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To: Board Members

Subject: Agenda Item XVI. Executive Officer Report

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

As the pandemic continues, the Board continues to dedicate significant resources 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.

The Board's website has centralized COVID related information on a dedicated webpage that is accessed from the Board's <u>homepage</u>. This allows for stakeholders to find the information easily, while also ensuring stakeholders can easily find other important including alerts about changes in the law and recent information.

The COVID-19 Information page includes a list of all current and expired <u>Pharmacy Law waivers</u>, with the text of the waivers available through a link and important information from the California COVID-19 Vaccination Program, vaccine coadministration, information on monoclonal antibody treatment, and waivers issued by the DCA Director.

DCA Director Waivers

On July 11, 2022, DCA Director Kirchmeyer issued <u>DCA Waiver DCA-22-217</u> Waiving Restrictions of Pharmacists Independently Initiating and Furnishing Paxlovid to Individual Patients. Under the provisions of the waiver, pharmacists may independently initiate and furnish Paxlovid for individual patients subject to specified conditions. There is no expiration date included on this wavier. Board staff will monitor for implementation issues and if necessary, develop guidance to assist pharmacists in understanding the provisions of the waiver.

Several other waivers issued by Director Kirchmeyer also remain in effect. <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. 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 pharmacies wishing to use pharmacy technicians as part of the vaccination team outside of the license pharmacy. To date the Board has approved over 3,284 mobile pharmacies for this purpose.

<u>DCA Waiver-20-44</u>, an order that waives restrictions on pharmacies, pharmacists, and pharmacy technicians related to ordering, collecting specimens for, and performing COVID-19 Tests.

Similar to the Board's waivers, some waivers previously issued by Director Kirchmeyer have been allowed to expire. Waivers remaining are largely to facilitate immunization and testing efforts.

Broad Waivers Issued/Extended

President Oh, through delegate authority granted by the Board, continues to consider if new waivers or extensions of waivers are appropriate.

The Board currently has four 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, this allows for an increase in the ratio of pharmacist to pharmacy technicians under specified conditions. **Effective**: April 21, 2021

Expiration: December 31, 2022, or 30 days following termination of the declared disaster, whichever is **sooner**.

- <u>Remote Processing</u>
 <u>Summary</u>: Waives limitations on the provisions of remote order entry.
 <u>Reinstated</u>: September 3, 2021
 <u>Expires</u>: December 31, 2021, or 30 days after the emergency declaration is lifted, whichever is **later**.
- Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision Immunizations (BPC section 4114)
 Summary: Increases the ratio of pharmacists to intern pharmacist under

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

Amended and Reissued: October 14, 2021 Expiration: December 31, 2022, or 30 days after the emergency declaration is lifted, whichever is **sooner**.

4. <u>Prescriber Dispensing of COVID-19 Oral Therapeutic Medication to Emergency</u> <u>Room Patient (Including BPC sections 4068(a)(1), 4068(a)(5), 4068(a)(6) and</u> <u>4076.5</u> **Summary**: Lifts prohibition against a prescriber dispensing FDA authorized or approved COVID-19 therapeutics to an emergency room patient under specified conditions.

Effective: January 14, 2022 **Expiration**: 30 days following the end of the declared disaster.

Site Specific Waivers

As conditions in California have improved and out of state travel has resumed, site specific waivers have decreased. As of June 30, 2022, the Board has issued 73 licenses and renewed 272 licenses with an approved waiver of the in-person inspection. 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. As of June 30, 2022, the Board has issued 41 temporary licenses.

b. 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 subsequently resumed activities. Business process maps for all licensing and cashiering activities have been completed and approved. Eighteen business process maps require finalization and/or approval. It is anticipated that these items will be completed by the end of August.

c. 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 2022, there are over 241,232 registered users in the CURES system, including 48,628 pharmacists. In addition, system usage indicates that over 24,450,034 Patient Activity Reports were run during the fiscal year, and an additional over 94,988,774 reports were requested through an integrated system. These requests represent both pharmacist and prescriber requests.

