CALIFORNIA STATE BOARD OF PHARMACY

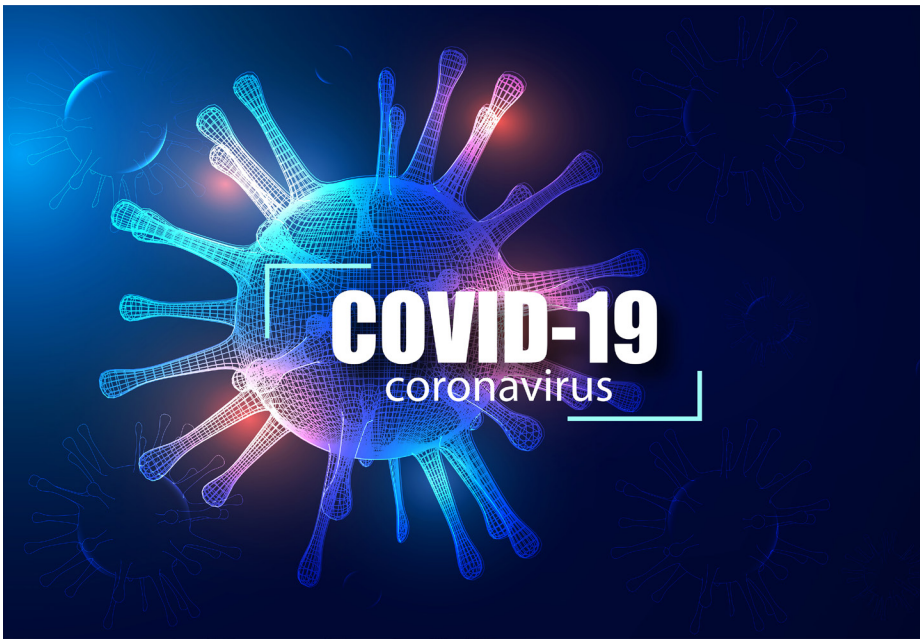
September 2020

THE SCRIPT

BE AWARE & TAKE CARE: Talk to your pharmacist!

Contents

Board provides guidance for licensees on COVID-19



On March 4, 2020, Governor Gavin Newsom declared a state of emergency in California as a result of the impacts of the COVID-19 pandemic. Pursuant to orders from the Governor and state laws, the Department of Consumer Affairs (DCA) and the California State Board of Pharmacy have taken important steps to help licensees respond to the health care needs of California consumers.

Important information is posted and updated regularly under COVID-19 Information on the homepage of the Board's website, www.pharmacy.ca.gov. To receive electronic alerts about important actions and updates, sign up to join the Board's email notification system.

Pharmacy Board Waivers

Consistent with Business and Professions Code (BPC) section 4062, the Board or the Board president has issued a variety of Pharmacy Law waivers to assist licensees in protecting public

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PRESIDENT'S MESSAGE

By Gregory Lippe, President, Board of Pharmacy

On behalf of the California State Board of Pharmacy, I extend our sincerest gratitude to all of our licensees who, as essential workers, are serving on the front lines caring for patients during the COVID-19 pandemic.

Since the beginning of March, the Board has focused significant resources on the COVID-19 public health crisis. The Board has taken important steps to assist your efforts in caring for patients during the public health emergency. These actions are reported in this newsletter, including Pharmacy Law waivers granted by the Board and waivers granted by the Department of Consumer Affairs. Be sure to check our website and sign up for subscriber alerts to receive important updates.

Pharmacists and pharmacy workers have been designated "essential critical infrastructure workers." The Board encourages you to read Guidance for Pharmacies and Pharmacy Staff from the California Department of Public Health, CDC Guidance for Pharmacies, and general worker protection information from Cal/OSHA to minimize your staff's risk of exposure to the virus that causes COVID-19. These documents are on the Board's website.

Meanwhile, the Board continues its normal operations as a regulatory and consumer protection agency. Staff continues to process applications, issue and renew licenses, investigate consumer complaints, and carry out all the duties of the Board.

The Board also remains committed to licensee training. Staff is developing a WebEx video conference format for providing prescription drug abuse training and continuing education. In addition, the 2020 Pharmacy Law webinar is now posted online; pharmacists who complete the video tutorial can receive one hour of credit in Board-provided continuing education.

We invite licensees, stakeholders, and the public to remain aware and engaged in the Board's activities. During the pandemic, our Board and committee meetings have switched from live events held throughout the state to a WebEx format. Information about how to observe and participate in teleconference meetings is included in all meeting agendas. A list of action items and webcasts from Board meetings are posted online at the Board Meetings page.

