SUNSET OVERSIGHT REVIEW SUPPLEMENTAL REPORT

2020 Vol 2



BE AWARE AND TAKE CARE: Talk to your pharmacist!

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Attachment A

Board Member Information

Updated Board Member Biographies

Updates Board Member Biographies

Gregory N. Lippe, Public Member, President

Gregory Lippe of Woodland Hills was appointed to the California State Board of Pharmacy in 2009 and reappointed in 2012 and 2016 by Gov. Edmund G. Brown Jr.

Mr. Lippe, a certified public accountant, has been president at Gregory N. Lippe Accountancy Corporation since 1981. He was also a managing partner at Lippe Hellie Hoffer and Allison LLP from 1994 to 2009 and president at Solomon Ross and Company from 1983 to 1994. He was chief financial officer at Riverside Lumber Yard from 1981 to 1983 and a certified public accountant at Solomon Ross and Company from 1969 to 1981.

Mr. Lippe served as a Commissioner on the Los Angeles Community Redevelopment Agency and the Los Angeles Fire and Police Pension System. He has also been active in multiple civic and business organizations and is currently Chairman of the Woodbury University Board of Trustees. Mr. Lippe authored a political column in a local business journal for six years and has written newspaper articles published by the Los Angeles Times, the Los Angeles Daily News and the Sacramento Bee.

His term will expire in 2020.

Deborah Veale, R.Ph., Vice President

Deborah Veale of Palos Verdes Estates was appointed to the California State Board of Pharmacy in 2010 and was reappointed in 2013 and 2017 by Gov. Edmund G. Brown Jr.

Ms. Veale has been Director of Payer Relations for CVS Pharmacy since 2006, and from 1983 to 2006 served in several positions with Albertsons/Sav-On Drugs. She is a member of the National Council of Prescription Drug Programs and California Retailers Association. She earned her pharmacy degree from the University of Iowa, College of Pharmacy.

Her term will expire in 2021.

Maria D. Serpa, PharmD, Treasurer

Maria D. Serpa of Elk Grove was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2018.

Dr. Serpa has been a system support pharmacist at Sutter Medical Center, Sacramento, since 1996. She held several positions at Sutter Memorial Hospital from 1993 to 1996, including pharmacy services manager and drug use evaluation/adverse drug reaction and investigational drug service pharmacist. She previously worked in positions at Grossmont Hospital in San Diego from 1989 to 1993, including pharmacy program coordinator of clinical services and staff pharmacist.

Dr. Serpa is a past president of the California Society of Health-System Pharmacists and a fellow of the American Society of Health-System Pharmacists and the California Society of Health-Systems Pharmacists.

She earned a doctor of pharmacy degree from University of the Pacific and completed a clinical pharmacy residency and critical care residency at University of California, San Diego, Medical Center.

Her term will expire in 2022.

Ryan Brooks, Public Member

Ryan Brooks of San Francisco was appointed to the California State Board of Pharmacy in 2008 and reappointed by Governor Edmund G. Brown Jr. in 2012 and 2016.

Mr. Brooks serves as executive vice president of government affairs for OUTFRONT Media. He is responsible for creating and maintaining governmental and public affairs activities, community outreach, policy direction and fundraising activities for the United States market with over 20 years of experience in the field of environmental justice, environmental sciences, community relations and public policy.

In addition, Mr. Brooks serves as an appointee to the Industry Trade Advisory Committee on Services and Financial Industries (ITAC 10) and as a member of the California New Motor Vehicle Board. He is a member of the California International Relations Foundation, which provides assistance to the California State Senate in furthering the exchange of economic, educational and cultural information between government leaders and other citizens of foreign countries.

His term will expire in 2020.

Lavanza "Kercheryl" Butler, R.Ph.

Lavanza "Kercheryl" Butler was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2013 and was reappointed in 2013 and 2017.

Ms. Butler has been with the United Food and Commercial Workers International Union Local 770 since 2002, serving as pharmacist, vice president and union representative. Previously, she was head pharmacist at Rite Aid Pharmacy from 1980 to 2002.

She earned her pharmacy degree in 1975 from Xavier University in New Orleans and is a member of the California Pharmacists Association and the United Food and Commercial Workers Professional Division.

Her term will expire in 2021.

Shirley B. Kim, Public Member

Shirley B. Kim of Los Angeles was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2018.

Ms. Kim is the Director of Government Affairs and Community Relations at Byte. Prior to joining Byte, she served as the Motor Vehicle Software Corporation's Vice President of Government and Regulatory Affairs. She was an associate at Norton Rose Fulbright US LLP and Massumi + Consoli LLP from 2016 to 2019. She was a legislative director at the California Faculty Association from 2011 to 2013. She worked for then-Assembly Majority Leader Alberto Torrico and Assembly Member Henry T. Perea from 2007 to 2011.

She earned a bachelor's degree in sociology and political science from University of California, Davis, in 2006. She graduated from University of California, Irvine, School of Law in 2016.

Her term will expire in 2022.

Seung Oh, PharmD

Dr. Oh had been pharmacist-in-charge at Vons Pharmacy from 2014 to 2020. He was a staff pharmacist at Safeway Pharmacy in 2014, and a pharmacist and director of operations at Rainbow Pharmacy from 2013 to 2014.

He earned a master of advanced studies degree in leadership of health care organizations from University of California, San Diego, and a doctor of pharmacy degree from University of Arizona. He is a member of the California Pharmacists Association.

His term will expire in 2023.

Jignesh "Jig" Patel, R.Ph.

Jignesh "Jig" Patel, R.Ph., of Roseville was appointed to the California State Board of Pharmacy by Gov. Gavin Newsom in 2020.

Mr. Patel has been a division pharmacy manager for Safeway NorCal Division since 2006. He has held several positions at Safeway since 1999, including pharmacy manager, pharmacist, intern pharmacist, and pharmacy technician.

His term will expire in 2023.

Ricardo Sanchez, Public Member

Ricardo Sanchez of Hollister was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2014.

Mr. Sanchez has been an investigator at the California Department of Motor Vehicles since 1989 and has served as chief financial officer for the California Statewide Law Enforcement

Association since 1999. He earned a bachelor's degree in criminal justice from Union Institute and University. He is a member of the San Benito Masonic Lodge.

His term will expire in 2022.

Jason Weisz, Public Member

Jason Weisz of San Diego was appointed to the California State Board of Pharmacy by the California Senate Rules Committee in 2020.

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 term will expire in 2024.

Albert C. M. Wong, PharmD

Albert C. M. Wong of Orinda was appointed to the California State Board of Pharmacy by Governor Edmund G. Brown Jr. in 2012 and reappointed in 2016.

Dr. Wong has been the President of Oakland Pharmacy Inc. since 1980. Previously, he was a staff pharmacist at the Oakland Children's Hospital Medical Center from 1980 to 1983 and a Pharmacist Intern at Kaiser Permanente in San Francisco and Hayward from1976 to 1979. Dr. Wong also served as past President of Oakland Chinatown Chamber of Commerce and past Vice President of Oakland Chinatown Lion's Club. Dr. Wong is currently Board Member of Oakland Wong's Family Association.

Dr. Wong earned a Doctorate of Pharmacy degree from the University of California San Francisco (UCSF) School of Pharmacy.

His term will expire 2020.

Attachment B

COVID-19 Related Communications

- COVID-19 Related Communications to Licensees
- COVID-19 Related Communications to Consumers
- Pharmacy Law Waivers
- ✤ Guidances

COVID-19 Related Communications to Licensees

Twitter Messages and Subscriber Alerts



 California State Board of Pharmacy @CAPharmBoard · May 18
 ••••

 Pharmacy staff are "essential critical infrastructure workers" in the #COVID19

 pandemic. If you work in a #pharmacy, check out important guidance from

 @CAPublicHealth to keep you and your customers safe: bit.ly/2LAJsg4.b

 Image: California State Board of Pharmacy @CAPharmBoard · May 14

California State Board of Pharmacy @CAPharmBoard · May 14 With locations in many communities, #pharmacists are well positioned to expand access to #COVID19 testing in California. A waiver and guidance from @DCAnews is available on the @CAPharmBoard website, pharmacy.ca.gov.

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California State Board of Pharmacy @CAPharmBoard · Aug 3 Essential workers can help protect their households by always wearing a mask, washing hands after work, leaving work shoes outside, showering when first getting home, and frequently cleaning the house. #YourActionsSaveLives @CApublichealth



California State Board of Pharmacy @CAPharmBoard · Aug 27 •••• Links to the DCA waiver and guidance for #pharmacies, #pharmacists and #pharmacytechnicians also may be found on the @CAPharmBoard website at pharmacy.ca.gov.

CA Department of Consumer Affairs 🕗 @DCAnews · Aug 26

A new waiver allows pharmacists and pharmacists technicians - licensed by the California State Board of Pharmacy @CAPharmBoard - to collect specimens for, administer, and interpret results for authorized COVID 19 tests. Read more: thedcapage.blog/2020/08/26/exp...



Subscriber Alert Emails to Licensees

March 5, 2020: Process for Applying for a Pharmacy Law Waiver

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Thursday, March 5, 2020 11:21 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: State of emergency to help prepare for the broader spread of COVID-19

Gov. Gavin Newsom declared a statewide emergency March 4, 2020, to help the state prepare for the broader spread of COVID-19.

Under the provisions of Business and Professions Code section 4062, the board has the authority to waive provisions of Pharmacy Law or regulations adopted pursuant to it, if in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care. Further, under the board's policy, such a determination may be made at the discretion of the board's president for a period of up to 30 days.

Any licensee needing a waiver may submit a request for such to <u>compounding.waivers@dca.ca.gov</u>. The board respectfully requests that such submissions include the following:

- 1. License number(s)
- 2. A brief statement regarding the extent of the waiver sought.
- 3. A brief statement detailing how the declared emergency caused the need for the waiver.
- 4. Relevant laws that the licensee is requesting are waived.
- 5. Authorized contact person. An authorized contact person includes any owner, officer, member, pharmacist-in-charge, or other individual otherwise authorized to act on behalf of the licensee.

The authorized contact will receive a response via email.

March 12, 2020: Board Meeting Canceled Due to COVID-19

Emergency

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Tuesday, March 10, 2020 5:19 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: March 12 Board Meeting Canceled

The Board of Pharmacy received notice late Tuesday afternoon that Claremont Colleges are canceling public events on campus because of the COVID-19 outbreak. As a result, the Board meeting scheduled for Thursday, March 12, at Keck Graduate Institute School of Pharmacy in Claremont is canceled.

March 12, 2020: CE Training Canceled Due to COVID-19 Emergency

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, March 12, 2020 10:31 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Board Cancels March 21 CE Training

To protect against the possible spread of COVID-19, the California State Board of Pharmacy is canceling continuing education training scheduled for March 21, 2020, at Monterey Bay Event Center in Marina, CA.

