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To: Board Members

Subject: Agenda Item XII. Executive Officer's Report

a. <u>Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other</u> <u>Agencies</u>

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. The Board continues to rely on its subscriber alert system, Twitter account and website to serve as the primary communication tools for licensees and members of the public.

On its <u>homepage</u> the Board has consolidated resources for stakeholders. Information provided includes links to Pharmacy Law Waivers; information on how to request a Pharmacy Law waiver; critical and emerging updates, e.g. information on vaccine eligibility expansion and information released from the California Department of Public Health on the Johnson and Johnson/Janssen vaccine; links to DCA waivers impacting Board licensees; and links to guidance documents.

The website also includes a list of all current and expired <u>Pharmacy Law waivers</u>, with the text of the waivers available through a link. Under a separate agenda item, members will have the opportunity to discuss several broad waivers that remain in effect.

DCA Director Waivers

On April 20, 2021, DCA Director Kirchmeyer issued <u>DCA Waiver DCA-21-142</u> Order Waiving Staffing Ratio of Pharmacists to Pharmacy Technicians Relating to Administering COVID-19 Vaccines. Under the provisions of this waiver, pharmacists engaged exclusively in initiating and administering COVID-19 vaccines, and pharmacy technicians engaged exclusively in administering COVID-19 vaccines under the direct supervision and control of such pharmacist, may increase the ratio to allow one pharmacist to supervise no more than two pharmacy technicians.

Subsequent to the release of the DCA waiver, though his delegated authority, on April 21, 2021, President Lippe amended and reissued the <u>Board's Mass</u> <u>Vaccination Waiver</u> to provide for a similar ratio increase, where the pharmacist and pharmacy technicians are solely involved in vaccinations, as specified. This waiver was subsequently extended by President Oh and will expire October 16, 2021, unless otherwise extended. Several other DCA waivers remain in effect. On August 25, 2020, the DCA Director issued <u>DCA-20-45</u>, 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; this order 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 55 mobile pharmacies for this purpose of COVID-19 testing. The Board anticipates additional requests will be received as pharmacies receive approval from Laboratory Field Services.

On December 11, 2020, the DCA Director issued <u>DCA-20-84</u>, 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 <u>DCA-20-103</u>, 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 pharmacies wishing to use pharmacy technicians as part of the vaccination team outside of the license pharmacy. To date the Board has approved over 3,281 mobile pharmacies for this purpose.

Broad Waivers Issued/Extended

The Board currently has 9 broad waivers. Provided below is a brief summary of each waiver and the current expiration date.

1. Mass Vaccination Sites

Summary: Provides for the storage and redistribution of COVID-19 vaccines in compliance with CDPH and CDC Guidance Related to Mass Vaccination Sites and allows for the use of pharmacy technicians as part of the vaccination team at such sites sponsored by state or local authorities directly or through contractual arrangements with third parties. Further allows for an increase in the ratio of pharmacist to pharmacy technicians under specified conditions. **Effective**: April 21, 2021

Expiration: October 16, 2021

2. Intern Pharmacists (Business and Professions Code section 4114(a)) Summary: Allows for the supervision of an intern pharmacist performing all aspects of COVID-19 vaccine initiation and administration to include California-licensed physician, nurse practitioner or physician assistant, under specified conditions. Further allows for the supervision of an intern pharmacist solely performing vaccine administration to include any healthcare professional who is experienced in administering intramuscular injections under the specified conditions, including compliance with the provisions of <u>DCA Waiver 21-139</u>.

> Agenda Item XII - Executive Officer's Report July 28 - 29, 2021 Board Meeting Page 2 of 6

Effective: April 22, 2021

Expiration: September 18, 2021

- 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: August 27, 2021 or until 30 days after the emergency declaration is lifted, whichever is sooner.
- 4. <u>Restoration of Retired or Canceled Pharmacist License BPC section 4200.5(d),</u> <u>Related to Retired Licensees; BPC section 4402(b), Related to Canceled</u> <u>Pharmacist Licenses; and BPC section 4403, Related to Payment of Fees for</u> <u>Reissuance or Renewal of License</u>

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

Effective: April 3, 2020

Expires: September 1, 2021, or when the state of emergency ceases to exist, whichever is sooner.

<u>Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))</u>
 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.

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

7. <u>Prelicensure Inspection at Proposed Location of an Automated Drug Delivery</u> 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.

8. <u>Prescriber Dispensing Medication to Emergency Room Patient (BPC sections</u> 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.

9. <u>Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision –</u> <u>Immunizations (BPC section 4114)</u>

Summary: Increases the ratio of pharmacists to intern pharmacist under specified conditions.

