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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Jason Weisz, Public Member, Chairperson
Nicole Thibeau, PharmD, Licensee Member, Vice Chairperson
Renee Barker, PharmD, Licensee Member
Jose De La Paz, Public Member
Kartikeya Jha, Licensee Member

I. Call to Order and Establishment of Quorum

II. Public Comment for Items Not on the Agenda; Matters for Future Meetings
The committee may not discuss or act on any matter raised during the public comment section that is not included on this agenda, except to place the matter on a future meeting agenda. [Government Code sections 11125 & 11125.7(a)]

III. Approval of the January 22, 2024, Communication and Public Education Committee Meeting Minutes

A draft of the minutes is in **Attachment 1**.

IV. <u>Update on the Website</u>

Background

The State is in the process of finalizing a new website design for state agencies. The vision for this new model is to create a seamless digital experience for Californians accessing the services they need. The CA Web Standards provides an online resource for state agencies to help support implementation of the standards, functionality and look and feel into websites. The State provides best practices, tools, resources, and implementation guidelines for the website and digital service community to implement state standards for usability, accessibility, and security.

The standards establish requirements for design, content area and footer. In January's meeting website designer Victor Perez gave a presentation on the website's progress.

At Today's Meeting

Staff has completed the conversion of the website to a newer template. The website is currently under review with DCA's internet team. The new website has a fresh, clean look and is easy to navigate. It is anticipated the transition to the new website will be completed by mid-August. During the meeting the Committee will receive an update on the timing of the transition if available.

V. <u>Update on the Talk to the Expert Consumer Poster and Public Education</u> <u>Campaign</u>

Background

Board and staff revised the Notice to Consumer poster that is required by law to be displayed in pharmacies. The text on the poster was approved by the Office of Administrative Law. A public awareness campaign was developed simultaneously to focus on the importance of patient consultation and actions consumers can take to prevent medication errors. The campaign highlights how pharmacists are healthcare professionals with expertise in drug therapy and emphasize the importance of patients speaking with their pharmacist.

<u>Update on the posters and campaign</u>

Approximately 6,000 posters have been mailed out to all pharmacies in California. In addition to the Talk to the Expert poster, a Point to Your Language poster was included in the mailing. The Point to Your Language posters include 16 translations and the posters were updated to include four new languages. The four new languages added were Japanese, Hindi, Thai, and Punjabi. A public education campaign was created to bring awareness to the revised NTC poster. The campaign was distributed the week of July 8th to the Department of Consumer Affairs (DCA), the Board's social media account (formally Twitter), on the Board's subscriber alert and on the Board website. The campaign will run again in August as a follow up reminder to licensees.

VI. <u>Discussion and Consideration of Committee's Strategic Objectives</u>

Background

The Board's <u>Strategic Plan 2022-2026</u> includes eight goals that guide policies and actions implemented by the Communication and Public Education Committee.

For Committee Consideration and Discussion

During the meeting members will have the opportunity to review the strategic objectives and actions taken related to the objectives. Staff requests the

Communication and Public Education Committee Meeting – July 18, 2024

committee consider whether the current objectives remain suitable or whether specific objectives should be revised or new objectives considered. Staff has listed the goals in this report and provided comments for each goal for the committee's consideration. After reviewing the goals, committee members are welcome to provide comments or direction to staff regarding the strategic goals.

4.1 Develop a consumer education campaign to educate consumers about the Board and the importance of pharmacy services, including patient consultation.

<u>July 2022 Status</u>: The Board undertakes a rulemaking to update the Board's Notice to Consumers poster and regulation, <u>CCR section 1707.6</u>, to give consumers more relevant information about their rights and an explicit reminder to speak to their pharmacist about their medications.

<u>July 2023 Status</u>: Staff propose revisions to Notice to Consumers poster and elements of consumer education campaign.