The California Department of Public Health (CDPH) has issued <u>guidance</u> that certain types of gatherings be postponed or canceled in March to protect public health and slow the rate of COVID-19 transmission. The recommendation applies to all nonessential professional, social, and community gatherings.

Additional information about COVID-19 is available online from <u>CDPH</u> and from the <u>U.S. Centers for Disease Control and Prevention</u> (CDC).

The Board of Pharmacy will work to reschedule continuing education training at a later date. For more information, <u>subscribe to email notifications from the Board</u>.

March 16, 2020: FDA Guidance for Compounding Hand Sanitizer During COVID-19 Emergency

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Monday, March 16, 2020 2:52 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Compounding hand sanitizer during COVID-19 pandemic

The federal Food and Drug Administration (FDA) has received inquiries from pharmacies regarding compounding hand sanitizer to meet demand during the COVID-19 pandemic. In response, the FDA has issued the following guidance:

Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency

March 17, 2020: Pharmacy Law Waivers – Receipt Signature Requirement; Compounding Requirements

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Tuesday, March 17, 2020 10:31 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Pharmacy Law Waivers Authorized Pursuant to BPC Section 4062

In light of the Governor's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, Greg Lippe, President of the California State Board of Pharmacy, has authorized the following waivers of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board President is limited to 30 days.

Waivers to General Pharmacy Law

Business and Professions Code section 4059.5

Waive the signature requirement for the receipt of the delivery of drugs as required in BPC 4059.5 under the following conditions:

The delivery personnel confirm that the employee accepting the delivery is a pharmacist.

The delivery personnel input the pharmacist's name and license number conveyed to them by the pharmacist directly into their signature capture device in lieu of the pharmacist physically signing the tablet as part of the delivery process.

Note: This waiver applies only to the **signature** requirement for the pharmacist accepting delivery.

Business and Professions Code sections 4068(a)(1), 4068(a)(5), and 4068(a)(6)

Waive provisions related to the prohibition against a prescriber to dispensing medications to an emergency room patient if the medication dispensed is a short-acting or long-acting bronchodilator.

Business and Professions Code sections 4182(a) & (b)/BPC 4192(a) & (b)

Waive the requirement for a consulting pharmacist to perform quarterly visits to a clinic under the following conditions:

The consulting pharmacist, using his or her professional judgment, determines that the quarterly inspection is not required during the declared emergency. When making such a determination, it may be appropriate to consider prior consultation report findings, potential impact to patients receiving care in the clinic, etc.

A consulting pharmacist performs a desk audit of the clinic's procedures and records in lieu of the visit.

A consulting pharmacist generates a report outlining any findings resulting from the desk audit and provides that report to the professional director or his or her designee.

The consultant receives confirmation to his or her satisfaction, that the corrections outlined in the findings of the audit have been made.

Waivers Related Specifically to Compounding

Business and Professions Code section 4126.8

Waive USP <797> requirements related to the use of personal protective equipment (PPE) as related to Business and Professions Code section 4126.8, in that a PPE masks and gowns may be reused by staff performing sterile compounding under the following conditions:

The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain the single-use provisions established in USP 797.

The pharmacy has developed a policy that details the conditions under which PPE may be reused. Such policies shall be consistent with standards of practice used during emergency situations.

Documented training on the policy is provided to all staff.

Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.

Surface sampling schedule was reviewed for the possible need to increase the frequency.

Documentation is maintained indicating the duration of time the pharmacy is operating under the waiver approval.

Title 16, California Code of Regulations, section 1751.5(a)(5)

Waive 16 CCR section 1751.5(a)(5) to allow for hand cleaning with the use of non-persistent activity alcohol sanitizer prior to donning sterile gloves.

March 18, 2020: Pharmacy Law Waiver – Remote Processing

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Wednesday, March 18, 2020 6:43 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waivers Authorized Pursuant to BPC Section 4062 – 3/18/20

In light of the Governor's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, Greg Lippe, President of the California State Board of Pharmacy, has authorized the following waivers of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board President is limited to 30 days.

Waiver of Remote Processing Provisions in Business and Professions Code Section 4071.1(a) in Response to COVID-19

For the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy as defined in Business and Professions Code (BPC) sections 4029 and 4037.

In addition to the provisions of BPC section 4071.1(a), pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under this waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The waiver does not include the dispensing of a drug or final product verification by remote processing.

Further, this waiver expands the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include **nondiscretionary tasks,** including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

Pharmacy and Pharmacist Remote Processing Waiver Conditions

Pharmacists are permitted to conduct remote processing as permitted by this waiver if in compliance with the following:

- The pharmacist must be a California-licensed pharmacist who either processes medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy.
- A California-licensed pharmacy may allow staff to engage in remote processing provided the pharmacy has policies and procedures that outline the authorized functions to be performed. Policies and procedures must include methods for protecting the confidentiality and integrity of patient information and must expressly prohibit the printing or storage of protected

ATTACHMENT B: COVID-19 RELATED COMMUNICATIONS

health information on a device that is outside of the licensed pharmacy. Such policies must be readily retrievable and provided to the board upon request (i.e. be able to be produced within three business days of request).

- A pharmacy utilizing remote processing shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order, prescription processing, and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy must ensure that any pharmacist performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site pharmacist has access to when the pharmacy is
- Each remote entry record must comply with all record keeping requirements for pharmacies, including capturing the positive identification of the pharmacist involved in the remote review and verification of a medication order or prescription.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

Pharmacy Intern and Pharmacy Technician Remote Processing Waiver Conditions

Pharmacy interns and pharmacy technicians are permitted to conduct **nondiscretionary tasks** related to remote processing as permitted by the waiver if in compliance with the following:

- The pharmacy intern or pharmacy technician who either enters medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy must be licensed by the Board.
- A pharmacy utilizing remote processing shall ensure that all pharmacy interns and pharmacy technicians providing such services have been trained on the pharmacy's policies and procedures relating to medication order or prescription processing and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy shall ensure that any pharmacy intern or pharmacy technician performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems to which an on-site pharmacy intern or pharmacy technician has access when the pharmacy is open.

- Each remote entry record must comply with all record keeping requirements for pharmacies.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

March 20, 2020: Pharmacy Law Waiver – Pharmacist to Pharmacy Technician Staffing Ratio

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Friday, March 20, 2020 7:51 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Waiver of Staffing Ratio Provisions - 3/19/20

In light of the Governor's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, Greg Lippe, President of the California State Board of Pharmacy, has authorized the following waivers of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board President is limited to 30 days.

Waiver of Staffing Ratio Provisions of Business and Professions Code (BPC) Sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations, Section 1793.7, in Response to COVID-19

The ratio of pharmacists to pharmacy technicians may increase to allow for one additional pharmacy technician for each supervising pharmacist under the following conditions:

- 1. The pharmacy documents the need for the ratio modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume, limitation on staff availability because of quarantine.
- 2. The supervising pharmacist, exercising their professional judgment, may refuse to supervise the additional pharmacy technician and provide the pharmacist-in-charge of their determination. When making such a determination, the supervising pharmacist must specify the circumstances of concern with respect to the pharmacy and patient care implications. Under such circumstances, the ratio may not increase.

The pharmacy must maintain a readily retrievable record, documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver and the staff operating under the waiver, and justification of the need. Records must be maintained for one year following the end of the declared emergency.

March 20, 2020: Pharmacy Law Waiver – Pharmacist to Intern Pharmacist Staffing Ratio

From: California State Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, March 20, 2020 4:40 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA <Pharmacy.Subscriberlist@dca.ca.gov>
Subject: Waiver of Pharmacist to Intern Pharmacist Staffing Ratio

Under statewide and national declarations of emergency, and consistent with Business and Professions Code (BPC) section 4062, Greg Lippe, President of the California State Board of Pharmacy, has authorized the following waiver of specific provisions of Pharmacy Law. Under the Board's policy, a waiver granted by the Board President is limited to 30 days.

Staffing Ratio of Pharmacists to Intern Pharmacists (BPC section 4114(b))

The ratio of pharmacists to intern pharmacists may increase to allow for one additional pharmacy intern for each supervising pharmacist under the following conditions:

- The pharmacy documents the need for the ratio modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume or limitation on staff availability because of quarantine.
- 2. The additional intern pharmacist meets one of the following criteria:
 - 1. Enrolled in a recognized school of pharmacy with an anticipated graduation date in 2020; or
 - 2. Graduated from a recognized school of pharmacy; or
 - 3. Is certified by the Foreign Pharmacy Graduate Equivalency Committee.
 - 2. The pharmacy maintains a readily retrievable record documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver, the staff operating under the waiver, and justification of the need. Records must be maintained for one year following the end of the declared emergency.

March 21, 2020: Pharmacy Law Waiver – Prohibited Acts Involving Dangerous Drugs or Devices

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Saturday, March 21, 2020 9:52 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Waiver of Pharmacy Law Provisions Issued Pursuant to BPC Section 4062 – 3/21/20

Waiver of Pharmacy Law Provisions Issued Pursuant to BPC Section 4062 – 3/21/20

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, Greg Lippe, President of the California State Board of Pharmacy, has authorized the following waivers of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board President is limited to 30 days.

Waiver of Prohibited Acts involving Dangerous Drugs or Devices Provisions of Business and Professions Code (BPC) sections 4169(a)(1) and 4161(b) in Response to COVID-19

A California-licensed pharmacy may receive dangerous drugs and dangerous devices from an unlicensed pharmacy, wholesaler, or third-party logistics provider located in another state to alleviate a temporary shortage of a dangerous drug or device that could result in the denial of health care under the following conditions:

- 1. The unlicensed location is appropriately licensed in its home state and documentation of the license verification is maintained by the California pharmacy.
- 2. The pharmacy maintains documentation of the temporary shortage of any dangerous drug or device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
- 3. The pharmacy complies with all record keeping requirements for each dangerous drug and device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
- 4. All documentation and records required above shall be maintained and readily retrievable for three years following the end of the declared emergency.

5. The dangerous drug or device was produced by an authorized FDA registered drug manufacturer.

March 21, 2020: Pharmacy Law Waiver – Renewal Requirements for Sterile Compounding Facilities in Hospitals

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Saturday, March 21, 2020 9:59 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Waiver of Pharmacy Law Provisions Issued Pursuant to BPC Section 4062 – 3/21/20

Waiver of Pharmacy Law Provisions Issued Pursuant to BPC Section 4062 – 3/21/20

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, Greg Lippe, President of the California State Board of Pharmacy, has authorized the following waivers of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board President is limited to 30 days.

