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Business, Consumer Services and Housing Agency
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To: Board Members

Subject: Agenda Item XV. Executive Officer's Report

Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies

As the pandemic has continued, the Board continues to dedicate significant resource to its response to the COVID-19 public health crisis; both independently as well as in collaboration with other government agencies. Provided below are updates on the efforts.

Conditions of the pandemic continue to evolve, Board activities pivot to respond to the needs of patients and licensees, approving waivers, issuing temporary licenses, collaborating on guidance documents, and approval of mobile pharmacies. The Board continues to use its subscriber alert system and Board's website as the primary communication tools.

Broad Waivers Issued/Extended

The Board currently has 13 Broad waivers. Provided below is a brief summary of each waiver and the current expiration date.

1. [Redistribution of Pfizer or Other FDA-Approved COVID-19 Vaccinations in Compliance with California Department of Public Health and CDC Guidance](#)
Summary: Waives restrictions or licensing requirements related to and solely for the purpose of redistributing COVID-19 vaccinations during Phase 1A, under specified conditions.
Effective: December 19, 2020
Expires: March 13, 2021, or when Phase 1A inoculation in California is completed, whichever is sooner.
2. [Pharmacists Initiating and Administering Vaccines \[\(Title 16, CCR 1764.d\(d\)\)\]](#)
Summary: Waives the requirement for a pharmacist to notify a primary care provider of COVID-19 vaccine administration under specified conditions.
Effective: December 17, 2020
Expiration: February 28, 2021
3. [Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision – Immunizations \(BPC section 4114\)](#)
Summary: Increases the ratio of pharmacists to intern pharmacist under specified conditions.
Effective: December 16, 2020
Expiration: August 31, 2021, or 30 days after the emergency declaration is lifted, whichever is sooner.

4. [Sterile Compounding Renewal Requirements for Facilities Located Within a Hospital \(BPC sections 4127.1\(c\) & \(d\) and 4127.15\(b\)\)](#)
Summary: Allows for the renewal of a sterile compounding license located within a hospital or satellite location without an inspection.
Effective: December 7, 2020
Expires: March 1, 2021
5. [Requirement for Consulting Pharmacist to Make Quarterly Visits to Clinic \(BPC sections 4182\(a\) and \(b\)/BPC 4192\(a\) and \(b\)\)](#)
Summary: Waives the requirement for a consulting pharmacist to perform quarterly visits to a clinic under specified conditions.
Effective: November 19, 2020
Expiration: March 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
6. [Signature Requirement for Receipt of Delivery of Drugs \(BPC section 4059.5\)](#)
Summary: Waives the signature requirement for the receipt of the delivery of drugs under specified conditions.
Effective: March 17, 2020
Expires: August 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
7. [Prescriber Dispensing Medication to Emergency Room Patient \(BPC sections 4068\(a\)\(1\), 4068\(a\)\(5\), and 4068\(a\)\(6\)\)](#)
Summary: Waives the prohibition against a prescriber dispensing medications to an emergency room patient under specified conditions.
Effective: March 27, 2020
Expires: August 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
8. [USP <797> Requirements Related to Use of Personal Protective Equipment \(BPC section 4126.8\)](#)
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: May 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
9. [Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic 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: May 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.
10. [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: July 1, 2021

11. [Inventory Reconciliation Report of Controlled Substances \(Title 16, California Code of Regulations Section 1715.65\(c\)\)](#)

Summary: Allows for an extension of the inventory reconciliation report to be completed at least every six months, under specified conditions.

Effective: December 14, 2020

Expiration: March 13, 2021

12. [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: August 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.

13. [Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System \(ADDS\) \(BPC 4119.11\(a\)\(9\) and BPC 4427.2\(e\)\)](#)

Summary: Allows for the issuance of an ADDS license without a prelicensure inspection.

Effective: November 20, 2020

Expiration: August 31, 2021, or until the 30 days after the emergency declaration is lifted, whichever is sooner.