The Board also is moving forward with new regulations, and we encourage stakeholders to participate in the rulemaking process. Information about pending regulations – including supporting documents and comment periods – is updated regularly on the website.

Thanks to all of our licensees who, as essential workers, are serving on the front lines caring for patients during the COVID-19 pandemic.

To learn and receive updates about pending regulations, meetings, and all Board programs and activities, sign up for News and Information alerts on the Board's email registration page. You can also follow us – @CAPharmBoard – on Twitter.

Thank you for your commitment to your patients and to the public health and well-being of all Californians. Be healthy and stay safe.

COVID-19

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health or providing patient care. Information is updated online as new waivers are approved and existing waivers are extended or set to expire. Licensees should read the provisions carefully, including the conditions for use, to understand the specific purpose of a waiver.

Information about how to request a waiver related to COVID-19 for a specific site is also posted on the Board's website.

COVID-19 FAQ

Board inspectors have received many questions from licensees related to COVID-19. A list of the most frequently asked questions (FAQ) and answers is compiled and posted on the Board's website.

COVID-19 Testing

Pursuant to Executive Order N-39-20, DCA issued an order on August 25, 2020, waiving restrictions on pharmacies, pharmacists and pharmacy technicians relating to ordering, collecting specimens for, and performing COVID-19 tests. In addition, DCA has issued guidance on the authority and permissible practices of pharmacies, pharmacists and pharmacy technicians to order, collect specimens for, perform and interpret results for authorized COVID-19 tests.

Other DCA Waivers

- Restore Inactive License: DCA has issued an order temporarily waiving statutory or regulatory requirements to restore an inactive, retired, or canceled license to full active status during the declared emergency to help during the COVID-19 pandemic. The full waiver and an electronic application to restore a license are available online.

- Renewal Requirements: DCA issued an order temporarily waiving continuing education (CE) requirements for renewing a license during the declared emergency. The initial order was issued March 31and extended July 1.

Visit the DCA Waivers and Guidance Documents website to review the waiver language, verify the status of these orders, and find current information regarding other DCA waivers related to the COVID-19 pandemic.

Additional Information

Visit the COVID-19 Information box on the Board's website for links to additional information from the Board of Pharmacy and other state and federal agencies.

Mission statement - California State Board of Pharmacy

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

Medication errors are top citations for pharmacies, pharmacists in 2019/20

Business and Professions Code (BPC) section 4314 authorizes the California State Board of Pharmacy to issue citations for violations of Pharmacy Law. California Code of Regulations (CCR) title 16, sections 1775 to 1775.4 describe how the Board exercises this authority.

Citations are administrative actions; they are considered less serious than disciplinary actions (which may result in license probation, suspension, or revocation). As part of its ongoing efforts to educate licensees on common violations that result in the issuance of citations, annual information is reported through the Board's Enforcement and Compounding Committee.

Most common citations – fiscal year 2019/20

Medication errors ranked as the top reason for citations issued by Board of Pharmacy to both pharmacies and pharmacists during the past fiscal year.

Top 10 Citations, FY 2019/20: Pharmacies

Code Violation	Description	Number of Violations
CCR 1716	Medication Error	157
CCR 1714(b)	Safe and Secure Pharmacy – Maintain Facilities, etc.	42
BPC 4081(a)	Records Kept Open for Inspection for Three Years	42
BPC 4113(d)	Notify Board within 30 Days of Change of PIC	31
CCR 1707.2	Duty to Consult	30
CCR 1764	Unauthorized Disclosure of Prescriptions	27
CCR 1761(a)	Erroneous or Uncertain Prescription	26
CCR 1718	Current Inventory	26
CIV 56.10	Disclosure of Medical Information	25
CCR 1735.2	Compounding Limitations and Requirements	24

Top 10 Citations, FY 2019/20: Pharmacists

Code Violation	Description	Number of Violations
CCR 1716	Medication Error	157
CCR 1761	Erroneous or Uncertain Prescription	97
CCR 1735.2	Compounding Limitations and Requirements	56
BPC 4306.5	Unprofessional Conduct	49
BPC 4081(a)	Records Kept Open for Inspection for Three Years	43

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Code Violation	Description	Number of Violations
CCR 1714(b)	Safe and Secure Pharmacy – Maintain Facilities, etc.	41
CCR 1707.2	Duty to Consult	34
CCR 1718	Current Inventory	30
CCR 1707.3	Duty to Review Drug Therapy and Patient Medication Record	24
HSC 11153	Controlled Substances Prescription for Legitimate Medical Purpose	20

In contrast with pharmacists, intern pharmacists and pharmacy technicians were cited most often for unprofessional conduct stemming from self-use of dangerous drugs or alcohol in a manner dangerous or injurious to oneself or others; and convictions of crimes substantially related to the practice of pharmacy.