Waiver of Sterile Compounding Renewal Requirements for Facilities Located within a Hospital, Provisions of Business and Professions Code (BPC) sections 4127.1(c) & (d) and 4127.15(b)

A sterile compounding pharmacy whose license expires on or before May 1, 2020, may have its license renewed without being subject to the renewal requirements in BPC sections 4127.1(c) and (d) and 4127.15(b)under the following conditions:

- 1. The sterile compounding facility is located within a hospital or satellite location regulated by the California Department of Public Health and issued a General Acute Care Hospital License.
- 2. The compounding facility complies with all other provisions of Pharmacy Law as applicable, unless otherwise waived by the board during this declared emergency.

March 23, 2020: Board of Pharmacy Office Closed During COVID-19 Emergency

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Monday, March 23, 2020 3:11 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Board of Pharmacy Office is Closed to Public During COVID-19 Emergency

Board of Pharmacy Office is Closed to Public During COVID-19 Emergency

Due to recommendations and guidance from local and state health officials to help prevent the spread of the Coronavirus (COVID-19), the California State Board of Pharmacy office building is closed to the public until further notice. If you would like to file a complaint, we strongly encourage you to do so by visiting or https://www.dca.ca.gov/consumers/complaints/consumer.shtml.

Individuals seeking to renew their license can do so online at <u>www.pharmacy.ca.gov</u> under "Quick Hits." If you need to make a payment, we encourage you to pay online or send a check or money order to: 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833. Our office remains open for employees.

The Board is exploring options for the public to participate at Board meetings through various platforms consistent with Governor Newsom's executive order. Information will be released as it becomes available on the Board's website and sent to "News and Information" subscribers.

During this time you may experience some delays in reaching staff. We appreciate your patience.

March 24, 2020: Important Information and Compilation of Pharmacy Law Waivers Related to COVID-19

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Tuesday, March 24, 2020 11:55 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Important Information for Licensees Related to COVID-19 Emergency

Important Information for Licensees Related to COVID-19 Emergency

As the nation faces this public health crisis, the California State Board of Pharmacy (Board) extends its gratitude for your individual and collective response to the health care needs of Californians. To assist licensees, the Board is providing a summary of important news and information related to the COVID-19 emergency.

Declared State of Emergency

In response to the declared state of emergency, the Board reminds licensees of key state laws and other important information intended to help provide prescription drugs – including controlled substances – for consumers during a declared state of emergency. Summaries are provided. Please click on the links to read the full text of each statute to understand all the conditions and requirements.

- California Business and Professions Code (BPC) <u>section 4062</u> establishes various authorities for the Board and its licensees during a federal, state or local emergency under specified conditions.
- BPC <u>section 4064</u> authorizes a pharmacist to refill a prescription for a dangerous drug or device if the prescriber is unavailable and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt ongoing care or have a significant adverse impact on the patient's well-being.
- BPC <u>section 4064.5</u> allows pharmacists under conditions specified in the law to dispense up to a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount.
- During a declared emergency, Health and Safety Code (HSC) <u>section 11159.3</u> authorizes a pharmacist to fill a prescription for a controlled substance that does not conform to the controlled substances security form requirements under specific conditions.

Waivers to Pharmacy Law and Regulations

The president of the Board has authorized <u>waivers to specific provisions of Pharmacy</u> <u>Law</u> or regulations adopted pursuant to it in response to the COVID-19 emergency. Waivers granted by the Board president are limited to 30 days.

ATTACHMENT B: COVID-19 RELATED COMMUNICATIONS

Information about <u>Pharmacy Law waivers</u> is updated regularly and can be found under "COVID-19 Information" on the Board's website, <u>www.pharmacy.ca.gov</u>. Updates also are emailed as <u>subscriber alerts</u>.

The Board president has granted waivers to the following provisions under specific conditions:

Sterile Compounding Renewal Requirements for Facilities Located within a Hospital (BPC sections 4127.1(c) & (d) and 4127.15(b) - 3/21/20

A sterile compounding pharmacy whose license expires on or before May 1, 2020, may have its license renewed without being subject to the renewal requirements in BPC sections 4127.1(c) and (d) and 4127.15(b) under the following conditions:

- 1. The sterile compounding facility is located within a hospital or satellite location regulated by the California Department of Public Health and issued a General Acute Care Hospital License.
- 2. The compounding facility complies with all other provisions of Pharmacy Law as applicable, unless otherwise waived by the Board during this declared emergency.

Prohibited Acts involving Dangerous Drugs or Devices (BPC sections 4169(a)(1) and 4161(b)) - 3/21/20

A California-licensed pharmacy may receive dangerous drugs and dangerous devices from an unlicensed pharmacy, wholesaler, or third-party logistics provider located in another state to alleviate a temporary shortage of a dangerous drug or device that could result in the denial of health care under the following conditions:

- 1. The unlicensed location is appropriately licensed in its home state, and documentation of the license verification is maintained by the California pharmacy.
- 2. The pharmacy maintains documentation of the temporary shortage of any dangerous drug or device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
- 3. The pharmacy complies with all record-keeping requirements for each dangerous drug and device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
- 4. All documentation and records required above shall be maintained and readily retrievable for three years following the end of the declared emergency.
- 5. The dangerous drug or device was produced by an authorized FDA registered drug manufacturer.

Staffing Ratio Provisions (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations, section 1793.7) – 3/19/20

The ratio of pharmacists to pharmacy technicians may increase to allow for one additional pharmacy technician for each supervising pharmacist under the following conditions:

ATTACHMENT B: COVID-19 RELATED COMMUNICATIONS

- 1. The pharmacy documents the need for the ratio modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume, limitation on staff availability because of quarantine.
- 2. The supervising pharmacist, exercising their professional judgment, may refuse to supervise the additional pharmacy technician and provide the pharmacist-in-charge of their determination. When making such a determination, the supervising pharmacist must specify the circumstances of concern with respect to the pharmacy and patient care implications. Under such circumstances, the ratio may not increase.

The pharmacy must maintain a readily retrievable record, documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver and the staff operating under the waiver, and justification of the need. Records must be maintained for one year following the end of the declared emergency.

Remote Processing Provisions (BPC section 4071.1(a)) - 3/18/20

For the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy as defined in Business and Professions Code (BPC) sections 4029 and 4037.

In addition to the provisions of BPC section 4071.1(a), pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under this waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The waiver does not include the dispensing of a drug or final product verification by remote processing.

Further, this waiver expands the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

Pharmacy and Pharmacist Remote Processing Waiver Conditions

Pharmacists are permitted to conduct remote processing as permitted by this waiver if in compliance with the following:

- The pharmacist must be a California-licensed pharmacist who either processes medication orders or prescriptions from a remote site or on the premises of a California licensed-
- A California-licensed pharmacy may allow staff to engage in remote processing provided the pharmacy has policies and procedures that outline the authorized functions to be performed. Policies and procedures must include methods for protecting the confidentiality and integrity of patient information and must expressly prohibit the printing or storage of protected health information on a device that is outside of the licensed pharmacy. Such policies must be readily retrievable and provided to the board upon request (i.e. be able to be produced within three business days of request).
- A pharmacy utilizing remote processing shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order, prescription processing, and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy must ensure that any pharmacist performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site pharmacist has access to when the pharmacy is
- Each remote entry record must comply with all record keeping requirements for pharmacies, including capturing the positive identification of the pharmacist involved in the remote review and verification of a medication order or prescription.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information

Pharmacy Intern and Pharmacy Technician Remote Processing Waiver Conditions

Pharmacy interns and pharmacy technicians are permitted to conduct **nondiscretionary tasks** related to remote processing as permitted by the waiver if in compliance with the following:

- The pharmacy intern or pharmacy technician who either enters medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy must be licensed by the Board.
- A pharmacy utilizing remote processing shall ensure that all pharmacy interns and pharmacy technicians providing such services have been trained on the pharmacy's policies and procedures relating to medication order or prescription processing and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy shall ensure that any pharmacy intern or pharmacy technician performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems to which an on-site pharmacy intern or pharmacy technician has access when the pharmacy is
- Each remote entry record must comply with all record keeping requirements for
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information

ATTACHMENT B: COVID-19 RELATED COMMUNICATIONS

Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5) - 3/17/20

Waive the signature requirement for the receipt of the delivery of drugs as required in BPC section 4059.5 under the following conditions:

- 1. The delivery personnel confirm that the employee accepting the delivery is a pharmacist.
- 2. The delivery personnel input the pharmacist's name and license number conveyed to them by the pharmacist directly into their signature capture device in lieu of the pharmacist physically signing the tablet as part of the delivery process.

Note: This waiver applies only to the **signature** requirement for the pharmacist accepting delivery.

Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6)) – 3/17/20

Waive provisions related to the prohibition against a prescriber to dispensing medications to an emergency room patient if the medication dispensed is a short-acting or long-acting bronchodilator.

Requirement for Consulting Pharmacist to Perform Visits to Clinic (BPC section 4182(a) & (b) and section 4192(a) & (b)) - 3/17/20

Waive the requirement for a consulting pharmacist to perform quarterly visits to a clinic under the following conditions:

- 1. The consulting pharmacist, using his or her professional judgment, determines that the quarterly inspection is not required during the declared emergency.
- 2. When making such a determination, it may be appropriate to consider prior consultation report findings, potential impact to patients receiving care in the clinic, etc.
- 3. A consulting pharmacist performs a desk audit of the clinic's procedures and records in lieu of the visit.
- 4. A consulting pharmacist generates a report outlining any findings resulting from the desk audit and provides that report to the professional director or his or her designee.
- 5. The consultant receives confirmation to his or her satisfaction, that the corrections outlined in the findings of the audit have been made.

USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8) – 3/17/20

Waive USP <797> requirements related to the use of personal protective equipment (PPE) as related to Business and Professions Code section 4126.8, in that a PPE masks and gowns may be reused by staff performing sterile compounding under the following conditions:

 The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain the single-use provisions established in <USP 797>.

ATTACHMENT B: COVID-19 RELATED COMMUNICATIONS

- 2. The pharmacy has developed a policy that details the conditions under which PPE may be reused. Such policies shall be consistent with standards of practice used during emergency situations.
- 3. Documented training on the policy is provided to all staff.
- 4. Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.
- 5. Surface sampling schedule was reviewed for the possible need to increase the frequency.
- 6. Documentation is maintained indicating the duration of time the pharmacy is operating under the waiver approval.

Use of Hand Sanitizer Before Donning Sterile Gloves (Title 16, California Code of Regulations, section 1751.5(a)(5)) – 3/17/20

Waive Title 16, C.C.R., section 1751.5(a)(5) to allow for hand cleaning with the use of non-persistent activity alcohol sanitizer prior to donning sterile gloves.