<u>July 2024 Status</u>: Staff completes <u>Notice of Consumer poster</u> and mailed out to all pharmacies in California. In addition to the NTC poster, which is titled Talk to an Expert, a <u>Point to Your Language poster</u> was included in the mailing. There are 16 languages on the Point to Your Language posters, 4 of those languages are new to the list. They include Japanese, Hindi, Thai, and Punjabi. A public education campaign was created to bring awareness to the revised NTC poster.

4.2 Reevaluate, and update, if necessary, educational materials related to pharmacy law to assist licensees in operating in compliance.

<u>July 2022 Status</u>: The Board continuously updates key resources to keep licensees informed on pharmacy law and regulations. The online <u>Pharmacy Lawbook</u> is updated regularly with newly adopted laws and regulations. The Board also creates a new <u>pharmacy law webinar</u> each year. In addition, the Board posts constant updates to <u>pharmacy law waivers</u> online and proactively disseminates updates about laws, regulations, and waivers in subscriber alerts and The Script.

<u>July 2023 Status</u>: Frequently Asked Questions are developed related to the use of <u>mobile units</u>. Further FAQs are revised to ensure information remains current, including the <u>continuing education FAQ</u> and <u>ADDS FAQs</u>. Various <u>self-assessment forms</u> are updated to reflect changes in pharmacy law and the new 2023 pharmacy law webinar is available.

July 2024 Status:

Frequently Asked Questions developed for <u>Assembly Bill 1286.</u>
Developed notice regarding exemptions with <u>Tribal Health Care Providers</u>.
Updated Pharmacy Law Webinar for 2024.

Revised materials to ensure information is current, including:

- Continuing Education,
- the FAQs for the Revision to Inventory Reconciliation,
- Mobile Units,
- Pharmaceutical and Sharps Waste Stewardship Programs,
- Compounding Policy Statement,
- Notice to Licensees Regarding CURES version update,
- Digital Signature policy statement.

4.3 Promote the self-assessment process to educate licensees about the importance of the tool.

<u>July 2022 Status</u>: Staff is currently working with DCA's Office of Information Services to evaluate the feasibility of transforming the self-assessment forms to an online, more interactive process that would actively engage pharmacists in ensuring their operations comply with pharmacy law.

<u>July 2023 Status</u>: Staff complete business process mapping with the DCA's Organizational Improvement Office.

<u>July 2024 Status</u>: Staff completed and implemented the Surgical Clinic Self-Assessment developed under AB 1286. The Board approved self-assessments for the Automatic Drug Delivery System (ADDS), the Community Pharmacy/Hospital Outpatient, and the Whole Seller; the Board is currently pursuing role making action to implement.

4.4 Create an educational program for the colleges of pharmacy and a required training prior to obtaining an intern license to ensure an understanding of the Board and its consumer protection mandate.

<u>July 2022 Status</u>: Board staff provide outreach at pharmacy schools by providing presentations to pharmacy students on licensing requirements and how to complete applications for both pharmacist and intern pharmacist licenses.

<u>July 2023 Status</u>: Board staff provide outreach at pharmacy schools by providing presentations to pharmacy students on licensing requirements and how to complete applications for both pharmacist and intern pharmacist licenses.

<u>July 2024 Status</u>: President Oh and Board staff provided presentations to students at several pharmacy schools in California. This was part of pharmacy law curriculum.

4.5 Increase outreach and education to licensees to expand knowledge of the Board and to promote compliance.

July 2022 Status: Staff continue to provide continuing education to pharmacists on preventing drug abuse and drug diversion. The online platform has enabled staff to provide the training to more pharmacists statewide than live events permitted before the pandemic. As conditions improve, staff hopes to offer more outreach events in person as well as via WebEx. In addition, licensing staff has started providing presentations at California schools of pharmacy on how to apply for an intern pharmacist license and how to apply to take the pharmacist exam. Staff provides in-person and live WebEx presentations on Board activities and changes in pharmacy law.

<u>July 2023 Status</u>: Staff continue to provide continuing education to pharmacists on preventing drug abuse and drug diversion. The online platform continues to enable staff to provide the training to a larger audience statewide than live events permitted before the pandemic. Staff provides inperson and live WebEx presentations on Board activities and changes in pharmacy law.

