

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 IV. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code section 4062 - **UPDATED**

Background

Beginning in March 2020, the Board has been granting waivers of Pharmacy Law and its regulations consistent with the authority of BPC section 4062.

For Discussion and Consideration

President Lippe, through his delegated authority has extended waivers; however, as conditions continue to worsen and President Lippe's maximum delegated authority is reached, staff are offering recommendations for the Board's consideration.

1. 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: July 23, 2020 Expiration: January 18, 2021

Recommendation: August 31, 2021, or until the emergency declaration is lifted,

whichever is sooner.

2. Restoration of Retired or Canceled Pharmacist License – BPC section 4200.5(d), Related to Retired Licensees; BPC section 4402(b), Related to Canceled Pharmacist Licenses; and BPC section 4403, Related to Payment of Fees for Reissuance or Renewal of License

Summary: Waives conditions for reinstatement of a cancelled or retired pharmacist

license.

Effective: April 3, 2020 Expires: January 1, 2021

Recommendation: Extend consistent with the DCA License Restoration waiver.

3. 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: December 28, 2020

Recommendation: August 31, 2021, or until the emergency declaration is lifted,

whichever is sooner.

4. <u>Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic</u>
Containment Isolators (Title 16, California Code of Regulations, section 1751.5)

Summary: Allows for the potential waiver of required PPE requirements for compounding

performed in a CAI or CACI under specified conditions.

Effective: April 1, 2020 **Expires**: December 28, 2020

Recommendation: May 31, 2021, or until the emergency declaration is lifted, whichever

s sooner.

5. <u>USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section</u> 4126.8)

Summary: Waive USP <797> requirements related to the use of PPE, to allow for a PPE mask and gown to be reused by staff performing sterile compounding under specified conditions.

Effective: March 17, 2020 Expires: December 21, 2020

Recommendation: May 31, 2021, or until the emergency declaration is lifted, whichever

is sooner.

6. <u>Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5)</u>

Summary: Waives the signature requirement for the receipt of the delivery of drugs under specified conditions

Effective: March 17, 2020

Expires: December 21, 2020, or until the emergency declaration is lifted, whichever is

sooner.

Recommendation: August 31, 2021, or until the emergency declaration is lifted, whichever is sooner.

7. <u>Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6))</u>

Summary: Waives the prohibition against a prescriber dispensing medications to an emergency room patient under specified conditions.

Effective: March 27, 2020

Expires: December 21, 2020, or until the emergency declaration is lifted, whichever is sooner.

Recommendation: August 31, 2021, or until the emergency declaration is lifted, whichever is sooner.

8. Remote Processing (BPC section 4071.1(a))

Summary: Waives limitations on the provisions of remote order entry.

Effective: November 19, 2020 **Expires**: January 16, 2021

Recommendation: May 31, 2021, or until the emergency declaration is lifted, whichever is

sooner.

9. <u>Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System</u> (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: January 17, 2021

Recommendation: March 31, 2021, or until the emergency declaration is lifted,

whichever is sooner.

10. Requirement for Consulting Pharmacist to Perform Visits to Clinic (BPC section 4182(a) & (b) and section 4192(a) & (b))

Summary: Waives the requirement for a consulting pharmacist to perform quarterly visits

to a clinic under specified conditions.

Effective: March 17, 2020 Expires: January 16, 2021

Recommendation: March 31, 2021, or until the emergency declaration is lifted,

whichever is sooner.