How to Request a Pharmacy Law Waiver

Information about <u>Pharmacy Law waivers</u> is updated regularly and can be found under "COVID-19 Information" on the Board's website, <u>www.pharmacy.ca.gov</u>. Updates also are emailed as <u>subscriber alerts</u>.

If you would like to request a waiver of a provision that has not already been granted to all licensees by the Board, please include the following information in your request:

- 1. License number(s).
- 2. A brief statement regarding the extent of the waiver sought.
- 3. A brief statement describing how the declared emergency has caused a need for the waiver.
- 4. Relevant laws that you are requesting be waived.
- 5. An authorized contact person Any owner, officer, member, pharmacist-in-charge, or other individual authorized to act on behalf of the licensee.

Send your waiver request to <u>compounding.waivers@dca.ca.gov</u>. (Note: This address if for waiver requests regarding any provisions of Pharmacy Law or regulations, not just compounding.) The Board will respond to the authorized contact person by email.

In addition, the Board is set to discuss and consider waivers to Pharmacy Law provisions during a teleconference meeting at 2 p.m. March 27. The <u>meeting agenda</u> is posted under "Meetings" on <u>the Board's website</u>.

The public may provide written comments in advance of the meeting. The Board requests that written comments state the item to which they are addressed and be provided by 5 p.m. March 26 to allow time to post the comments on the website and provide the comments to members. As noted on the agenda, the meeting will not be

webcast, and written comments received in advance will not receive any personal response.

Additional Information

The Board encourages licensees to go online to <u>covid19.ca.gov</u> for the latest information on the coronavirus emergency in California from the Governor's Office. The website includes links to other sources of important health care information, including the <u>California Department of Public Health</u> (CDPH). Important information also is available online from the federal <u>Centers for Disease Control and Prevention</u> (CDC) and the <u>Food and Drug Administration</u> (FDA).

For additional updates and information from the California State Board of Pharmacy, visit <u>www.pharmacy.ca.gov</u> and <u>submit your email address to receive subscriber alerts</u> from the Board.

March 24, 2020: Waiver Requests Beyond the Authority of the Board of Pharmacy

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> **On Behalf Of** California State Board of Pharmacy **Sent:** Tuesday, March 24, 2020 2:18 PM **To:** PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV **Subject:** Waiver Requests Beyond the Board's Authority

Waiver Requests Beyond the Board's Authority

In response to Governor Gavin Newsom's declaration of emergency on March 4, 2020, the Board of Pharmacy has authority to waive provisions of Pharmacy Law or regulations adopted pursuant to it if, in the Board's opinion, the waiver will aid in the protection of public health or provision of patient care. Under the Board's policy, such a determination may be made at the discretion of the Board president for a period of up to 30 days.

A number of waiver requests submitted to the Board apply to provisions outside the purview of its waiver authority – i.e., beyond Chapter 9, Division 2 of the Business and Professions Code and Title 16, California Code of Regulations. The Board lacks the authority to approve such requests.

In addition, the Board has received a number of requests seeking to expand the scope of practice for its licensees. The Board has been advised that its waiver authority does not provide permission to expand the functions under BPC sections

4051 or 4052, or any of the additional functions allowed. As such the Board cannot consider or take action on these requests.

March 24, 2020: Pharmacy Law Waiver – Use of Mobile Pharmacies and Clinics

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Tuesday, March 24, 2020 2:48 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Temporary Use of Mobile Pharmacy or Clinic

Board Authorizes Temporary Use of Mobile Pharmacies and Clinics

In response to Governor Gavin Newsom's declaration of emergency, the California State Board of Pharmacy will permit the employment of mobile pharmacies or clinics pursuant to Business and Professions Code (BPC) section 4062(c) for the purpose of ensuring continuity of patient care during the COVID-19 public health crisis.

Under the Board's policy, this permission granted by the Board president is limited to 30 days.

Temporary Use of Mobile Pharmacy or Clinic (BPC section 4062(c)) – 3/24/20

The Board will allow the temporary use of a mobile pharmacy or clinic to ensure the continuity of patient care. Notwithstanding BPC section 4110, an allowable mobile pharmacy or clinic includes an ancillary location approved by the pharmacist-in-charge that satisfies all the following requirements:

- 1. The mobile pharmacy or clinic provides services only on or contiguous to the site of the licensed pharmacy or clinic.
- 2. The mobile pharmacy or clinic shares common ownership with the licensed pharmacy or clinic, and that licensed pharmacy or clinic is in good standing.
- 3. The mobile pharmacy or clinic is under the control and management of the same pharmacist-in-charge or professional director as the licensed pharmacy or clinic.
- 4. The mobile pharmacy or clinic retains records of dispensing.
- 5. A licensed pharmacist is on the premises of a mobile pharmacy while drugs and other pharmacy services are provided. A licensed prescriber is on the premises of the mobile clinic while drugs are being dispensed.
- 6. Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy or clinic.

Notification shall be provided to the Board of the use of a mobile pharmacy or clinic. As part of the notification, the license number of the pharmacy or clinic must be provided along with the location of the mobile pharmacy or clinic. Notification should be sent to <u>phystatus@dca.ca.gov</u>.

March 24, 2020: Pharmacy Law Waiver – Inventory Reconciliation Report

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Tuesday, March 24, 2020 3:23 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Waiver of Inventory Reconciliation Report Provision

In response to Governor Gavin Newsom's declaration of emergency and consistent with Business and Professions Code (BPC) section 4062, Greg Lippe, President of the California State Board of Pharmacy, has authorized the following waiver of specific provisions of Pharmacy Law. Under the Board's policy, a waiver granted by the Board president is limited to 30 days.

Inventory Reconciliation Report of Controlled Substances Provision (Title 16, California Code of Regulations, section 1715.65(c)) - 3/24/20

A pharmacy or clinic must complete the required inventory reconciliation report specified in 16 CCR section 1715.65(c) at least once every six months rather than every three months if determined to be necessary by the pharmacist-in-charge or professional director to ensure continuity of direct patient care activities that would otherwise be impacted.

March 27, 2020: Board Meeting and Actions on Pharmacy Law

Waivers

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Friday, March 27, 2020 8:20 PM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Board Meeting Actions – March 27, 2020

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Board Meeting Actions – March 27, 2020

The California State Board of Pharmacy met via teleconference March 27, 2020.

The Board took the following actions:

- Elected member Maria Serpa as treasurer.
- Determined that an emergency exists allowing the Board to consider whether the president should have additional discretion to waive Pharmacy Law provisions pursuant to Business and Professions Code (BPC) section 4062.
- Voted to grant the president discretion to waive Pharmacy Law provisions for up to 90 days in light of the Governor's declaration of a statewide emergency and the national declaration of emergency pursuant to BPC section 4062.
- Granted the president discretion to extend previously granted waivers for 90 days that were not considered by the Board.

In addition, the Board took action on the following existing Pharmacy Law Waivers posted on the Board's website, <u>https://urldefense.proofpoint.com/v2/url?u=http-</u> 3A__www.pharmacy.ca.gov&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMb R6Jyy9zHSWNI2CvWOWnZeKnQ2Nqs2w&m=4_s7xUm_PRo_IYxjRmQLCapXKFVoDuZC1so7y 3yT5vw&s=1JBXXVjFe3goBoC9Me48n5MFvj9fdloodMVHgVMFT1Y&e= :

- Amended an existing waiver of renewal requirements for sterile compounding pharmacies located within a hospital to apply to pharmacies whose licenses expire on or before July 1, 2020, under specific conditions (BPC sections 4127.1(c) & (d) and 4127.15(b))
- Extended for 120 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to prohibited acts involving dangerous drugs or devices (BPC sections 4169(a)(1) and 4161(b)).
- Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to the staffing ratio of

ATTACHMENT B: COVID-19 RELATED COMMUNICATIONS

pharmacists to pharmacy technicians under specified conditions (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations (CCR), section 1793.7).

- Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to remote processing of medication orders or prescriptions (BPC section 4071.1(a)).
- Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of the signature requirement for receipt of delivery of drugs, under specific conditions (BPC section 4059.5).
- Modify and extend for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to prescribers dispensing medication to an emergency room patient if the medications are short-acting, beta-agonist inhalation products, under specific conditions (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6)).
- Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of a requirement for a consulting pharmacist to make quarterly visits to a clinic, under specific conditions (BPC sections 4182(a) & (b)/BPC 4192(a) & (b)).
- Extended for 120 days a waiver of USP <797> requirements related to the use of personal protective equipment (PPE), under specific conditions (BPC section 4126.8).
- Extended for 120 days an existing waiver related to the use of alcohol sanitizer before donning sterile gloves (Title 16, CCR section 1751.5(a)(5)).
- Voted to extend any intern pharmacist license expiring on or before July 1, 2020, for an additional six months if the license is current and in good standing.
- Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver related to the staffing ratio of pharmacists to intern pharmacists, under specific conditions (BPC section 4114(b)).

April 1, 2020: Guidance Regarding Non-Discrimination in COVID-19 Treatment of Patients with Disabilities

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Wednesday, April 1, 2020 9:22 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Guidance: Non-Discrimination in Medical Treatment for COVID-19

The California State Board of Pharmacy is disseminating this information on behalf of the California Departments of Health Care Services (DHCS), Public Health (CDPH), and Managed Health Care (DMHC).

Guidance Relating to Non-Discrimination in Medical Treatment for Novel Coronavirus 2019 (COVID-19)

As the COVID-19 situation continues to evolve, the Departments of Health Care Services (DHCS), Public Health (CDPH), and Managed Health Care (DMHC) continue to closely monitor and assess appropriate next steps as well as release guidance for all health care practitioners.

The State of California understands that people with disabilities are concerned that medical providers might consider an individual's disability status when determining which patients to treat if hospitals or other health care facilities experience a surge of patients needing life-saving care. This joint bulletin reminds health care providers and payers that rationing care based on a person's disability status is impermissible and unlawful under both federal and state law.

Please read <u>Guidance Relating to Non-Discrimination in Medical Treatment for Novel</u> <u>Coronavirus 2019 (COVID-19)</u> for more information.

April 2, 2020: Statement Regarding Improper Prescribing of Medications Related to COVID-19 Treatment

From: Board of Pharmacy News and Information <PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, April 2, 2020 11:06 AM
To: PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Statement Regarding Improper Prescribing of Medications Related to Treatment for Novel Coronavirus (COVID-19)

Statement Regarding Improper Prescribing of Medications Related to Treatment for Novel Coronavirus (COVID-19)

The California Department of Consumer Affairs (DCA) is aware of recent news and social media reports of prescribers wrongfully hoarding and prescribing for themselves and family members certain medications referenced in the media relating to the novel coronavirus (COVID-19).

