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



COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

Jason Weisz, Public Member, Chairperson
Nicole Thibeau, PharmD, Licensee Member, Vice Chairperson
Renee Barker, PharmD, Licensee Member
Jay Newell, Public Member
Kartikeya Jha, Licensee Member

a. Transition to a New Website Template

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.

Summary of Committee Discussion

Members were advised that Staff completed the conversion of the website to a newer template. The website was 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.

Recent Update

Following the meeting, the conversion to the new website was completed. A subscriber alert was released announcing the new website template.

b. <u>Talk to the Expert Consumer Poster and Public Education 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>Summary of Committee Discussion</u>

During the meeting members were advised that 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.

Members were reminded about the 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. Members requested that staff maintain the education campaign for use in the future as a reminder beyond August as an important resource for patients.

Further, as part of the discussion, members requested that staff evaluate for opportunities to partner with the Enforcement and Compounding Committee on efforts to address barriers to patient consultation.

Attachment 1 includes a copy of the public education campaign.

c. Draft Educational Material Related to IV Hydration Clinics

Background

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 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. The Enforcement and Compounding Committee considered a draft policy statement during its July 17, 2024, meeting on compounding at IV Hydration Clinics.

Summary of Committee Discussion

During the meeting members reviewed draft educational materials intended to be provided to personnel at IV hydration clinics as well as made available on the Board's website. The focus of the education is around legal requirements and patient safety considerations for such clinics.

During the meeting members generally spoke in support of the concept of the education and requested that staff work to refine the materials. Members requested that staff work with Member Barker to incorporate edits requested by the committee and to provide an updated version for the Board's consideration.

Following the meeting staff had an opportunity to work with Member Barker. Some of the significant changes made to the document include:

- 1. Reorganization of information and simplifying language to more explicitly state the potential harm to patients.
- 2. More directly referenced the relevant sections of USP 797 Pharmacy Compounding Sterile Preparations

Consistent with the request from the committee, staff will also be exploring the ability to create an educational video.

Board staff will continue to engage with other healing arts boards on the materials and will continue to offer co-branding of the document with programs that are interested.

Provided in **Attachment 2** is the updated draft information sheet intended to provide guidance to compounding facilities that are not regulated by the Board.

d. Communication and Public Education Activities by Staff

1. 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).

In <u>May 2024</u>, 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.

2. Staff Outreach

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

3. Fake Botox

 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.

4. News Media Inquires

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

Notice to Consumer (NTC) Campaign

Day	Message	Graphic
Monday	Protect yourself by learning about the medications you are taking. Talk to your pharmacist to prevent medication errors. Visit: www.pharmacy.ca.gov #TalktotheExpert #PreventMedicationErrors	TALK TO THE EXPERT PHARMACISTS ARE HEALTH CARE PROVIDERS Remember to ask for a patient consultation to prevent medication errors. BE AWARE AND TAKE CARE: Talk to your pharmacists Talk to THE EXPERT
Tuesday	Before leaving the pharmacy, check that you have the right medication. Taking one minute to read the label can protect you from a medication error. To learn about the Board, visit: www.pharmacy.ca.gov #TalktotheExpert #PreventMedicationErrors	TALK TO THE EXPERT DOES YOUR Before you leave the pharmacy, check: BEFORE YOUR MEDICATION MATCH THE DESCRIPTION ON THE LABEL? MAKE M
Wednesday	Do you have questions about your medication? Don't hesitate to ask! As a licensed healthcare provider, pharmacists can answer questions regarding: · A missed dose · Side effects · Medication interactions Visit: www.pharmacy.ca.gov #TalktotheExpert #PreventMedicationErrors	TALK TO THE EXPERT OUESTIONS YOU MAY HAVE: • What should I do if I miss a dose? • What should I do if I mis a dose? • What should I do if I mis a dose? • Does my medication work safely with other medicines or supplements? Speak with your pharmacist Talk to your pharmacist RE AWARE AND TAKE CARE: Talk to your pharmacist Talk to your pharmacist Talk to your pharmacist

Day	Message	Graphic
Thursday	Have questions about your medication and need assistance in a different language? Free interpreter services available in 16 languages. Ask your pharmacist for assistance. To learn more, visit: https://www.pharmacy.ca.gov/publications/point-to-your language.pdf #TalktotheExpert #PreventMedicationErrors	TALK TO THE EXPERT INTERPRETER SERVICES ARE AVAILABLE TO YOU AT NO COST UPON REQUEST. Know Your Rights Translation Traducción Traducción Traducción Wight Wiggre MARCHINE MARCH MARCHES Translation Traducción Traducción Wiggre Miggre Miggre Miggre
Friday	Remember, California law requires a pharmacist to speak with you when you get: • A new prescription • New dosage • New medication strength • New written directions Get to know the Board by visiting: www.pharmacy.ca.gov #TalktotheExpert #PreventMedicationErrors	TALK TO THE EXPERT A PHARMACIST IS REQUIRED TO SPEAK WITH YOU EVERY TIME TO GET: NEW PRESCRIPTION NEW DOSAGE FORM NEW STRENGTH NEW WRITTEN DIRECTIONS BE AWARE AND TAKE CARE: Talk to your pharmacist! CAUTORMA STATE BOARD OF PHARMACY MARKET