<u>July 2024 Status</u>: Staff continue to provide continuing education to pharmacists on preventing drug abuse and drug diversion. The online platform continues to enable staff to provide the training to a larger audience statewide than live events permitted before the pandemic. Staff provides inperson and live WebEx presentations on Board activities and changes in pharmacy law. Staff provide a presentation at patient safety conference.

4.6 Create more webinars to post on the website to disseminate basic information.

<u>July 2022 Status</u>: The Board recently posted a training webinar for pharmacists furnishing HIV PrEP/PEP medications pursuant to SB 159. To gauge participants' comprehension of the training material, the webinar includes a 10-question assessment that participants must pass in order to receive a certificate of completion. The training program is the latest in a series of educational webinars of important topics – including law, ethics, furnishing naloxone, and

preparing for an inspection – that the Board has developed and made available for free to inform and educate licensees.

4.7 Improve communication to licensees by personalizing it and decreasing verbiage to encourage licensee engagement.

<u>July 2022 Status</u>: The Board has established listservs for each type of personal license to better target subscriber alerts to pharmacists, pharmacy technicians, designated representatives, and intern pharmacists. In addition, staff keep communications in subscriber alerts and Script article as succinct and direct as possible.

<u>July 2023 Status</u>: The Board continues to use the dedicated listservs to target information to appropriate audiences.

<u>July 2024 Status</u>: The Board continues to use listservs and The Script newsletter to communicate with licensees. Social media X is also used to encourage licensee engagement.

4.8 Research creating a recognition program for pharmacists to help build relationships between public, licensees, and the Board.

<u>July 2022 Status</u>: The Board honors pharmacists who have maintained their California pharmacy license on active status for 40 years or more. These pharmacists are identified publicly in The Script and <u>online</u> and invited to be recognized and honored at Board meetings.

<u>July 2023 Status</u>: The Board continues to honor pharmacists who have maintained their California pharmacy license on active status for 40 years or more. These pharmacists are identified publicly in The Script and <u>online</u> and invited to be recognized and honored at Board meetings.

<u>July 2024 Status</u>: The Board continues to honor pharmacists who have maintained their license on active status for 40 years or more. These pharmacists are identified publicly in The Script and <u>online</u> and invited to be recognized and honored at Board meetings.

VII. Discussion and Consideration on IV Hydration Clinic Outreach

<u>Background</u>

The Enforcement Committee is drafting a policy statement on compounding at IV Hydration Clinics. In recent years, the U.S. Food and Drug Administration (FDA) has released warnings about instances of drug products being compounded under insanitary conditions. Many of these warnings stem from compounding occurring in sites that are not regulated by the Board or other Communication and Public Education Committee Meeting – July 18, 2024

regulatory agencies, including IV hydration clinics. Although business models vary, such clinics have been identified as operating in a variety of locations, including mobile vans, beauty salons, and gymnasiums. These locations generally do not have the appropriate equipment, storage, or classified areas, nor do they have authorized healthcare professionals performing the sterile compounding.

Summary of Committee Discussion

The Board has referred to the Committee development of materials that could be released to provide education on the legal requirements and patient safety considerations for such clinics. Provided in **Attachment 2** is a draft information sheet intended to provide guidance to compounding facilities that are not regulated by the Board.

VIII. Update on Communication and Public Education Activities by Staff

a. The Script

The Board has recently released two newsletters. In <u>March 2024</u>, a special edition of The Script was released that focused on AB 1286, the patient safety measure. This edition included a summary of changes, the implantation statement, an explanation on how the Board will hire a third party for collecting and reporting medication errors, and frequent asked questions (FAQ's).