14. [Remote Processing \(BPC section 4071.1\(a\)\)](#)

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

Effective: December 14, 2020

Expires: Effective through May 31, 2021, or until 30 days after the emergency declaration is lifted, whichever is sooner.

Site Specific Waivers

Site specific waivers continue to be granted. Such waivers typically address a specific challenge at a worksite, that on balance, can be granted without negatively impacting consumers. Members have previously reviewed some site-specific waivers during public meetings and will be considering one such waiver during this meeting. Other site-specific waivers are granted because the entity cannot meet the requirements of the law, e.g., conducting an in-person inspection as required by Business and Professions Code (BPC) section 4127.2(c).

DCA Director Waivers

On August 25, 2020, the DCA Director issued [DCA-20-45](#), an order that waives specified professional licensing requirements and amends the scopes of practice of pharmacists and pharmacy technicians to allow them to perform waived, point-of-care tests used to detect SARS-CoV-2 remains in effect. As previously reported, the Board developed a process to issue mobile pharmacy licenses under the provisions of BPC 4062 to pharmacies wishing to provide testing at temporary locations consistent with authorizing provisions found within the purview of Laboratory Field Services with the

California Department of Public Health. To date the Board has approved 2 mobile pharmacies for this purposes of COVID-19 testing. The Board anticipates additional requests will be received as pharmacies received approval from Laboratory Field Services.

On December 11, 2020, the DCA Director issued [DCA-20-84](#), an order that waived the provisions limiting a pharmacist from independently initiating and administering a COVID-19 vaccine under specified conditions. This waiver served as a bridge until the provisions of AB 1710 (Statute of 2020) took effect. Such provisions established permanent authority for pharmacists to perform such functions.

Further, on December 22, 2020, the DCA Director issued [DCA-20-103](#), an order that waived provisions that prohibit pharmacy technicians from administering COVID-19 vaccines under specified conditions. Further, consistent with the mobile pharmacy licenses under the provisions of BPC 4062, a process was established for to pharmacies wishing to use pharmacy technicians as part of the vaccination team outside of the license pharmacy. To date the Board has approved over 2,400 mobile pharmacies for this purpose.

Temporary Licenses

Since early in the pandemic, the Board has worked to issue temporary license, to address distribution of PPE, ventilators, vaccinations, as well as temporary licenses for surge locations and other pharmacies. To date the Board has issued 23 temporary licenses.

Operational Changes

Staff continue to respond to the fluidity of the pandemic by making adjustments to operations to ensure the safety of staff and the public. As previously report, there are several limiting factors that must be addressed long term to sustain this rotational teleworking schedule, most notably more robust and portable computers and a decreased reliance on paper. We continue to complete internal assessments to identify the best methods to make the necessary operational changes to facilitate teleworking while minimizing impacts to processing timeframes.

As reported in July, in partnership with several other state agencies, inspector staff began assessing for compliance with the statewide face mask requirement and other physical distancing and protective measures. In response to the surge, in early December, inspector staff were redirected to prioritize other investigative activities and limit field inspections to only those instances with the potential for imminent public harm. Since that time inspector staff have been assessing for compliance with the provisions of the requirements through phone calls. To date staff have perform about 1,400 such assessments, either in person or over the phone.

Update on Implementation of Controlled Substances Security Forms as required by Assembly Bill 149 (Statutes of 2019)

Effective January 2, 2021, the new requirements for controlled substances security forms took effect. These new requirements were established in Assembly Bill 149 (Statutes of 2019) and included a transition period to allow licensees to transition to the new forms.

The Board started its educational efforts on the new requirements in 2019, including information on the requirements in the Board's Law webinar. Further, to minimize the impact to patients, in November 2020, the Board collaborated with Medical Board of California and the Department of Justice to releasing a [joint statement](#) on the requirements followed by the development and release of FAQs. Information was also prominently posted on the Board's website.