Top Citations, FY 2019-20: Intern Pharmacists

Code Violation	Description	Number of Violations
BPC 4301(h)	Self-Use of Dangerous Drug/Alcohol	8
BPC 4301(l)	Conviction of a Crime	7
BPC 4301(k)	Conviction Involving Self-Use	2
BPC 4301(c)	Gross Negligence	1
BPC 4301(o)	Violating or Attempting to Violate Federal or State Laws/ Regulations Governing Pharmacy	1
CCR 1714(d)	Security of Prescription Department	1

Top Citations, FY 2019-20: Pharmacy Technicians

Code Violation	Description	Number of Violations
BPC 4301(h)	Self-Use of Dangerous Drug/Alcohol	99
BPC 4301(l)	Conviction of a Crime	93
BPC 4301(f)	Commission of an Act Involving Moral Turpitude, Dishonesty, Fraud, Deceit or Corruption	19
BPC 4301(k)	Conviction Involving Self-Use	9
BPC 4115(e)	Unlicensed Technician	6

The information in this overview article was presented with additional details and discussion at the July 9, 2020, Enforcement Committee meeting. To view the presentation, go to the webcast at 1:51:50.

Top 10 corrections, violations found in routine inspections in 2019/20

An important goal of the California State Board of Pharmacy is to inspect all pharmacies at least once every four years. Inspections are performed for a variety of reasons – including consumer complaints, as a condition of license issuance or renewal, to monitor probation activities, and as a routine visit to verify compliance with state and federal laws and regulations.

While the inspection enables staff to observe and evaluate for compliance, it also provides an opportunity to educate licensees. During an inspection, an inspector may order a correction for a minor violation of Pharmacy Law or issue a written notice of violation for a more substantial violation.

To aid licensees in understanding the top corrections ordered and violations identified as part of the inspection process, the Board's Enforcement and Compounding Committee receives an annual presentation on those most frequently identified during the inspection process.

Top 10 Corrections Ordered during Routine Pharmacy Inspections, FY 2019/20

Code Violation	Description	Examples
CCR 1707.5(a)(1)	Prescription Label Requirements – Patient-Centered Labeling, 12pt Font	• "Generic for" missing from label. • "Generic for" not printed in 12pt font.
CCR 1707.5(d)	Policies and Procedures – Provide Interpretive Services	• Pharmacy fails to provide proof of compliance. • No policies or procedures for interpretive services.
CCR 1714(c)	Pharmacy Clean and Orderly	• No hot running water. • Sink handle loose, no continuous hot running water.
CCR 1714(b)	Safe and Secure Pharmacy – Maintain Facilities	• Ice buildup in fridge, cluttered pharmacy. • No working temperature monitor for medication storage fridge. • Pharmacy cluttered with baskets of medications, boxes, dirty carpet stains, pills and paper on floor.
CCR 1707.2(b)(2)	Written Notice of Right to Consultation When Patient or Agent is Not Present (including but not limited to drugs shipped by mail)	• Medications for delivery did not have notice of consultation. • Delivery patients not being informed of right to request consultation along with phone number and hours pharmacist may be reached for consultation. • Rx ready for delivery is missing right to consultation; PIC presented note to insert in package, but the ink was faded and words not legible.
CCR 1715.65(a)	Inventory Reconciliation Report of Controlled Substances	• Inventory reconciliation not performed/not completed.

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Code Violation	Description	Examples
CCR 1715(a)	Self-Assessment	• No current self-assessment available during inspection, e.g. during 1/9/20 inspection, last self-assessment completed on 4/18/17; no self-assessment for 2019 was completed. • No self-assessment available during inspection; PIC said he took it home.
BPC 4104(b)	Policies and Procedures / Theft / Impairment / Self-Use	• No written polices and procedures available for review addressing chemical, mental, or physical impairment as well as theft, diversion, or self-use of dangerous drugs.
BPC 4058	License Display	• Pharmacy did not display the original pharmacy license and PIC had no knowledge of the whereabouts. • New original license identifying PIC was not located during the time of inspection. • Premise's original and renewal permit not posted in public view.
CCR 1714.1(f)	Pharmacy Shall Have Written Policies and Procedures Regarding Operations of the Pharmacy during Temporary Absence of the Pharmacist	• No policy and procedure for temporary absence of pharmacist.

Top 10 Violation Notices Issued during Routine Inspections, FY 2019/20

Code Violation	Description	Examples
CCR 1715(a)	Self-Assessment	• Self-assessment was not completed in 2019 (inspection 1/2020). • Self-assessment was last filled out 4/20/18. Self-assessment should be filled out prior to July 1 of every odd year (inspection 11/2019).
CCR 1714(c)	Pharmacy Clean and Orderly	• During inspection large trash bin which was dirty and had many bugs (small flies) flying around on top and within the pharmacy. Stepping stool was dirty. • No sink suitable for pharmacy use, counting machines dirty, drugs stored in fridge with food. Injections done by pharmacist without a useable sink.