Several states have recently issued emergency restrictions on how the drugs can be dispensed. Many require that medications be prescribed and dispensed only to patients with a legitimate and current medical condition. Further, the FDA recently issued an Emergency Use Authorization to allow for the use of hydroxychloroquine sulfate and chloroquine phosphate products donated by the Strategic National Stockpile for certain hospitalized patients with COVID-19.

DCA, the Medical Board of California, and the California State Board of Pharmacy remind health care professionals that inappropriately prescribing or dispensing medications constitutes unprofessional conduct in California. Prescribers and pharmacists are obligated to follow the law, standard of care, and professional codes of ethics in serving their patients and public health.

April 3, 2020: Pharmacy Law Waivers – Duty to Consult with Patients; Use of PPE in Certain Compounding Conditions

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Friday, April 3, 2020 11:12 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waivers Related to COVID-19 Emergency

The California State Board of Pharmacy has issued waivers to Pharmacy Law related to the **Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))** and the **Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (Title 16, California Code of Regulations, section 1751.5).** Both waivers expire July 1, 2020.

The waivers appear on an updated <u>Pharmacy Law Waivers</u> page at the Board's website, <u>www.pharmacy.ca.gov</u>. Licensees are urged to monitor the website for waivers and other important COVID-19 information and to <u>sign up to receive subscriber alerts</u> for updates.

Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))

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If the pharmacist-in-charge makes the determination that oral consultation, as required under Title 16, California Code of Regulations, section 1707.2(a), places the public and/or personnel at risk for exposure to COVID-19, in-person oral consultation may be waived under the following conditions:

- 1. The patient or patient's agent receives a verbal and prominently written notice of his or her right to request consultation by telephone.
- 2. The written notice includes the telephone number to call and the hours of availability during which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's records.
- 3. A pharmacist is readily available to speak to the patient or patient's agent during any regular hours of operation, unless additional hours of availability are provided and a return call is scheduled to occur within that time in the same business day, if acceptable to the patient. The pharmacist must make two good faith attempts to contact the patient by telephone and document the attempts or consultation. Documentation shall include the name of patient or prescription number, date, time and identification of pharmacist who provided consultation.
- 4. A pharmacist may provide oral consultation to the patient or patient's agent prior to the sale or delivery of a prescription.
- 5. The pharmacy has policies and procedures in place to ensure compliance with the requirements of this waiver prior to implementation.
- 6. A pharmacist may consult with patients or patients' agents using telephone, video chat or other method as acceptable to the patient.
- 7. If a pharmacist deems consultation is warranted in the exercise of his or her professional judgment or if there is an adverse drug therapy warning deemed necessary after the review as required by Title 16, California Code of Regulations, section 1707.3, consultation must occur prior to the patient or the patient's agent receiving the prescription.
- 8. Documentation required by this waiver shall be maintained and readily retrievable for one year following the end of the declared emergency.

Effective: April 1, 2020

Expiration: July 1, 2020

Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (Title 16, California Code of Regulations, section 1751.5)

Provisions of Title 16, California Code of Regulations, section 1751.5(a)(1)-(3) related to the requirement to don PPE garb (including masks, gowns, head, and shoe covers) when compounding in a compounding aseptic isolator or compounding aseptic containment isolator may be waived under the following conditions:

- 1. The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain garbing requirements established in the regulation.
- 2. The isolator manufacturer has provided written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required. This documentation must be readily retrievable by the licensed location.
- 3. A policy is developed that details the revised conditions for use of PPE for compounding pursuant to this waiver.
- 4. Applicable pharmacy staff are trained on the policy and the training is documented prior to implementation.
- 5. Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.
- 6. Surface sampling schedule will be reviewed for the possible need to increase the frequency.
- 7. Documentation indicating the duration of time the pharmacy is operating under the waiver approval is maintained.

Note: This waiver not does extend to the requirements for the use of sterile gloves.

Effective: April 1, 2020

Expiration: July 1, 2020

April 4, 2020: Pharmacy Law Waiver – Related to Retired Licensees, Canceled Licenses, and Payment of Fees for License Reissuance or Renewal

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Saturday, April 4, 2020 11:07 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Waivers issued Pursuant to Business and Professions Code section 4062

Waivers issued Pursuant to Business and Professions Code section 4062

In light of Governor Gavin Newsom's declaration of emergency and the more recent national declaration of emergency, and consistent with the provisions of Business and Professions Code section 4062, Greg Lippe, the President of the Board of Pharmacy (Board), has authorized as appropriate the following waivers of specific provisions of Pharmacy Law. Under the Board's policy, the granting of a waiver by the Board's president is limited to a 90-day period.

Waiver of Business and Professions Code section 4200.5(d) Related to Retired Licensees, Business and Professions Code section 4402(b) Related to Cancelled Pharmacist Licenses and Business and Professions Code section 4403 Related to Payment of Fees for Reissuance or Renewal of License

To allow for the restoration of previously retired or cancelled pharmacist license for a maximum of six months, or until the declaration of emergency is lifted, whichever is sooner, the Board waives the provisions of Business and Professions Code sections 4200.5(d), 4402(b), 4403 under the following conditions:

- 1. At the time of cancellation or transition to a retired status, the license was not subject to any disciplinary conditions or subject to any disciplinary proceeding.
- 2. The license has been in such a status no longer than five years.
- The individual applies for restoration by completing the required form "Application to Restore Your License" located on the board's website at <u>https://urldefense.proofpoint.com/v2/url?u=http-</u> 3A__www.pharmacy.ca.gov&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyK <u>MbR6Jyy9zHSWNI2CvWOWnZeKnQ2Nqs2w&m=CzkN5iu9Xy5sWmO6laeuXCc7j67jgYUY</u> <u>YOMQe17mvQs&s=6Xcq4Khjlyqd6G7b4taoSabjPwEZMqoowhFJp6mhW3g&e=</u> under COVID-19 Information.

Upon processing of the application for restoring the license, the individual will receive email notification from the board.

Effective: April 3, 2020

Expiration: July 1, 2020

April 4, 2020: Pharmacy Law Waiver – Use of Sterile Disinfectant Agents

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Saturday, April 4, 2020 10:59 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Waivers issued Pursuant to Business and Professions Code section 4062

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Waivers issued Pursuant to Business and Professions Code section 4062

In light of Governor Newsom's declaration of emergency and the more recent national declaration of emergency, and consistent with the provisions of Business and Professions Code section 4062, Greg Lippe, the President of the Board of Pharmacy, has authorized as appropriate the following waivers of specific provisions of Pharmacy Law. Under the board's policy, the granting of a waiver by the board's president is limited to a 90-day period.

Waiver of Provisions in Title 16, California Code of Regulations, section 1751.4(d)(1) Related to the Use of Sterile Disinfectant Agents

Waiver of Title 16 of CCR section 1751.4(d)(1) to allow for the use of a non-sterile alcohol-based disinfectant after cleaning on work table surfaces, carts, and counters under the following conditions:

- 1. The pharmacist-in-charge has made a determination that the current and potential stock of sterile alcohol (sIPA) on hand is insufficient to maintain the requirements established in the regulation.
- 2. The surface or equipment is NOT contained within an ISO Class 5 environment.
- 3. Surface sampling schedule is reviewed for the possible need to increase the frequency of cleaning and disinfection.
- 4. Documentation indicating the duration of time the pharmacy is operating under this waiver is maintained.

Effective: April 3, 2020

Expiration: July 1, 2020

April 9, 2020: Requirements to Provide PPE to Protect Pharmacy Consumers and Coworkers

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, April 9, 2020 7:38 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Personal Protective Equipment for Pharmacy Employees

The California State Board of Pharmacy (Board) has been informed by public comments that some pharmacy personnel may not have appropriate personal protective equipment (PPE) to safely provide health care and related services during the COVID-19 pandemic and to help avoid contracting and transmitting the virus when interacting with the public and co-workers.

The Board would like to remind pharmacies of their professional obligations to protect both employees and the public from hazards and transmission of diseases.

Department of Industrial Relations (DIR) regulations and California Code of Regulations (C.C.R.), title 8, section 3380 (Personal Protective Devices) require all California employers to conduct a hazard assessment. If COVID-19 is determined to be a workplace hazard, the employer must provide employees with appropriate PPE. In addition, to the extent that a pharmacy is subject to the DIR requirements of C.C.R., title 8, section 5199 (Aerosol Transmissible Diseases), that section explicitly requires provision of PPE.

To protect workers and prevent exposure to the virus, Cal/OSHA has developed interim guidance, educational materials, and model programs and plans. This <u>information</u> is provided on Cal/OSHA's website.

April 9, 2020: Delays in License Issuance and Renewal Related to COVID-19 Emergency

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> **On Behalf Of** California State Board of Pharmacy **Sent:** Thursday, April 9, 2020 7:48 AM **To:** PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV **Subject:** Delays in Licenses and Renewal Notices

Because of the COVID-19 emergency, the California Board of Pharmacy (Board) is experiencing delays in mailing licenses and renewal notices to licensees.

To verify your license status online: Go to <u>the Board's website</u> and click on <u>License Search</u> in the "Quick Hits" column to view and print your license record. California law allows the printout of a license record from the Board's website to serve as license verification.

Renewing your license: The Board reminds licensees of their responsibility to renew licenses before they expire. Renewal application forms and fees may be submitted up to 60 days before expiration.

- **To renew online**: Pharmacists, advance practice pharmacists, pharmacy technicians, and designated representatives may <u>renew licenses online</u>. Go to <u>the Board's website</u> and click on <u>License Renewal Online</u> in the "Quick Hits" column.
- To renew by mail: Individuals and all facilities can renew by mail. Go to the Board's website and click on License Renewal by Mail in the "Quick Hits" column.

April 4, 2020: Pharmacy Law Waiver – Basic Life Support Certification

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, April 9, 2020 10:03 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Waiver: Certification of Basic Life Support

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with the provisions of Business and Professions Code section 4062, California State Board of Pharmacy (Board) President Greg Lippe has authorized the following waiver of Pharmacy Law. Under the Board's policy, a waiver granted by the Board president is limited to 90 days.

Certification in Basic Live Support - Business and Professions Code section 4052.8(b)(2)

Waiver of Business and Professions Code section 4052.8(b)(2), requiring certification in basic life support (BLS) in order to initiate and administer immunizations, under the following conditions:

1. The pharmacist held a BLS certification that expired on or after March 15, 2020.

Effective: April 6, 2020 Expiration: July 4, 2020

April 13, 2020: Sources for Compounding Products in High Demand Due to COVID-19

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> **On Behalf Of** California State Board of Pharmacy **Sent:** Monday, April 13, 2020 11:03 AM **To:** PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV **Subject:** Sources for Compounded Products in High Demand

In light of the COVID-19 public health emergency, the California State Board of Pharmacy has compiled a list of California licensed outsourcing facilities and compounded preparations that may be available from the facilities. This list is not a full representation of all preparations available but includes preparations that appear to be in high demand. This list was developed from information reported to the FDA.