And in May 2024, an issue of The Script was released, and a few of things that were published included how San Diego is expanding access to care with their pharmacy mobile unit, protected reproductive and gender affirming health care services, a reminder for pharmacist about Medicare prescription costs, the statewide standing order in schools on epinephrine, name and gender request changes, and more.

b. Staff Outreach

1. Presentation and Training A list of activities by individual staff members is in **Attachment 3** from January to June.

c. Fake Botox

1. Messaging was shared on social media from the California Department of Public Health (CDPH) on the serious health risks

related to counterfeit versions of Botox. Pictures were included to show what to look for in packaging.

d. News Media Inquires

1. A list of media inquiries from July 2023 to January 2024 is in **Attachment 4**.

IX. <u>Future Meeting Dates</u>

January 9, 2025 – proposed date June 12, 2025 – proposed date

X. Adjournment

Upon Conclusion of Business

Attachment 1



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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



Communication and Public Education Committee
DRAFT Meeting Minutes

DATE: Monday, January 22, 2024

LOCATION: California State Board of Pharmacy

2720 Gateway Oaks Drive, Hearing Room, First Floor

Sacramento, CA 95833

Participation also through teleconference via Webex

COMMITTEE

MEMBERS PRESENT: Jason Weisz, Public Member, Chairperson

Nicole Thibeau, PharmD, Licensee Member, Vice

Chairperson

Jose De La Paz, Public Member

Renee Barker, PharmD, Licensee Member

COMMITTEE MEMBERS

NOT PRESENT: Kartikeya "KK" Jha, Licensee Member

STAFF PRESENT: Anne Sodergren, Executive Officer

Julia Ansel, Assistant Executive Officer

Debbie Damoth, Executive Specialist Manager

Sara Jurrens, Public Information Officer

Corinne Gartner, Board Counsel

I. Call to Order and Establishment of Quorum

Chairperson Weisz called the Communication and Public Education Committee meeting to order at 2:00pm. Mr. Weisz reminded all present that the Board is a consumer protection agency. Mr. Weisz advised the meeting was being conducted in person and through teleconference via Webex. Mr. Weisz asked the moderator to provide general instructions on providing public comment via Webex. The meeting moderator provided updated WebEx instructions for members of the public participating in the meeting. Mr. Weisz took roll call: Present: Renee Barker, Jose De La Paz, Nicole Thibeau, Jason Weisz. Absent: Kartikeya Jha. Quorum established.

II. Public Comment for Items Not on the Agenda; Matters for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, no comment was provided.

III. Approval of the July 19, 2023 Communication and Public Education Committee Meeting Minutes

Chairperson Weisz referenced the draft minutes from the July 19, 2023 Communication and Public Education Committee meeting.

Members were provided an opportunity to comment.

No comments were made.

Motion: Approve the July 19, 2023, Communication and Public Education Committee meeting minutes as presented in the meeting materials.

M/S: De La Paz/Barker

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Barker	Support
De La Paz	Support
Jha	Not Present
Thibeau	Support
Weisz	Support

IV. Presentation on Transition of Board's Website to a New Template

Members received a presentation on the website's progression from the Board's website designer, Victor Perez. Victor showed the Committee updates made on the homepage and several back pages. Members were advised that staff anticipate the transition to be ready by the end of April.

Members noted that the new template appears straightforward and looks cleaner. Members commented that the calendar of meeting dates will be useful and improve ease of use.

Members of the public were provided with an opportunity to provide public comment. No comments were made in person in Sacramento or via WebEx.

V. <u>Public Education Campaign Related to Revised Notice to Consumer Poster</u>

Members received a presentation on the proposed campaign from the Board's public information officer, Sara Jurrens.

Members spoke in support of the campaign and provided feedback on the proposed campaign including providing guidance to staff on their preference for images to support the messaging. Members preferred the black background version and encouraged staff to incorporate additional images highlighting diversity.

Members of the public were provided with an opportunity to provide public comment. No comments were made in person in Sacramento or via Webex.

VI. <u>Communication and Public Education Activities by Staff</u>

a. The Script

Chairperson Weisz noted that the next issue of *The Script* is targeted for the early spring and will cover a variety of different topics including the most common violations that result in the issuance of a citation and fine, and the top corrections ordered during inspections.

b. Staff Outreach

- Chairperson Weisz noted the education campaign for ISMP was included in the October 2023 issue of *The Script* and the Board's website home page, under Important Information for Licensees.
- 2. Chairperson Weisz noted that the meeting materials included a list of presentations and trainings recently offered by staff.