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Inspections

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Code Violation	Description	Examples
HSC 11165(d)	Reporting to CURES	• During inspection 10/17/2019, pharmacy had not reported to CURES since 10/01/2018 following its purchase from previous owner. • During inspection, observed there was no transmission of CURES data.
CFR 1304.11(c)	Biennial Inventory – Date on Form	• During inspection, there was no DEA controlled substances inventory conducted at all. PHY maintains a C2 perpetual inventory logbook (initial inventory received was approximately 7/24/19). • At inspection pharmacy did not have a printout of the biennial inventory.
CCR 1714(b)	Safe and Secure Pharmacy – Maintain Facilities	• Expired drugs in boxes on the floor and in active inventory. Pictures of expired drugs and a list were generated. Boxes of trash and drugs on the floor. PIC to send proof all expired drugs have been removed from the PHY, provide list of drugs sent to a reverse distributor or pharmaceutical waste contractor. The boxes and excess stuff need to be removed - send photos of excess stuff. • Sink in the compounding area drains slowly. Faucet in the fill room drips. Send proof both fixed. Med fridge doesn't have a temp log/thermometer stopped working. C2s kept in cabinets and drawers with no locks.
CCR 1735.7(b)	Maintaining Compounding Training Records	• PHY compounded magic mouthwash at least 26 times and did not have ongoing staff training or competency evaluation. PHY does not have an ongoing training program. Last compounding training for the PIC was 6/2014.
CCR 1735.2(k)	Compounding Self-Assessment	• Most recent compounding self-assessment was dated 3/15/2017 (inspection on 10/7/19). • PIC did not fill out a compounding self-assessment prior to allowing at least 26 magic mouthwash prescriptions to be compounded at the pharmacy.
CCR 1735.8(c)	Compounding Quality Assurance for Products Outside Minimum Standards	• QA plan which included at least annual testing of potency was not in place. • PHY could not provide any records of end product testing.

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Code Violation	Description	Examples
CCR 1714(d)	Security of Prescription Department	• As it relates to 1707(g)(2) & 56.101. Rx records were stored upstairs in an open area where all other store merchandise was located. The records were accessible and not secured. • As it relates to 1707(g)(2) and 56.101. Rx records were stored in a locked cage which was not secure from the top. The records were overflowing from the top and were accessible and unsecured.
BPC 4110(a)	Unlicensed Activity	• As it relates to BPC 4037(a), in that the pharmacy moved dangerous drugs to a new location that was not licensed by the board. • PHY expired on 12/1/19 and was not renewed, dangerous drugs and PHY records were maintained at this expired location. Inspection 12/19/2019.

The information in this overview article was presented with additional details and discussion at the July 9, 2020, Enforcement Committee meeting. To view the presentation, go to the webcast at 2:28:52.

Licensees also can view an informational video on how to prepare for a California State Board of Pharmacy inspection on the Board's website at Licensees > Important Information for Licensees > Ask an Inspector. The Board has also created a Pharmacy Inspections brochure.

www.pharmacy.ca.gov

PICs must complete self-assessment forms in odd-numbered years

Has your pharmacy completed a self-assessment form? PICs are required to complete a self-assessment of the pharmacy's compliance with state and federal laws before July 1 of each odd-numbered year. Find current and updated self-assessment forms and get more information on the Board's self-assessment forms webpage.

Check Board website for CPJE dates in 2020, additional testing information

The Board of Pharmacy has posted CPJE testing dates for 2020 online. To schedule an exam date within your eligibility period, go to candidate.psiexams.com or call (877) 392-6422. Be sure also to check out additional CPJE information and sign up to receive subscriber alerts for important updates from the Board.

Medication errors: 3 case studies

Case 1

Overview:

A prescription for tramadol 50 mg was dispensed containing topiramate 50 mg mixed with the tramadol 50 mg. The prescription for 90 tablets of tramadol contained 12 tablets of topiramate, and the patient took one dose of topiramate 50 mg.

Investigation:

A Board inspection of the pharmacy showed tramadol 50 mg and topiramate 50 mg were located at different shelves in the pharmacy. However, both medications were dispensed by the pharmacy's automated drug delivery system (ADDS), and the cell for topiramate 50 mg was located four cells above the cell for tramadol 50 mg. The pharmacy's internal investigation showed the tramadol 50 mg cell also contained topiramate 50 mg.