Listserv

Revised Notice to Consumer Poster

A reminder that starting today, July 1, 2024, all California pharmacies are required to post the **revised** <u>Notice to Consumer</u> poster. The current poster is titled "Talk To The Expert". This notice must replace the Ask Your Pharmacist! poster, and the previous poster must be removed.

The California State Board of Pharmacy (BOP) has mailed out the posters, if you did not receive the NTC materials, please visit the <u>Board's website</u>.

According to pharmacy law, every pharmacy shall post a notice to consumer poster in a conspicuous place and consumers must be able to use the QR code to obtain translation of the notice. The Board provides posters in the top 16 languages spoken by limited-English-proficient individuals in California. Click here for posters in multiple languages.

CONTACT: Sara Jurrens

(279) 226-4542; sara.jurrens@dca.ca.gov

Pharmacists are Licensed Healthcare Providers

A new consumer protection poster is now displayed in every pharmacy in California. The state's Board of Pharmacy (BOP) recently released its new campaign, "Talk to the Expert". This campaign is to remind consumers that pharmacists are licensed healthcare providers who are there to protect them and keep them safe. Medication errors can be reduced when a consumer accepts the pharmacy consultation.

By law, a pharmacist is required to talk with the consumer when they pick up a new prescription, a prescription with a new dosage, or medication with new written directions. Pharmacists can educate consumers on possible side effects and what to do if they occur. Also, they can explain to consumers whether the medication will work safely with other medications or supplements, and what food, drinks or activities should be avoided while taking the medicine. "Taking that extra minute to understand your prescription can protect you from medication errors, and in some cases, it could mean the difference between life and death," said Jason Weisz, Chairperson for the Board's Communication and Public Education Committee.

It is the law that in every pharmacy in California a Notice to Consumer poster is onsite to assist consumers with their rights. The poster includes a QR Code for consumers to scan with their phone if they need the information translated for them, interpreter services are available for free in the top 16 languages spoken within California.

Every pharmacy in the state must display your rights on the Notice to Consumer poster or display the notice on a video screen accessible to all consumers.

The California State Board of Pharmacy protects and promotes the health and safety of California consumers by pursuing the highest quality of pharmacist care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.

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Education for all Compounders

The California State Board of Pharmacy (Board) is aware of a number of clinics that offer walk-in intravenous (IV) hydration services. IV hydration is, as the name implies, administered directly to the patient's bloodstream, thereby bypassing many of the body's natural defenses. This can result in severe or life-threatening reactions if the IV mixture is compounded (mixed) or administered in an unsafe manner. Retail IV therapy, commonly referred to as "IV hydration," "IV nutrient therapy," or "vitamin infusion," is provided in a number of different types of businesses including med spas and IV therapy clinics. Board inspections of some locations have revealed violations of legal requirements, including purchasing products from unlicensed sources and compounding requirements including national standards. 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 – Pharmaceutical Compounding – Sterile Preparations.

Things to know about sterile compounding.

Compounders **must** understand and comply with the requirements in USP Chapter 797 including:

- Personnel training and evaluation
- Personal hygiene and garbing
- Facilities and engineering controls
- Certification and recertification
- Microbiological air and surface monitoring
- Cleaning, disinfecting and applying sporicidal disinfectants and sterile 70%
- Equipment, supplies and components
- Sterilization and depyrogenation
- Master formulation and compounding records
- Release inspections and testing
- Labeling
- Establishing beyond-use dates
- Use of conventionally manufactured products as components
- Use of CSPs as components
- Standard operating procedures
- Quality assurance and quality control
- CSP handling, storage, packaging, shipping and transport
- Documentation

Note: If you are compounding a non-sterile preparation (CNSP), your practices need to be compliant with the requirements in USP Chapter 795 – Pharmaceutical Compounding Nonsterile Preparations.

The Board strongly recommends that prior to purchasing products for IV hydration, 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.

Board of Pharmacy (BOP)

Attachment #2 - 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.
 - University of San Diego was given on 3/11/2024.
 - Western University was given on 3/13/2024.
 - o Loma Linda University was given on 3/29/2024.
 - o Chapman University was given on 3/29/2024.
 - University of Southern California was given on 4/1/2024.
 - University of San Francisco was given on 4/3/2024.
 - 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.

<u>Attachment #3 - News Media Inquires</u>

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.