Members of the public were provided with an opportunity to provide public comment. No comments were made in person in Sacramento or via Webex.

VII. News Media Inquiries

During the meeting members reviewed the list of recent media inquiries covering topics such as semiglutide, flavoring, medication errors, and working conditions.

Members of the public were provided with an opportunity to provide public comment. No comments were made in person in Sacramento or via Webex.

VIII. Future Meeting Dates

California State Board of Pharmacy Communication and Public Education Committee DRAFT Meeting Minutes – January 22, 2024 Page 3 of 4 Chairperson Weisz thanked everyone for their time and noted that the next meeting will be July 18, 2024.

IX. Adjournment

The meeting was adjourned at 2:35pm.

Attachment 2

Education for all Compounders

The California State Board of Pharmacy (Board) is aware of a number of clinics that offer walk-in intravenous therapy services. The Board is aware of patient harm that has occurred at some such clinics, including sepsis and other conditions requiring hospitalization. Board inspections of some locations have revealed violations of legal requirements, including purchasing products from unlicensed sources. The Board is providing information as education to all healthcare providers on some legal requirements to safely provide such services. The Board notes that this is not intended to be a comprehensive legal document and health care providers should seek guidance from their regulatory agencies to gain a full understanding of all legal requirements.

Did you know.....

The U.S. Food & Drug Administration (FDA) defines compounding as "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved." FDA has <u>FAQs</u> available on its website.

The United States Pharmacopeia (USP) describes the minimum requirements which apply to all persons who prepare compounded preparations (CPs) and all places where CPs are prepared. This includes but is not limited to pharmacists, pharmacy technicians, nurses, nurse practitioners, physicians, physician assistants, dentists, naturopathic doctors, and chiropractors in all places, including but not limited to hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physician or veterinarian practice sites. **Note:** USP standards **DO NOT** establish authority to compound. You will need to confirm with your respective healing arts board to confirm if state law allows you to compound and under what circumstances.

What does this mean for you....

If you are compounding it must be in compliance with the applicable USP chapters, no matter what or where you compound.

If you are compounding a **sterile** preparation (CSP), your practices need to be compliant with the requirements in USP Chapter 797.

Things to remember for sterile compounding:

 Compounders must have appropriate training, be able to demonstrate knowledge of principles and competency of skills for performing sterile

- Compounders must understand the requirements in USP Chapter 797.
- Compounders must comply with personal hygiene and garbing requirements.
- Compounders must compound in only compliant facilities with appropriate engineering controls.
- Compounders must ensure the compounding environment is monitored for microbiological air and surface burden.
- Compounders must ensure the compounding environment is appropriately cleaned, disinfected, and treated for spores.
- Compounders must ensure the introduction of items into the compounding environment is appropriate to ensure the compounding environment is not compromised.
- Compounders must ensure the equipment, supplies, and components are appropriate for the compounding being performed.
- Compounders must ensure appropriate documentation and records are created and maintained.
- Compounders must ensure appropriate labeling, testing, assignment of beyond-use-dates (BUDs), storage, shipping, and transportation for all CSPs.

If you are compounding a **non-sterile** preparation (CNSP), your practices need to be compliant with the requirements in USP Chapter 795.

Things to remember for non-sterile compounding:

- Compounders must complete training and be able to demonstrate knowledge of principles and competency of skills for performing nonsterile manipulations as applicable to their assigned tasks.
- Compounders must understand the requirements in USP Chapter 795.
- Compounders must comply with personal hygiene and garbing requirements.
- Compounders must compound in only compliant facilities with appropriate engineering controls.
- Compounders must ensure the compounding environment is appropriately cleaned and sanitized.
- Compounders must ensure the equipment and components are appropriate for the compounding being performed.
- Compounders must ensure appropriate documentation and records are created and maintained.
- Compounders must ensure appropriate labeling, testing, assignment of BUDs, storage, shipping, and transportation for all CSNPs.