The investigation concluded the ADDS cell for tramadol 50 mg was inadvertently filled by a pharmacy technician with topiramate 50 mg from a prescription vial that was returned to stock, and the process was not checked by the pharmacist. In addition, the label adhered to the prescription vial did not have the manufacturer's bar code to scan to confirm the medication added to the ADDS cell was the same medication.

Discussion:

ADDS provides a fast and efficient way to fill prescriptions, provided the pharmacy follows the manufacturer's recommendations and safety features. However, the technology still involves human elements, which often are the cause of dispensing errors with the use of an ADDS. The error involving ADDS can have a larger impact, affecting multiple prescriptions, not just one patient, since ADDS are used to fill medications that are frequently dispensed. The use of an ADDS can provide the pharmacist a false sense of assurance that the ADDS dispensed the correct medication.

It is important for pharmacies to develop policies and procedures and to train staff on the use of an ADDS, and for pharmacists to continue to incorporate safe dispensing practices when verifying a prescription prior to furnishing a prescription to a consumers. Examples of best practices to consider include:

- Labeling the ADDS cell with the correct name of the drug, strength, manufacturer, lot number and expiration date each time a cell is stocked.
- Having the pharmacist verify the drug added in the ADDS cell is the correct drug, strength, and within good dating, and documenting the restocking.
- Limiting the restocking to full manufactured bottles with the same lot number and expiration date with the ability to scan the bar code on the bottle for verification.
- Avoiding restocking drugs that are returned to stock from will call without a barcode on the prescription label to confirm the content in the prescription container matches the content in the ADDS cell and to record the manufacturer, lot number and expiration date of the contents.
- Pouring the contents of the prescription container on a counting tray to confirm the contents are uniform and to match the visual image of the drug displayed on the computer screen.

Case 2

Relevant provisions from Title 16, California Code of Regulations (CCR):

Section 1761 (a) states "no pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to

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obtain the information needed to validate the prescription."

Section 1707.3 states "prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems."

Section 1716 states in pertinent part "pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber."

Overview:

A patient at a hospital was administered an uncertain prescription for potassium chloride resulting in overdose and patient death.

Investigation:

A physician prescribed 40meq potassium chloride (KCL) liquid to be given enterally, one dose to be taken now and one dose two hours later. However, the order was entered into the computer system as 40meq KCL every two hours for 31 days with additional directions to administer 40meq now and again two hours later for a total dose of 80meq KCL.

The verifying pharmacist failed to notice that the stop date on the order did not match the number of doses specified in the prescriber's clinical directions. Furthermore, due to a computer glitch, the pharmacist did not receive a maximum total daily dose alert or a hard stop intervention.

The pharmacist approved the order as 40meq KCL every two hours. The patient was administered 10 doses of 40meq KCL, for a total of 400meq, five times the ordered dose. Patient died from hyperkalemia leading to cardiac arrest.

Discussion:

Potassium chloride is a high alert drug when prescribed enterally or intravenously. Verifying pharmacists should use their professional education and not solely rely on the computer to provide a warning message. The pharmacist in this case failed to intervene and contact the prescriber to clarify the uncertainty in the order prior to approving the use of KCL.

Case 3

Relevant provisions from Title 16, California Code of Regulations (CCR): See Case 2.

Overview:

A patient at a community pharmacy presented a prescription for micronized progesterone 200mg but received misoprostol 200mcg instead.

Investigation:

A handwritten prescription for micronized progesterone 200mg was presented to the pharmacy for a patient undergoing IUI treatments to get pregnant. The physician's handwriting was difficult to read, and the pharmacist interpreted the written prescription incorrectly. The prescription was entered and verified as misoprostol 200mcg and dispensed to the patient.

Misoprostol 200mcg at this dose is used to terminate pregnancy. Other medications on patient's profile that were recently picked up indicated the patient was trying to get pregnant. The error resulted in patient harm, causing abdominal cramps and delayed pregnancy.

Discussion:

The pharmacist acknowledged the prescription was difficult to read but failed to contact the prescriber to clarify the prescription. Moreover, the pharmacist failed to review the patient's medication record, which indicated the patient was trying to get pregnant, before dispensing misoprostol 200mcg. Additionally, the pharmacist failed to consult the patient and verify what the drug was being used for.

Damaged pharmacy sites: What to do

Walgreens and Rite Aid stores in downtown Los Angeles are boarded up after civic unrest in 2020.

In 2019, wildfires damaged or destroyed properties in many California communities, including pharmacies. This year, pharmacies also suffered damage or destruction from vandalism, looting and arson in violence that occurred at the same time or in close proximity to some social protests.

When civic unrest occurs or natural disaster strikes, the California State Board of Pharmacy's top concerns are the safety of pharmacy workers, continuity of health care for patients, and the security of the drug supply.