By providing this information the Board is endorsing neither the companies nor their products but hopes this information may be useful during this pandemic. The Board recommends that staff contact companies to confirm availability.

Athenex Pharma Solutions LLC – NSF 118 1-888-629-8593 APSORDERS@ ATHENEX.COM EPINEPHRINE NOREPINEPHRINE BITARTRATE PHENYLEPHRINE HYDROCHLORIDE VASOPRESSIN

Avella of Deer Valley Inc. #38 – NSF 104

Avella/source.com

ATROPINE SULFATE

EPINEPHRINE

NOREPINEPHRINE BITARTRATE

PHENYLEPHRINE HYDROCHLORIDE

VANCOMYCIN HYDROCHLORIDE

Central Admixture Pharmacy Services Inc. Central Admixture Pharmacy Services Inc. (154626886) 855-275-2270 option 4 – OSF 106, NSF 130, NSF 135 ATROPINE SULFATE EPHEDRINE SULFATE FENTANYL CITRATE HYDROMORPHONE HYDROCHLORIDE LIDOCAINE HYDROCHLORIDE MIDAZOLAM HYDROCHLORIDE MORPHINE SULFATE NOREPINEPHRINE BITARTRATE

PHENYLEPHRINE HYDROCHLORIDE ROCURONIUM BROMIDE SODIUM BICARBONATE SUCCINYLCHOLINE CHLORIDE VANCOMYCIN HYDROCHLORIDE VECURONIUM BROMIDE

Denver Solutions LLC, dba Leiters Health (080586798)

855-275-2270 - NSF 119

ATROPINE SULFATE

EPHEDRINE SULFATE

EPINEPHRINE

FENTANYL CITRATE

HYDROMORPHONE

LIDOCAINE HYDROCHLORIDE

MIDAZOLAM HYDROCHLORIDE

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PHENYLEPHRINE HYDROCHLORIDE

ROCURONIUM BROMIDE

SODIUM BICARBONATE

SUCCINYLCHOLINE CHLORIDE

VANCOMYCIN HYDROCHLORIDE

Edge Pharmacy Services LLC – NSF 132 802-992-1178 sales@edgepharma.com LIDOCAINE LIDOCAINE HYDROCHLORIDE PHENYLEPHRINE HYDROCHLORIDE

SUCCINYLCHOLINE CHLORIDE

VANCOMYCIN HYDROCHLORIDE

Fagron Compounding Services LLC dba Fagron Sterile Services LLC – NSF 115877-405-8066LIDOCAINE HYDROCHLORIDEPHENYLEPHRINE HYDROCHLORIDEROCURONIUM BROMIDESUCCINYLCHOLINE CHLORIDEMidazolam and Fentanyl to be released April 2020

JCB Laboratories LLC – NSF 116

877-405-8066

EPHEDRINE SULFATE

EPINEPHRINE

PHENYLEPHRINE HYDROCHLORIDE

VANCOMYCIN HYDROCHLORIDE

Midazolam and Fentanyl to be released April 2020

Nephron Sterile Compounding Center LLC – NSF 102 844-224-2225 NOFaccounts@nephronpharm.com ATROPINE EPHEDRINE SULFATE EPINEPHRINE FENTANYL CITRATE HYDROMORPHONE HYDROCHLORIDE LIDOCAINE HYDROCHLORIDE MORPHINE SULFATE

PHENYLEPHRINE HYDROCHLORIDE

ROCURONIUM BROMIDE

SODIUM BICARBONATE

SUCCINYLCHOLINE CHLORIDE DIHYDRATE

Hand sanitizer

Pine Pharmaceuticals LLC – NSF 122 844-218-4183 EPHEDRINE SULFATE LIDOCAINE LIDOCAINE HYDROCHLORIDE VANCOMYCIN HYDROCHLORIDE

QuVa Pharma and QuVa Pharma Inc. – NSF 100, NSF 101, NSF 117 888-339-0874 Customer.Service@QuVaPharma.com ATROPINE SULFATE EPHEDRINE SULFATE EPINEPHRINE FENTANYL CITRATE HYDROMORPHONE HYDROCHLORIDE LIDOCAINE HYDROCHLORIDE LIDOCAINE HYDROCHLORIDE ANHYDROUS MIDAZOLAM MIDAZOLAM HYDROCHLORIDE MORPHINE SULFATE NOREPINEPHRINE BITARTRATE PHENYLEPHRINE HYDROCHLORIDE ROCURONIUM BROMIDE SODIUM BICARBONATE

SUCCINYLCHOLINE CHLORIDE

VANCOMYCIN HYDROCHLORIDE

VECURONIUM BROMIDE

SCA Pharmaceuticals LLC – NSF 106, NSF 120

877-550-5059

ATROPINE SULFATE

EPHEDRINE SULFATE

FENTANYL CITRATE

HYDROMORPHONE HYDROCHLORIDE

LIDOCAINE HYDROCHLORIDE

LIDOCAINE HYDROCHLORIDE ANHYDROUS

MIDAZOLAM HYDROCHLORIDE

MORPHINE SULFATE

NOREPINEPHRINE BITARTRATE

PHENYLEPHRINE HYDROCHLORIDE

ROCURONIUM BROMIDE

SODIUM BICARBONATE

SUCCINYLCHOLINE CHLORIDE

VANCOMYCIN HYDROCHLORIDE

SterRx – NSF 131 518-324-7879 NOREPINEPHRINE PHENYLEPHRINE HYDROCHLORIDE SODIUM BICARBONATE **US Compounding Inc. – NSF 111** 877-693-4376 EPHEDRINE SULFATE MORPHINE SULFATE PHENYLEPHRINE HYDROCHLORIDE SUCCINYLCHOLINE CHLORIDE

VANCOMYCIN HYDROCHLORIDE

April 13, 2020: Pharmacy Law Waiver – Prelicensure Inspection of Automated Drug Delivery System Location

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Monday, April 13, 2020 4:43 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Waiver: Prelicensure Inspection at ADDS Location

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, California State Board of Pharmacy President Greg Lippe has authorized the following waiver of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board president is limited to 90 days.

Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System (ADDS) - Business and Professions Code (BPC) sections 4119.11(a)(9) and BPC 4427.2(e).

A California licensed pharmacy applying for an ADDS license for a proposed location or relocation of an ADDS will not be subject to the required prelicensure inspection at the proposed location provided the pharmacy submits the following:

- 1. A description of the proposed ADDS location with pictures, video and/or a floor plan with the surrounding areas labeled and how the ADDS is secured.
- 2. A copy of the pharmacy's policies and procedures to operate the ADDS regarding security, safety, accuracy, accountability, patient confidentiality, maintenance, maintaining the quality, potency and purity of the dangerous drugs and devices, restocking, record keeping and quality assurance.
- 3. Proof of training or plans for training pharmacy staff and personnel at the pharmacy applying for the proposed ADDS location on the policies and procedures.

4. A statement that a copy of the policies and procedures will be maintained as required by BPC section 4427.3(c).

If the ADDS is an Automated Patient Dispensing System (APDS), the pharmacy must also provide the following with its application (see BCP section 4427.6):

- Policies and procedures that include all of the following: criteria used to determine which drugs are placed in the APDS; methods of ensuring patients are aware that consultation is available; a description of assignments of responsibility; training on using the APDS; plans for orienting participating patients; plans for ensuring delivery of drugs when the APDS is disabled or malfunctioning; and plans for handling of complaints, errors, omissions and other incidents with the use of the APDS.
- 2. A statement explaining how a written consent from participating patients is obtained and what means are used to identify the patient or patient's agent before releasing the drug.
- 3. A statement confirming the APDS has a two-way audio and video for consultation; records are maintained for all transactions; child resistant containers are used; drug warning labels are used for drugs causing risk of overdose, addiction, impairment while operating a vehicle, and risk if alcohol is consumed; a sign is prominently posted on the APDS with the pharmacy's name, address and phone number; the prescription label meets the patient-centered labeling requirements; and translation and interpretive services are available.

Effective: April 13, 2020

Expiration: July 11, 2020

April 15, 2020: Pharmacy Law Waiver – Sterile Compounding Training Requirements

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Wednesday, April 15, 2020 2:38 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Waiver: Sterile Compounding Training Requirements

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, California State Board of Pharmacy President Greg Lippe has authorized the following waiver of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board president is limited to 90 days.

Waiver of Provisions in Title 16, California Code of Regulations, sections 1751.6(e)(2) and 1751.7(b) and (d), related to Reassessment/Revalidation/Re-evaluation Requirements for Sterile Compounding Staff Competencies

This waiver extends the reassessment, revalidation, or re-evaluation requirements in Title 16 CCR sections 1751.6(e)(2) and 1751.7(b) and (d) for up to an additional 90 days with respect to semi-annual and annual reassessment, revalidation, or re-evaluation requirements for individuals involved in sterile compounding under the following conditions:

- 1. The pharmacist-in-charge makes a determination that such a suspension in the reassessment, revalidation, or re-evaluation frequency is necessary and appropriate, balancing site-specific limitations and current staff competencies.
- 2. The pharmacist-in-charge ensures only properly trained persons are allowed to perform compounding.
- 3. Documentation is maintained identifying when reassessments, revalidations, or reevaluations pursuant to this waiver were extended for each staff member involved in sterile compounding. Such documentation must be maintained for three years from the date of making.

Effective: April 15, 2020

Expires: July 13, 2020

April 21, 2020: Pharmacy Law Waiver – Pharmacist Supervision of Intern Pharmacist

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Tuesday, April 21, 2020 4:47 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Waiver: Pharmacist Direct Supervision of Interns

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code section 4062, California State Board of Pharmacy President Greg Lippe has authorized the following waiver of specific provisions of Pharmacy Law.

Under the Board's policy, a waiver granted by the Board president is limited to 90 days.

Waiver of Business and Professions Code section 4114 Related to Pharmacist Direct Supervision of Interns

Waiver of the provision of Business and Professions Code section 4114(a) to allow for general supervision of an intern pharmacist **at the discretion of the supervising pharmacist** under the following conditions:

- 1. The pharmacy documents the need for the supervision modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume, or limitation on staff availability because of shelter-in-place orders or quarantine.
- 2. The intern pharmacist meets one of the following criteria:
 - Enrolled in a recognized school of pharmacy with an anticipated graduation date in 2020; or
 - Graduated from a recognized school of pharmacy; or
 - Is certified by the Foreign Pharmacy Graduate Equivalency Committee.
- 3. The pharmacy maintains a readily retrievable record documenting the intern pharmacists operating under the general supervision of a pharmacist under the waiver and justification of the need. Records must be maintained for one year following the end of the declared emergency.
- 4. Under general supervision, the supervising pharmacist is generally aware of all activities performed by the intern pharmacist without direction from the pharmacist.