Effective: December 16, 2020

Agenda Item XII - Executive Officer's Report July 28 - 29, 2021 Board Meeting Page 3 of 6 **Expiration**: August 31, 2021, or 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). The Board has issued 55 licenses with an approved waiver of the in-person inspection as well as renewed 203 licenses. In such instances a desk audit was completed prior to submission of a recommendation to the President for consideration of the waiver request.

Temporary Licenses

Since early in the pandemic, the Board has worked to issue temporary licenses to address distribution of PPE, ventilators, and vaccinations, as well as temporary licenses for surge locations and other pharmacies. To date the Board has issued 31 temporary licenses.

Operational Changes

Staff continues to respond to the fluidity of the pandemic by making adjustments to operations to ensure the safety of staff and the public. As reported by DCA during the January Board meeting, until recently the goal was to maintain 75 percent of office employees teleworking on any given day. However, with the Governor's reopening plans, several staff members are returning to the office with greater frequency. Operationally all management staff has completed 6 hours of mandated training in the hybrid workforce. Management staff is working with staff to complete SWOT analyses to determine long term teleworking strategies for each of the office positions.

b. <u>Summary of Annual Meeting of the National Association of Boards of</u> <u>Pharmacy</u>

The 117th Annual Meeting of the NABP was held virtually on May 13-14, 2021. Vice-President Veale represented the Board. Elections were held for open officer and member positions on the Executive Committee, and members discussed and voted upon several resolutions and an amendment to NABP Bylaws. Specifically, members approved resolutions addressing the following:

- Encourage states to continue to allow pharmacists to provide point-of-care testing and vaccinations post-pandemic and plan for future pandemics and other natural disasters
- Convene a work group to review all provisions waived by the state boards of pharmacy during the COVID-19 public health emergency and amend, if

Agenda Item XII - Executive Officer's Report July 28 - 29, 2021 Board Meeting Page 4 of 6 necessary, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

- Continue to educate policymakers about the complexities of purchasing drugs outside the current drug supply chain model and ensuring boards of pharmacy can reasonably fulfill requirements for protecting patient safety and properly overseeing importation programs.
- Convene a task force to examine pharmacy workplace safety and well-being and the effects on patient safety.
- Convene a task force to encourage and support member state boards of pharmacy in the transition to a "just culture" type of regulatory approach that addresses the identification and resolution of medication errors and to identify resources to assist the boards of pharmacy and other stakeholders in the transition.

Next year the annual meeting will be held May 19-21, 2022, in Phoenix Arizona.

c. Update on Business Modernization Activities

Beginning in Fiscal Year 2019/20, Board staff has participated in numerous workshops with the Department to develop business process maps for the various application, renewal and enforcement processes performed by staff. Regrettably in response to the COVID-19 pandemic and competing priorities, work on many of the activities was delayed. Staff has recently resumed activities. Over the next few months staff is hopeful to finalize 48 business process maps previously developed as well as finish the development of the remaining 26 identified processes.

d. Annual CURES Update

The CURES system continues to serve as an essential tool for health care practitioners and regulators. Based on a recent report from the Department of Justice, as of June 2021, there are over 231,000 registered users in the CURES system, including 47,736 pharmacists. In addition, system usage indicates that over 23,103,718 Patient Activity Reports were run during the fiscal year, and an additional over 61,701,776 reports were requested through an integrated system. These requests represent both pharmacist and prescriber requests.

Data indicates that 34,009,734 Schedule II – V controlled prescriptions were reported to CURES over the fiscal year, including:

C-II: 15,432,088 C-III: 2,873,745 C-IV: 14,727,950 C-V: 975,951

AB 528 CURES Reporting Implementation

Agenda Item XII - Executive Officer's Report July 28 - 29, 2021 Board Meeting Page 5 of 6 Under the provisions of Assembly Bill 528 (Low, Chapter 677, Statutes of 2019), several changes were made to the reporting requirements into the CURES system. Although many of these changes have been implemented, staff has been advised that some provisions related to the development of provisions related to authorized delegates will be delayed. It is anticipated that the work will be completed and implemented by April 1, 2022; however, pending legislation would extend the implementation date to October 2022 if enacted.

AB 1751 Interstate Data Sharing

Assembly Bill 1751 (Low, Chapter 478, Statutes of 2018), established authority for the DOJ to enter into an agreement with an entity operating an interstate data sharing hub or other specified entity for purposes of interstate data sharing of prescription drug monitoring program. The Department of Justice reports that implementation of the interstate data sharing is ongoing. It is anticipated the first phase of implementation will begin March 31, 2022. Under the proposed rollout, DOJ will focus the first phase of implementation with neighboring states that enter into a memorandum of understanding.