Data indicates that 34,281,679 Schedule II – V controlled prescriptions were reported to CURES over the fiscal year, including:

C-II: 15,284,183 C-III: 2,760,728 C-IV: 13,683,986 C-V: 1,739,047

AB 528 CURES Reporting Implementation

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 was advised that some provisions related to the development of provisions related to authorized delegates would be delayed. As reported during the April Meeting, the Department of Justice implemented additional changes to the CURES functionality including provisions for delegate users. The provisions specific to delegates are established in regulations currently undergoing review by the Office of Administrative Law. In response to the review by OAL, DOJ released for another 15-day comment period additional changes to the proposed regulations to address issues raised by OAL. The revised rulemaking package was resubmitted to OAL on July 7, 2022. DOJ estimates the proposed CURES regulations will become effective in August 2022. Provisions for interstate sharing are also in process. Additional information is available is available here.

AB 1751 Interstate Data Sharing

Assembly Bill 1751 (Low, Chapter 478, Statutes of 2018), established authority for the Department of Justice (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. In April 2022, DOJ reported that the technology is ready to facilitate interstate sharing. DOJ is in the process of finalizing the required MOU with Oregon to allow for the interstate data sharing. DOJ will also be working to finalize MOUs with Nevada and Arizona.

d. Medical Board of California Interested Parties Meeting

In 2014, the Medical Board of California released <u>Guidelines for Prescribing</u> <u>Controlled Substances for Pain</u>.

In March 2016, the CDC released <u>CDC Guideline for Opioids for Chronic</u> <u>Pain</u>. More recently, February 10, 2022, <u>Proposed 2022 Clinical Practice</u> <u>Guideline for Prescribing Opioids</u> was released for public comment. The comment period closed on April 11, 2022.

Earlier this year the Medical Board of California developed proposed revisions to its guidelines on prescribing controlled substances. Public information on the Medical Board's website suggests that as part of this endeavor Medical Board staff evaluated the CDC proposed updates. As part of the May 11, 2022, Medical Board Meeting materials, it indicates that its drafted guidelines are consistent with the approach taken by the CDC and reiterate that physicians should use their best clinical judgement in treating patients for pain. More recently, on July 14, 2022, the Medical Board of California convened an <u>Interested Parties Meeting</u>, allowing members of the public to provide comments on the proposed revisions. Members of the public were also provided with an opportunity to provide written comments. The proposed revisions, summary of changes, and written comments are <u>posted</u>.

Board staff attended the hearing last week. Public comments received ranged from patients who have experienced challenges receiving pain medications and the need to expand access to pain medications. Commenters spoke in support of removing MME (morphine milligram equivalents) as a criteria for prescribing opioids. Other commenters appeared to express concern that the guidelines were too strict and suggested changing some of the language to reflect recommendations as opposed to mandates.

Board staff will continue to monitor the efforts undertaken by the Medical Board. Once final, it may be appropriate for the Board to disseminate this information to pharmacists.

e. <u>Department of Health Care Access and Information – Licensure Data</u> <u>Collection</u>

The Department of Health Care Access and Information (HCAI), formerly known as the Office of Statewide Health Planning and Development, is partnering with the Department of Consumer Affairs (DCA) and various Boards within DCA to collect important health workforce data.

HCAI is launching the California Health Workforce Research Data Center (Center). The Center will serve as the state's central repository for health workforce data, and will collect, analyze, and distribute information on educational and employment trends for healthcare occupations in the state.

HCAI, has developed a workforce survey for licensees to complete during the electronic licensure renewal process. HCAI is asking Boards for assistance with disseminating this information and educating licensees on the importance of completing the survey as part of the online renewal process. Information on this survey will be included on the Board's website and the upcoming issue of the Script.