Effective: April 21, 2020 Expiration: July 19, 2020

May 12, 2020: COVID-19 Testing by Pharmacists; Guidance on Pharmacy Operations

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Tuesday, May 12, 2020 3:19 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: COVID-19 Testing by Pharmacists and CDPH Guidance on Pharmacy Operations

Governor Gavin Newsom announced today the Department of Consumer Affairs (DCA) and California State Board of Pharmacy (Board) will allow pharmacists to collect specimens for COVID-19 tests and order tests for consumers. The specimens will be delivered to and processed at public health, university or commercial labs.

A <u>waiver</u> and <u>guidance</u> regarding pharmacists ordering and collecting specimens for COVID-19 testing is posted on the <u>DCA Waivers</u> page.

In addition, the California Department of Public Health today issued new <u>guidance for</u> <u>pharmacies and pharmacy staff</u> on operations during the COVID-19 pandemic. A link to the CDPH guidance is posted under COVID-19 Information on the Board's website, <u>www.pharmacy.ca.gov</u>.

June 15, 2020: Board of Pharmacy Office Reopens to Public

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Monday, June 15, 2020 2:52 PM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: An Update for Board of Pharmacy Stakeholders: Board of Pharmacy Offices Reopen to the Public

Dear Stakeholders -

In response to state and local stay at home orders to help reduce the spread of COVID-19, the Board of Pharmacy temporarily closed all offices to the public in March. Following a detailed risk assessment and implementation of a COVID-19 prevention plan, we reopened our offices to the public on June 15 with normal hours of operation Monday through Friday from 8:00 a.m. to 5:00 p.m.

As we continue to monitor the COVID-19 situation, the Board of Pharmacy remains committed to updating our stakeholders and maintaining safe delivery of our programs and services. For additional information and updates, visit https://urldefense.proofpoint.com/v2/url?u=http-

3A__www.pharmacy.ca.gov&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMb R6Jyy9zHSWNI2CvWOWnZeKnQ2Nqs2w&m=pIDTYJjjr1SrKy4N2BcXZHAl2sfaiuxtPWyNmzLbi mo&s=Cw-dwbhoW7GQQJnZH1Lyi4i-H5Go2ntStsIxIivL2xY&e= .

Thank you for your patience and understanding as we work under new protocols and procedures and continue to adjust to this ever-changing situation.

Sincerely,

Board of Pharmacy

June 19, 2020: Specific Pharmacy Law Waivers Extended

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Friday, June 19, 2020 1:49 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waivers Extended

In response to the Governor's emergency declaration and consistent with the authority of the Board to waive Pharmacy Law or the regulations adopted pursuant to it, the Board president, through his delegated authority, extends the following previously approved limited waivers as detailed below:

- Requirement for Consulting Pharmacist to Make Quarterly Visits to Clinic (BPC sections 4182(a) and (b)/BPC 4192(a) and (b)) Effective through July 24, 2020
- <u>Remote Processing (BPC section 4071.1(a))</u> Effective through July 24, 2020
- Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5) Effective through September 22, 2020
- Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6)) Effective through September 22, 2020

Please use the links provided to review the conditions for use.

June 19, 2020: Specific Pharmacy Law Waivers Set to Expire

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Friday, June 19, 2020 1:58 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waivers Set to Expire

The California State Board of Pharmacy announces that the following limited waivers previously issued pursuant to Business and Professions Code section 4062 will expire as detailed below:

- Inventory Reconciliation Report of Controlled Substances (Title 16, California Code of Regulations, section 1715.65(c)) – Valid through June 22, 2020.
- <u>Staffing Ratio of Pharmacists to Intern Pharmacists (BPC section 4114(b))</u> Valid through June 24, 2020.
- Staffing Ratio of Pharmacists to Pharmacy Technicians (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations, section 1793.7) Valid through June 24, 2020.

The Board reminds licensees that although the broad waivers are expiring, an individual or entity may request consideration for a site-specific waiver. To submit a request, please follow the guidelines posted on the Board's website: <u>How to Request a</u> <u>Pharmacy Law Waiver</u>.

June 29, 2020: Specific Pharmacy Law Waivers Extended

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Monday, June 29, 2020 12:53 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waivers Extended

In response to the Governor's emergency declaration and consistent with the authority of the Board to waive Pharmacy Law or the regulations adopted pursuant to it, the Board president, through his delegated authority, extends the following previously approved limited waivers as detailed below:

- <u>Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic</u> <u>Containment Isolators</u>– Effective through August 30, 2020
- <u>Duty to Consult</u> Effective through September 29, 2020
- <u>Restoration of Retired or Cancelled License</u> Effective through October 1, 2020
- Certification of Basic Life Support Effective through August 5, 2020
- <u>Prelicensure Inspection of Proposed ADDS Location</u> Effective through October 9, 2020
- Reassessment/Revalidation/Re-evaluation Requirements for Sterile Compounding Staff Competencies – Effective through August 12, 2020

Please use the links provided to review the conditions for use.

The Board strongly encourages licensees to consider transition plans for waivers set to expire in the next 30 to 45 days to ensure compliance with legal provisions upon expiration of waivers.

June 29, 2020: Specific Pharmacy Law Waiver Set to Expire

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Monday, June 29, 2020 1:36 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waiver Set to Expire

The California Board of Pharmacy reminds licensees that the following limited waiver previously issued pursuant to Business and Professions Code section 4062 will expire July 1, 2020, as previously set:

 Use of Sterile Disinfectant Agents (Title 16, California Code of Regulations, section 1854.4(d)(1) – Valid through July 1, 2020

Although the broad waiver is expiring, an individual or entity may request that the Board issue a site specific waiver. To submit a request, please follow the guidelines posted on the Board's website at <u>How to Request a Pharmacy Law Waiver</u>.

July 16, 2020: Specific Pharmacy Law Waivers Set to Expire

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Thursday, July 16, 2020 9:41 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Pharmacy Law Waivers Set to Expire

The California State Board of Pharmacy reminds licensees that the following limited waivers previously issued pursuant to Business and Professions Code section 4062 will expire as indicated below:

- <u>Pharmacist Direct Supervision of Interns</u>– Valid through July 19, 2020.
- <u>Prohibited Acts Involving Dangerous Drugs or Devices</u> Valid through July 24, 2020.
- <u>Use of Alcohol Sanitizer Before Donning Sterile Gloves</u> Valid through July 24, 2020.

Although the broad waivers are expiring, an individual or entity may request that the Board issue a site specific waiver. To submit a request, please follow the guidelines posted on the Board's website at <u>How to Request a Pharmacy Law Waiver</u>.

July 17, 2020: Specific Pharmacy Law Waivers Extended

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Friday, July 17, 2020 9:21 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Pharmacy Law Waivers Extended

In response to the Governor's emergency declaration and consistent with the authority of the Board to waive Pharmacy Law or the regulations adopted pursuant to it, the Board president, through his delegated authority, extends the following previously approved limited waivers as detailed below:

- <u>Remote Processing</u> Effective through September 22, 2020
- Requirements for Consulting Pharmacist to Make Quarterly Visits Effective through September 22, 2020
- <u>USP <797> Requirements Related to Use of PPE</u> Effective through September 22, 2020

Please use the links provided to review the conditions for use.

July 23, 2020: Pharmacy Law Waiver – Staffing Ratio of Pharmacists to Intern Pharmacists for Immunizations

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Thursday, July 23, 2020 9:25 AM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Waiver: Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision - Immunizations - BPC section 4114

Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision -Immunizations - BPC section 4114

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code (BPC) section 4062, the California State Board of Pharmacy (Board) or the Board president through delegated authority has issued the following waiver.

The ratio of pharmacists to intern pharmacists may increase to allow for one additional intern pharmacist for each supervising pharmacist under the following conditions:

- 1. The additional intern pharmacist is administering immunizations consistent with the provisions of Pharmacy Law.
- 2. The pharmacy maintains a readily retrievable record documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver and the staff operating under the waiver. Records must be maintained for one year following the end of the declared emergency.

Intern pharmacists providing immunizations under the provisions of this waiver may do so under the general supervision of a pharmacist at the discretion of the supervising pharmacist.

Effective: July 23, 2020

Expiration: October 20, 2020

July 23, 2020: Updated Guidance for COVID-19 Testing

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Thursday, July 23, 2020 4:29 PM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Updated COVID-19 Testing Guidance

As the public health battle against COVID-19 continues, your help in slowing the spread is critical. COVID-19 affects us all -- friends, family, neighbors and co-workers. That's why it so important that we wear a mask, wash our hands, maintain physical distancing and don't gather with people we don't live with.

Most recently, the California Department of Public Health's (CDPH) issued updated testing guidance. The guidance outlines different tiers to help determine who should be tested given the current context of the COVID-19 pandemic in California. We encourage you to review this guidance and assist in testing by ensuring your patients who need to be are tested.

You can access the new <u>COVID-19 Industry Guidance for testing</u> on CDPH's website.

DCA has developed a testing priority flyer to be placed in provider offices. You can download and print the flyer <u>here</u>.

Please ensure you are following the guidance provided by CDPH and your local county requirements. For the most up-to-date information about COVID-19 and best practices on preventing its spread visit the covid19.ca.gov website.

DCA maintains a list of <u>waivers and guidance</u> on its Coronavirus page at <u>www.dca.ca.gov</u>. Specific information for Board of Pharmacy licensees can be found on our webpage at <u>www.pharmacy.ca.gov</u>.

Thank you for doing your part in helping California slow the spread of COVID-19. Our collective actions will save lives.

August 26, 2020: News Release: Expanded DCA Waiver to Allow Pharmacists to Interpret COVID-19 Test Results

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Wednesday, August 26, 2020 7:16 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: News Release: Expanding the State's COVID-19 Testing

The California State Board of Pharmacy is providing the following news release on behalf of the California Department of Consumer Affairs (DCA). Links to the waiver and guidance issued by DCA are provided below the news release.

NEWS RELEASE

FOR IMMEDIATE RELEASE August 25, 2020

Contact: Veronica Harms Veronica.harms@dca.ca.gov

Expanding the State's COVID-19 Testing

DCA Issues Waiver to Expand Access to Tests and Ensure the Timely and Accurate Reporting of Test Results

SACRAMENTO – The Department of Consumer Affairs (DCA) issued a new waiver today to expand COVID-19 testing in California and allow for timely and accurate reporting of COVID-19 test results. DCA Waiver <u>DCA-20-45</u> would allow pharmacists and pharmacists technicians to collect specimens for, administer, and interpret results for authorized COVID 19 tests. This waiver supersedes DCA waiver <u>DCA-20-14</u>, which only allowed pharmacists to order and collect specimens necessary to perform tests for the virus.