Licensees with questions or concerns can contact a Board inspector on duty to answer inquiries at (916) 581-3100 or ask.inspector@dca.ca.gov. Please include your name, license number, organization, phone number, and the best time to reach you.

Some additional practical guidance and relevant legal provisions are summarized below to assist licensees:

- Pharmacies in impacted areas should consider boarding up the property to minimize damage and prevent drug losses.
- Safety of pharmacy staff and patients should be the primary concern. The Board does not expect pharmacy staff to enter the premises unless it is safe to do so.
- When it is safe to enter, notify the Board by email if the pharmacy was damaged, looted, vandalized, set afire, etc. Provide the pharmacy name and license number. If inventory or records are being moved (see below), include the location of any inventory of dangerous drugs and devices or records being transferred. If the damage has been assessed, provide a brief description.
- Secure any drugs, records and computers containing confidential patient information in the pharmacy when it is safe to do so. Inventory all dangerous drugs and devices to identify any losses. (Note: The inventory may be performed before or immediately following the transfer to a secure location.)

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- If drugs, records and computers in the pharmacy cannot be secured, consider the following options pursuant to Business and Professions Code section 4126:
    - Transfer or store the drugs with a wholesaler owned or under common control with the wholesaler from whom they were acquired.
    - Transfer the drugs to a licensed wholesaler acting as a reverse distributor.
    - Transfer or store the drugs with another pharmacy under common control.
    - Store the drugs at a Board-licensed premises, including another pharmacy, hospital pharmacy, clinic, wholesaler, or third-party logistics provider.

Prescription refills. If the pharmacy is unable to conduct business, notify patients how to get prescription refills. Consider these options:

- Another pharmacy may refill the prescription if the pharmacy shares a common electronic file without transferring the prescription.
- Advise patients to contact their doctor to obtain a new prescription to fill at another pharmacy.
- Another pharmacy may furnish in good faith a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency to further the health and safety of the public.
- Another pharmacy may contact the patient's prescriber to obtain a verbal or electronic prescription.

Adulterated drugs. Business and Professions Code section 4169(a)(2) states a person or entity shall not purchase, trade, sell or transfer dangerous drugs that the person knew or reasonably should have known were adulterated as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

Health and Safety Code section 111255 states any drug or device is adulterated if it has been produced, prepared, packed or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. In general, if a pharmacist has reason to believe that any drug was subject to extreme temperatures, humidity, tampering, etc., the drug should be considered to be adulterated and should be quarantined for proper disposal using a licensed wholesaler acting as a reverse distributor.

Guidance on handling adulterated drugs:

- When possible, secure and quarantine all drugs for assessment.
- Drugs damaged by fire or water: If drugs were exposed to high temperatures or water damage during a fire, they are considered adulterated and should be quarantined for proper disposal using a licensed wholesaler acting as a reverse distributor. This includes filled prescriptions waiting to be picked up.
- Drugs accessed by unauthorized individuals: If there is evidence that unauthorized people were in the drug storage area, consider whether drugs that are not in sealed manufacturer containers are adulterated. If so, they should be quarantined for proper disposal, including filled prescriptions that are waiting to be picked up.
- Drugs requiring refrigeration: If there is evidence of improper temperature storage, the drugs in the refrigerator are considered adulterated and should be quarantined for

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proper disposal using a licensed wholesaler acting as a reverse distributor.

- Before destroying any adulterated drugs, check with local law enforcement, the Drug Enforcement Administration (DEA), and your business insurance provider to determine if any of the drugs need to be examined as evidence.

Reporting crimes. All crimes should be reported to law enforcement, especially theft of controlled substances. Save any security video for the police or DEA.

Reporting controlled substance losses. Pharmacies must report all losses of controlled substance to the Board and DEA.

- The DEA requires pharmacies to report all theft and significant losses of controlled substance within one business day using DEA Form 106.
- The Board requires pharmacies to report all losses of controlled substances within 30 days.

Operating at a temporary location. If the pharmacy plans to operate at a temporary location while the licensed premises are under construction, contact the Board's duty inspector at (916) 518-3100 or ask.inspector@dca.ca.gov.

Discontinuance of business. If the pharmacy will discontinue business pursuant to California Code of Regulations, title 16, section 1708.2, complete the discontinuance of business form available at the Board's website, www.pharmacy.ca.gov. All drugs must be inventoried. All records of acquisition and disposition and records of dangerous drugs must be moved to a Board-licensed premises.

Board issues statement on compounding rules following USP final decision on appeals

In light of USP's March 12, 2020, final decision on appeals of the proposed revised Chapters <795> and <797> and the new Chapter <825>, the California State Board of Pharmacy at its May 7, 2020, meeting provided stakeholders with this current status of the legal requirements for pharmacies compounding drug preparations.