Attachment 1 includes a copy of the Licensure Data Collection FAQ's.

f. <u>Report of Actions Taken at the Annual National Association of Boards of</u> <u>Pharmacy Meeting</u>

The 118th Annual Meeting of the NABP was held May 19-21, 2022 in Arizona. President Oh 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:

- Convening a task force to amend the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy to include a foundational definition of pharmacists as health care providers
- Conducting a survey of states and United States jurisdictions to collect data regarding pharmacy e-prescribing concerns and, if appropriate, convene a task force to further study the issue and make recommendations for improving e-prescribing functionality.
- Examining the development of a national standardized pharmacy jurisprudence examination for the state boards of pharmacy to assess competence for licensure.
- Request that Food and Drug Administration (FDA) provide timely guidance to states regarding how the agency intends to assess state licensing statutes, regulations, and processes for consistency with the agency's National Standards for the Licensure of Wholesaler Drug Distributors and Third-Party Logistics Providers that the FDA focuses on issues impacting patient safety; and encouraging boards of pharmacy to provide public comment on the proposed rule.
- Communicate with the DEA and Congress about the importance of state regulation of telepharmacy and the potential impact that DEA regulation could have on patient access to medications.
- Examine the feasibility of creating a system to allow efficient interstate portability through a multistate licensure compact.

The text of the <u>resolutions</u> is available on the NABP Website. Members interested in serving on a task force, standing committee or examination committee can <u>apply</u> online.

Next year the annual meeting will be held May 11-13, 2023, in Nashville, TN.

Attachment 1

HCAI Department of Health Care Access and Information

2020 West El Camino Avenue, Suite 800 Sacramento, CA 95833 hcai.ca.gov



LICENSURE DATA COLLECTION FAQ'S

What types of health workforce licensure data will be collected?

At time of online licensure renewal, licensees will be asked questions about the following:

- Anticipated year of retirement
- Area of practice or specialty
- Location of practice
- Educational background
- Gender or gender identity
- Hours spent in direct patient care
- Languages spoken
- National Provider Identifier
- Ethnicity and/or race
- Practice setting
- Sexual orientation
- Work hours
- Disability status

Why are these data being collected?

The Department of Health Care Access and Information (HCAI) is partnering with the Department of Consumer Affairs (DCA) to collect important workforce data. HCAI is a leader in collecting data and disseminating information about California's healthcare infrastructure. HCAI promotes an equitably distributed health workforce and publishes valuable information about healthcare outcomes.

HCAI is launching the California Health Workforce Research Data Center (Center). The Center will serve as the state's central repository for health workforce data, and will collect, analyze, and distribute information on educational and employment trends for healthcare occupations in the state. The Center will also produce an annual report discussing:

- Supply and demand of the health workforce
- Geographical distribution of the health workforce
- Diversity of the health workforce, by specialty (including, but not limited to, data on race, ethnicity, and languages spoken)
- Current and forecasted demand for healthcare workers, by specialty
- Educational capacity to produce trained, certified, and licensed healthcare workers, by specialty and by geographical distribution

HCAI, in partnership with DCA, has developed a workforce survey for licensees to complete as part of the electronic online licensure renewal process. This workforce survey will be available for completion beginning July 2022, to those renewing online and will be an important data source for the Center. The purpose of this survey is to collect critical workforce related data which will be used to inform stakeholders and be an input into important workforce policy development.

How will the security and privacy of data be ensured?

HCAI and DCA adhere to strict data security and confidentiality standards. Both organizations have strong protocols in place to ensure data is stored securely. DCA and HCAI have strong subject matter expertise on data security and have been successful in securing sensitive data for decades.

California and Federal law (including the Information Practices Act of 1977, Government Code Section 11015.5., and the federal Privacy Act of 1974) requires departments to maintain the confidentiality of this data and only allows release in aggregate form that cannot be used to identify an individual. HCAI, or DCA, will never share or publicly release data that can be used to identify an individual (Business and Professions Code § 502). These data will not, and cannot, be used to impact your licensure status in any manner.

For more information about HCAI's Privacy Policy, please visit HCAI's website: https://hcai.ca.gov/home/privacy-policy/

How can I be notified of products that will be released from the Center?

HCAI will work with DCA and licensing boards to communicate the release of products coming out of the Center. Respective websites and social media platforms will be utilized. In addition, HCAI will present at Board meetings on a consistent basis with updates on the Center.

Who may I contact with any questions about this data collection effort and the Center?

You may contact HCAI directly at: workforcedata@hcai.ca.gov