The Board strongly recommends that prior to purchasing products for IV therapy, a <u>license search</u> is performed to ensure the entity from which the products will be purchased is appropriately licensed with the Board.

Consistent with its authority (Business and Professions Code section 4008(a)), the Board will be conducting inspections at locations where drugs and devices are compounded, prepared, furnished, dispensed, or stored. Board inspectors will identify themselves with a Board-issued badge and provide a business card and will provide a receipt for any records taken. If requested, the inspector will leave a copy of the inspection report with the healthcare provider on the premises. The inspector can also answer questions about compounding requirements.



Attachment 3

Board of Pharmacy (BOP)

Attachment #3 - Staff Outreach Activities

January 1- June 28, 2024

Board staff reported the following outreach activities:

- January 2, 2024, President Seung Oh and Executive Officer Anne Sodergren provide presentation to students at Touro University.
- February 14, 2024, Board hosts day-long training covering a range of topics include diversion trends, loss prevention, corresponding responsibility, inspection expectations and changes in pharmacy law.
- February 14, 2024: Staff provide day-long training on Prescription Drug Abuse Prevention, Diversion Trends and Loss Prevention, CURES, and legal updates.
- March 1: EO presents at West Coast Patient Safety Conference.
- April 16: EO presents at California Society of Health Systems Pharmacists Legislative Day.
- April 19-20, President Oh and EO Sodergren attend California Pharmacists Association Western Exchange representing the Board and providing a presentation on legal updates.
- Staff provides pharmacist examination application presentations for:
 - o Northstate University was given on 2/29/2024.
 - o University of San Diego was given on 3/11/2024.
 - Western University was given on 3/13/2024.
 - Loma Linda University was given on 3/29/2024.
 - o Chapman University was given on 3/29/2024.
 - o University of Southern California was given on 4/1/2024.
 - o University of San Francisco was given on 4/3/2024.
 - o Marshall B. Ketchum University was given on 4/8/2024.
- Intern Pharmacist application presentations for University of San Diego was given on 5/29/2024.

Attachment 4

Attachment #4 - News Media Inquires

January 1 – June 29, 2024

- 1/22/24, Carrie Cochran with Scripps News submitted a Public Records
 Act request to the Board of Pharmacy for probation and disciplinary
 reports for Empower Pharmacy of Texas; specifically Quarterly Reports,
 Quarterly Inspection Reports, and Inspection Reports, stemming from the
 Stipulated Settlement and Disciplinary Order issued 12/19/22.
- 2/1/2024, Shelby Livingston with the Business Insider contacted the Board to request information on Empower Pharmacy regarding semaglutide and tirzepatide.
- 3/6/2024, Carlos Mendoza with KRON contacted the Board asking if BOP is investigating a CVS pharmacy in San Ramon and if the pharmacy is closing due to violations.
- 3/7/2024, Jeff von Kaenel with News and Review contacted the Board requesting a quote for a article on the importance of medication take back bins and safe disposal of unused prescriptions and other drugs.
- 4/25/2024, Madison Muller with Bloomberg contacted the Board to request information on how weight loss drugs are tracked. Muller is reaching out to states to get an understanding on how it is tracked in different areas of the country. The reporter asked how many prescriptions are written for compounded GLP-1 drugs, how many are being dispensed to patients in California, and if pharmacies are required to report prescription data.
- 4/29/2024, Samantha Spinaci with ABC10 in Sacramento, contacted the Board and the Medical Board of California to request information on complaints involving weight management drugs since January 2022. On 6/13/2024, Samantha contacted the Board with a follow up question asking if the Board tracks which counties and cities that complaints are made.
- 5/7/2024, Kasturi Pananjady with Associated Press contacted the Board to ask if the addresses listed on the DCA Public Information Licensee List Overview webpage are the physical addresses of the pharmacies.

 6/11/2024, Ike Swetlitz with Bloomberg contacted the Board to request information on California banning out of state shipments of compounded semaglutide and disciplinary actions and investigations related to weight loss drugs.