As the Board reads the decisions, some of the appeals to Chapters <795> and <797> were granted, sending the chapters back to the committee for further discussion. Accordingly, the current chapters of <795> (last revised in 2014) and <797> (last revised in 2008) remain official.

In addition, all licensees must adhere to all relevant sections of Pharmacy Law and regulations. These include but are not limited to the Board's current regulations – California Code of Regulations, title 16, sections 1735 et. seq (Article 4.5, Compounding); 1751 et. seq (Article 7, Sterile Compounding); and 1708.3 to 1708.5 (related to radioactive drugs) – and Business and Professions Code section 4126.8 and other relevant sections.

Although USP has indicated Chapter <800> is informational and not compendially applicable unless and until Chapters <795> and <797> are revised and reference Chapter <800>, the Board's current regulations on compounding hazardous drug preparations remain in effect. Like USP, the Board encourages utilization of Chapter <800> in the interest of advancing public health.

The Board's Compounding Committee has been reintegrated into the Enforcement Committee. At this time, the Board does not intend to pursue changes to the current regulations governing compounded preparations. The Board will continue to communicate with stakeholders as information becomes available.

Training requirements set to furnish HIV PrEP/PEP

The California State Board of Pharmacy has adopted training requirements for pharmacists to independently initiate and furnish HIV preexposure and postexposure prophylaxis – known as HIV PrEP and PEP – to patients, as authorized by SB 159 (Wiener, Chapter 532, Statutes of 2019).

The training requirements are specified in an emergency regulation – California Code of Regulations, title 16, section 1747 – that took effect May 1, 2020.

A training program must be approved by the Board or provided by a provider accredited by an approved accreditation agency. In addition, the regulation specifies that pharmacists who initiate or furnish HIV PrEP and/or PEP must keep documentation of completing a training program for four years.

The Board of Pharmacy is developing a training program that will meet requirements of CCR section 1747. Information will be posted on the Board's website and in subscriber alerts when the program is available.

Pharmacists are trusted health care providers who are widely accessible in local communities. Being trained to independently initiate and furnish HIV PrEP and PEP, which have been demonstrated to reduce the risk of infection, will help save lives and contribute to the health, safety and general welfare of Californians.

Consultation rules for drugs ordered by mail begin on Oct. 1

Effective October 1, 2020, there are new requirements for mail-order pharmacies in providing consultation to California patients under a regulation adopted by the California State Board of Pharmacy.

The Board amended Title 16, California Code of Regulations, section 1707.2, to require pharmacies that either mail or deliver prescriptions to provide patients with written notice of their right to consultation. Such pharmacies also must give written notice of the hours of availability for consultation and a phone number patients can call to consult with a pharmacist who has ready access to the patient's records.

The amended regulation requires a pharmacist to be available to speak to the patient or the patient's agent during regular hours of operation within 10 minutes, unless a return call is scheduled to occur within one hour. A pharmacist must be available to provide consultation at least six days a week and at least 40 hours a week.

Another regulation, Title 16, California Code of Regulations, section 1706.2, related to abandoned license applications, also was amended and takes effect October 1, 2020.

Transition set for security Rx forms

AB 149 (Cooper, Chapter 4, Statutes of 2019) delayed the requirement for controlled substances prescription forms to have unique serialized numbers until January 1, 2020, while adding new requirements for such forms.

However, AB 149 also included a transition period to allow for an orderly transition by prescribers to the new forms. The following controlled substance prescription forms are valid for filling, compounding, or dispensing until January 1, 2021:

- Any prescription written on a form that does not have a unique serialized number but was otherwise valid before January 1, 2019.
- Any prescription written on a form approved by the Department of Justice as of January 1, 2019. This includes the fifteen (15) digit serialized number format approved by the Department of Justice.
- Any prescription written on a form that complies with the new requirements imposed by AB 149, including a compliant serial number and a bar code.

The California State Board of Pharmacy is working with the Department of Justice to develop and provide additional information to licensees regarding requirements for controlled substances prescription forms. Information will be posted on the Board's website and in subscriber alerts when it is available.

New rules for CURES reports

Effective January 1, 2021, pharmacies must report the dispensing of a controlled substance prescription to CURES no more than one working day after the medication is released to a patient or patient's representative.

Also effective January 1, 2021, pharmacies must begin reporting dispensing Schedule V controlled substances to CURES, in addition to Schedules II, III, and IV.

The new requirements are among the key provisions of AB 528 (Low, Chapter 677, Statutes of 2019). The law was passed by the Legislature and signed by Governor Gavin Newsom in 2019.

