surrounding the COVID-19 pandemic, the California State Board of Pharmacy has issued the following waivers to California Board of Pharmacy statutory and regulatory requirements.

California Board of Pharmacy Office and Staff Availability

The California Board of Pharmacy office in Sacramento is closed to the public until further notice because of the COVID-19 pandemic. Although staff continues working in the office, California Board of Pharmacy response times may be delayed.

Dispensing Prescription Drugs

(California Business and Professions Code (BPC) Sections 4062, 4064 and 4064.5)

New Prescriptions

A pharmacist 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. The pharmacist is required to communicate the prescription information to the patient's attending physician as soon as possible thereafter.

Refill Prescriptions

A pharmacist may refill a prescription for a dangerous drug or device in reasonable quantities and without a prescription 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. The pharmacist is required to inform the prescriber of any refills dispensed without authorization within a reasonable period of time. In addition, a pharmacist may 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 under certain specified conditions.

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Controlled Substances Prescriptions

(California Health & Safety Code (HSC) Section 11159.3)

A pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of a declared local, state, or federal emergency, regardless of whether the prescription form does not meet controlled substances security form requirements, if the prescription meets certain specified conditions.

Inventory Reconciliation Report of Controlled Substances

(Title 16, CCR, Section 1715.65(c))

A pharmacy or clinic may complete the required inventory reconciliation report at least once every six months rather than at least every three months if determined to be necessary by the pharmacist-in-charge or professional director to ensure continuity of direct patient care activities that would otherwise be impacted.

Duty to Consult

(Title 16, California Code of Regulations (CCR), Section 1707.2(a))

If the pharmacist-in-charge makes the determination that oral consultation places the public and/or personnel at risk for exposure to COVID-19, in-person oral consultation may be waived under certain specified conditions, including a requirement that the patient or patient's agent receives a verbal and prominently written notice of his or her right to request consultation by telephone, and the written notice includes the telephone number to call and the hours of availability during which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's records.

Compounding Pharmacy Waivers

(BPC Section 4126.8; Title 16, CCR, Sections 1751.4(d)(1), 1751.5 and 1751.5(a)(5))

Use of Personal Protective Equipment

USP <797> personal protective equipment (PPE) requirements that a PPE mask and gown may be reused by staff performing sterile compounding; and the requirement to wear PPE (including masks, gowns, head, and shoe covers) when compounding in a compounding aseptic isolator or compounding aseptic containment isolator are each waived under certain specified conditions, including a requirement that 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>. It is important to note that the waivers do not extend to the requirements for the use of sterile gloves.

Use of Sterile Disinfectant Agents

The requirements for hand cleaning with the use of non-persistently active alcohol sanitizer prior to donning sterile gloves; and the use of a non-sterile alcohol-based disinfectant after cleaning on work table surfaces, carts, and counters each may be waived under certain specified conditions, including a requirement that the pharmacist-in-charge has made a determination that the current and potential stock of non-persistently active hand sanitizer or sterile alcohol on hand is insufficient to maintain regulatory requirements established in the regulation.

Sterile Compounding Renewal Requirements for Facilities Located Within a Hospital

(BPC Sections 4127.1(c) & (d) and 4127.15(b))

A sterile compounding pharmacy whose license expires on or before July 1, 2020, may have its license renewed without being subject to renewal requirements under certain specified conditions, including a requirement that the sterile compounding facility be located within a hospital or satellite location regulated by the California Department of Public



Health and issued a General Acute Care Hospital License.

Prohibited Acts Involving Dangerous Drugs or Devices

(BPC Sections 4169(a)(1) and 4161(b))

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 certain specified conditions, including a requirement that the unlicensed location is appropriately licensed in its home state, and documentation of the license verification is maintained by the California pharmacy, and 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.

Staffing Ratio of Pharmacists to Pharmacy Technicians and Intern Pharmacists

(BPC Sections 4114(b), 4115(f)(1) and 4127.15(c)(2); and Title 16, CCR, Section 1793.7)

The ratio of pharmacists to pharmacy technicians and/or intern pharmacists may increase to allow for one additional pharmacy technician or intern for each supervising pharmacist under certain specified conditions, including a requirement that the pharmacy documents the need for the ratio modification due to the public health emergency.

Remote Processing

(BPC Section 4071.1(a))

Remote Processing by Pharmacists

Pharmacists performing remote processing may receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances. This waiver expands the scope of remote processing to additionally 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. It is important to note that the waiver does not include the dispensing of a drug or final product verification by remote processing.

Remote Processing by Pharmacy Technicians and Pharmacy Interns

The waiver further expands the scope of remote processing to allow pharmacy technicians and pharmacy interns to perform remote processing 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.

Signature Requirement for Receipt of Delivery of Drugs

(BPC Section 4059.5)

The signature requirement for the receipt of the delivery of drugs is waived if the delivery personnel confirm that the employee accepting the delivery is a pharmacist, and 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.



Requirement for Consulting Pharmacist to Make Quarterly Visits to Clinic

(BPC Sections 4182(a) & (b)/BPC 4192(a) & (b))

Waives the requirement for a consulting pharmacist to perform quarterly visits to a clinic under certain specified conditions, including a requirement that the consulting pharmacist, using his or her professional judgment, determines that the quarterly inspection is not required during the declared emergency.

Prescriber Dispensing Medication to Emergency Room Patient (BPC Sections 4068(a)(1), 4068(a)(5), and 4068(a)(6))

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

Restoration of Retired Pharmacist Licenses (BPC Sections 4200.5(d), 4402(b), and 4403)

The Board will restore a previously retired or canceled pharmacist license for a maximum of six months or until the declaration of emergency is lifted, whichever is sooner, under the following conditions:

- At the time of cancellation or transition to a retired status, the license was not subject to any disciplinary conditions or subject to any disciplinary proceeding;
- The license has been in such a status no longer than five years.
- The individual applies for restoration by completing the required form [Application to Restore Your License](#) located on [the Board's website](#) under "COVID-19 Information."

Intern Pharmacist Licenses (BPC Section 4208)

The Board will automatically extend any intern pharmacist license with an expiration date on or before July 1, 2020, for an additional six months, if the intern pharmacist license is current and in good standing.

Mobile Pharmacy or Clinic (BPC Sections 4062(c))

The operation of a mobile pharmacy or clinic in public health emergency impacted areas is permitted in order to ensure the continuity of patient care, if specified conditions are met, including a requirement that the mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

Hinshaw has a team of health care law attorneys monitoring State Board of Pharmacy Drug Enforcement Administration and Federal Drug Administration policies and regulatory responses to COVID-19. Please contact your Hinshaw attorney with any questions and for additional guidance on how other COVID-19 considerations may impact pharmacy organization. Hinshaw has also has [published](#) additional guidance regarding how companies can address other COVID-19-related business and legal issues.