Law webinar updated for 2020; ethics webinar also on Board website

California Code of Regulations, title 16, section 1732.5(b) of the Board's regulations, requires that at least two of the 30 hours of CE required for renewal of a pharmacist license be completed by participating in law and ethics courses provided by the Board of Pharmacy. The requirement applies to pharmacists whose licenses expired on or after July 1, 2019.

The California Law Update 2020, a free continuing education (CE) webinar from the California State Board of Pharmacy, is now posted online at www.pharmacy.ca.gov.

The webinar covers important pharmacy laws enacted by the Legislature that took effect this year. The program replaces the previous webinar on 2019 Pharmacy Law, which remains posted online for reference.

In addition to the 2020 law webinar, a free CE webinar on ethics is available on the Board's website. Each webinar meets one hour of the two hours required for law and ethics CE courses provided by the Board. Pharmacists may view the video webinars anytime. Registration is not required.

Both law and ethics videos are posted on the Law and Ethics Webinar page on the Board's website. A link to the 2020 Law Webinar also can be found in the What's New box on homepage.

Taking CPJE? Check ID requirements

The California State Board of Pharmacy reminds pharmacist candidates taking the CPJE that two different forms of identification listed below must be presented at the testing site. At least one ID form must contain a photo. Photocopies, temporary identifications, and expired forms of ID will not be accepted.

Note: Your name on both ID forms must be identical – letter for letter – to your full legal name of record with the Board of Pharmacy, including middle name or initial.

Applicants must present two different types of ID from the list below:

- Driver's license or identification card issued by a U.S. state, commonwealth, or territory. (Only one may be presented.)
- Passport book or card issued by the United States government. (Only one may be presented.)
- Social Security card. (Cannot be laminated.)
- Identification issued by U.S. military.
- National identity card. (Must be in English.)

Be sure to verify your full legal name of record with the Board at PSI's CPJE website. If you registered for the CPJE with PSI by phone, you will have to create an account with PSI to verify your name of record.

Testing dates and other information about the CPJE and applying for a pharmacist license are posted on the Board's website under Applicants > Apply for a Personal License > Pharmacist – Examination and Licensure.

Board implements new license fees

The California State Board of Pharmacy has raised some fees for a variety of license types, effective April 1, 2020. The changes apply to application, renewal, delinquent, and miscellaneous fees.

The new fee schedule – including current rates effective since July 1, 2017 – can be found on the Board's website. On the homepage, click on Applicants tab at the top, then click on Apply for a Facility License or Apply for a Personal License and scroll down to find the link to the fee schedule.

Board, committtees meet via teleconference; schedules, agendas posted on website

Meetings of the California State Board of Pharmacy are held via teleconference, pursuant to Executive Order N-29-20 signed March 17, 2020, by Governor Gavin Newsom.

Remaining meetings in 2020 are scheduled:

- September 17.
- October 27-28.
- December 3.

Meeting agendas, materials, and instructions on how to join and participate are posted on the Board Meetings page at the Board's website, www.pharmacy.ca.gov. Schedules and information about committee meetings also are posted on the Board's website.

This newsletter is published by the

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Board of Pharmacy
STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

New pharmacists can request, pay for RPH license by mail or online

Pharmacist applicants who have passed both the CPJE and the NAPLEX can submit a Request for Issuance of Pharmacist License application and payment by mail or online.

To request and pay for your pharmacist license online, complete and submit the application on the board's website at Applicants > Apply for a Personal License > Online Payment for Request for Issuance of Pharmacist License.

Board salutes pharmacists active 40 years

The California State Board of Pharmacy proudly celebrates licensed pharmacists who have dedicated 40 years of service or more to California consumers! Your decades of contributions to patient care and the pharmacy profession are widely acknowledged and deeply appreciated.

In honor of their service, pharmacists who have been on active status with the Board for at least 40 years receive certificates of appreciation. In addition, their names are posted on the Board's website. Go online to view the names of dedicated pharmacists who have been licensed to serve California consumers since June 31, 1980, or earlier.

New board member appointed

Jason Weisz of San Diego has been appointed as a public member of the California State Board of Pharmacy by the California Senate Rules Committee.

Mr. Weisz is a senior district representative with California Senate President Pro Tempore Toni G. Atkins. He began his career with the California Legislature with then-Assemblymember Christine Kehoe in 2001. His focus has been working on health care and business issues.

Mr. Weisz earned a bachelor's degree in political science from San Diego State University in 1998. His Board term expires in 2024.

Contact *The Script*

Do you have any questions or comments about *The Script*? Are there topics you would like to see in the newsletter?

Let us know! Send a note to editor Bob Dávila at Bob.Davila@dca.ca.gov.