"Allowing additional healthcare personnel to perform tests, allowing tests at pharmacies, and getting test results quickly are crucial steps to help manage the spread of COVID-19," said Kimberly Kirchmeyer, Director of DCA. "Allowing pharmacists and pharmacists technicians to perform tests was a natural fit in finding ways to help slow the spread and keep consumers safe."

Prior to the waiver, COVID-19 tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) could not be performed by pharmacists or pharmacy technicians at pharmacies. Now, a pharmacy, pharmacist or pharmacy technician can perform on individual patients point-of-care clinical laboratory tests or examinations for the presence of the virus that are deemed or classified as CLIA waived.

The waiver is subject to the following conditions:

- Testing is limited to waived COVID 19 tests authorized by the United States Food and Drug Administration (FDA) and is performed consistent with the provisions of an Emergency Use Authorization issued by the FDA.
- The pharmacy complies with applicable federal requirements, including CLIA certificate of waiver requirements.
- The pharmacy is registered by the California Department of Public Health.
- Pharmacists must comply with disease reporting requirements applicable to health care providers ordering COVID 19 tests.
- Pharmacies must comply with the disease reporting requirements applicable to laboratories testing for COVID 19.
- The pharmacist or pharmacy technician is competent and trained to collect the specimen and perform the test, and the specimen is collected and the test is performed consistent with the provisions of an Emergency Use Authorization issued by the FDA.
- The pharmacy, pharmacist or pharmacy technician complies with such other requirements as the California Department of Public Health, in consultation with the Department of Consumer Affairs, may impose that are not inconsistent with this Order.

The full waiver can be read on the <u>DCA website</u> along with other waivers issued.

The waiver is issued as the Director exercises the authority under Governor Gavin Newsom's Executive Order <u>N-75-20</u>, which authorized the Director of DCA, in consultation with the Department of Public Health, to amend scopes of practice to allow pharmacists and pharmacy technicians to conduct any aspect of any point-ofcare test for the presence of COVID-19 that is deemed or classified as waived under CLIA.

The Department of Consumer Affairs is a consumer protection department under the Business, Consumer Services and Housing Agency and has been working closely with other state departments and stakeholders to respond to and protect all Californians during the COVID-19 pandemic.

ABOUT THE DEPARTMENT OF CONSUMER AFFAIRS: The Department of Consumer Affairs (DCA) promotes and protects the interests of California consumers while ensuring a competent and fair marketplace. DCA helps consumers learn how to protect themselves from unscrupulous and unqualified individuals. The department also protects professionals (licensees) from unfair competition by unlicensed practitioners. Consumers can file complaints against licensees by contacting DCA at (800) 952-5210. Consumers can also file a complaint online at dca.ca.gov.

- DCA Waiver DCA-20-45 Order Waiving Restrictions on Pharmacies, Pharmacists and Pharmacy Technicians Relating to Ordering, Collecting Specimens for, and Performing COVID-19 Tests
- Guidance on COVID-19 Testing Under Executive Orders N-25-20, N-39-20 and N-75-20, and DCA Waiver DCA-20-45

August 28, 2020: Specific Pharmacy Law Waiver Extended

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Friday, August 28, 2020 1:36 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waiver Extended

In response to the Governor's emergency declaration and consistent with the authority of the Board to waive Pharmacy Law or the regulations adopted pursuant to it, the Board president, through his delegated authority, extends the following previously approved limited waiver as detailed below:

• <u>Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic</u> <u>Containment Isolators</u> – Effective through September 29, 2020.

Please use the links provided to review the conditions for use.

The Board reminds licensees that, although the broad waiver is set to expire on September 29, 2020, an individual or entity may request consideration for a sitespecific waiver. To submit a request, please follow the guidelines posted on the Board's website at <u>How to Request a Pharmacy Law Waiver</u>.

September 15, 2020: Survey Regarding Flu Immunizations at Independent Pharmacies during COVID-19 Pandemic

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Wednesday, September 16, 2020 1:19 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Survey of Independent Pharmacies Regarding Flu Immunizations

The California State Board of Pharmacy is providing the following information on behalf of the California Department of Public Health.

Survey of Independent Pharmacies Regarding Flu Immunizations

The California Department of Public Health Immunization Branch in partnership with the California Immunization Coalition is conducting this survey of **Independent Pharmacies** to learn about plans for influenza vaccination services this flu season during the COVID-19 pandemic. We request one survey per pharmacy be completed. The results of this survey will assist Public Health and Immunization Coalitions to

better understand the strategies and capacity of pharmacy-based immunization efforts this Fall. This will also allow them to accurately promote the contribution of pharmacy-based immunization efforts to the public and other immunization stakeholders.

The survey does not require any information about you, just the pharmacy you are representing. It should take **no more than 15 minutes** to complete. We thank you in advance for completing this survey!

CLICK HERE to take the survey

September 18, 2020: Specific Pharmacy Law Waivers Set to Expire

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Friday, September 18, 2020 3:42 PM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Pharmacy Law Waivers Set to Expire

The California State Board of Pharmacy reminds licensees that the following limited waiver previously issued pursuant to Business and Professions Code section 4062 will expire as indicated below:

 Requirements for Consulting Pharmacist to Make Quarterly Visits – Effective through September 22, 2020 - The waiver can be found at: https://urldefense.proofpoint.com/v2/url?u=https-3A__www.pharmacy.ca.gov_licensees_waivers_4182-5Fa-5Fand-5Fb-5F4192-5Fa-5Fand-5Fb.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHSWN I2CvWOWnZeKnQ2Nqs2w&m=fdwuIbTTcK31ZdFt7lrIOSFRRrYg6yniwuuSn8I3mv4&s=LvN cZN9ioKscEdI8Hgq8-ph3IEfkxymdG1bqo-Bo3Io&e=

Although the broad waiver is expiring, an individual or entity may request that the Board issue a site specific waiver. To submit a request, please follow the guidelines posted on the Board's website at How to Request a Pharmacy Law Waiver - https://urldefense.proofpoint.com/v2/url?u=https-<u>3A www.pharmacy.ca.gov licensees waiver-</u>

5Frequest.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9z

HSWNI2CvWOWnZeKnQ2Nqs2w&m=fdwulbTTcK31ZdFt7lrIOSFRRrYg6yniwuuSn8l3mv4 &s=NCzUCDvSu90DWRL8oQ2BhuEC9G_dTyaNv-22JobsDxc&e= .

September 18, 2020: Specific Pharmacy Law Waivers Extended

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Friday, September 18, 2020 4:00 PM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Pharmacy Law Waiver Extended

In response to the Governor's emergency declaration and consistent with the authority of the Board to waive Pharmacy Law or the regulations adopted pursuant to it, the Board president, through his delegated authority, extends the following previously approved limited waivers as detailed below:

- Remote Processing Effective through October 31, 2020 https://urldefense.proofpoint.com/v2/url?u=https-3A__www.pharmacy.ca.gov_licensees_waivers_4071-5F1-5Fa.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHSWNI 2CvWOWnZeKnQ2Nqs2w&m=yOYHJnvkZPrchIDppTKH4Ri5ANPSN1EoOhmrw40bP9M&s =Uc2Q7Z1CXX-NtNQvvcMncpaaRzRdyt3A9otl2iHTAIc&e=
- Signature Requirement for Receipt of Delivery of Drugs Effective through December 21, 2020 – <u>https://urldefense.proofpoint.com/v2/url?u=https-</u> <u>3A_www.pharmacy.ca.gov_licensees_waivers_4059-</u> <u>5F5.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHSWNI</u> <u>2CvWOWnZeKnQ2Nqs2w&m=yOYHJnvkZPrchIDppTKH4Ri5ANPSN1EoOhmrw4obP9M&s</u> <u>=YII6wW-nyNpR9uoecSBHT5muVpAsZ7bbU3hDltd_dPl&e=</u>
- Prescriber Dispensing Medication to Emergency Room Patient Effective through December 21, 2020 – https://urldefense.proofpoint.com/v2/url?u=https-3A__www.pharmacy.ca.gov_licensees_waivers_4068-5Fa-5F1-5F4068-5Fa-5F5-5Fand-5F4068-5Fa-5F6.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHSWN I2CvWOWnZeKnQ2Nqs2w&m=yOYHJnvkZPrchIDppTKH4Ri5ANPSN1EoOhmrw4obP9M& s=RA9zG6gqExkfb8y0eAtU5bh4NHCoMy0ESG03cKbJoC4&e=
- Requirements Related to PPE Effective through December 21, 2020 - https://urldefense.proofpoint.com/v2/url?u=https- 34_www.pharmacy.ca.gov_licensees_waivers_4126-5F8.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHSWN

I2CvWOWnZeKnQ2Nqs2w&m=yOYHJnvkZPrchIDppTKH4Ri5ANPSN1EoOhmrw4obP9M& s=FwsDsO7FioLrq76R-uLoBwaLXgoVn3aW6Wb-qQtaLRQ&e=

- Duty to Consult Effective through December 28, 2020 https://urldefense.proofpoint.com/v2/url?u=https-3A__www.pharmacy.ca.gov_licensees_waivers_1707-5F2-5Fa.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHSWNI 2CvWOWnZeKnQ2Nqs2w&m=yOYHJnvkZPrchIDppTKH4Ri5ANPSN1EoOhmrw40bP9M&s =tYnh3wbKPK9CeTYonOdSNEFq8YqJ1NRq1gVEVpR24wY&e=
- Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators – Effective through December 28, 2020 -<u>https://urldefense.proofpoint.com/v2/url?u=https-</u> <u>3A__www.pharmacy.ca.gov_licensees_waivers_1751-</u> <u>5F5.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHSWNI</u> <u>2CvWOWnZeKnQ2Nqs2w&m=yOYHJnvkZPrchIDppTKH4Ri5ANPSN1EoOhmrw4obP9M&s</u> <u>=ll551EKO5IRHSJoVcGXN94oAOCyntY7v5YRYDD753Rk&e=</u>

Please use the links provided to review the conditions for use.

The Board reminds licensees that, although the broad waivers are set to expire on the dates provided above, an individual or entity may request consideration for a sitespecific waiver. To submit a request, please follow the guidelines posted on the Board's website at How to Request a Pharmacy Law Waiver -

https://urldefense.proofpoint.com/v2/url?u=https-

3A__www.pharmacy.ca.gov_licensees_waiver-

5Frequest.shtml&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMbR6Jyy9zHS WNI2CvWOWnZeKnQ2Nqs2w&m=yOYHJnvkZPrchIDppTKH4Ri5ANPSN1EoOhmrw4obP9M&s =ENx6wzXq32VbbNXaE9jhF4njeIKawKVV_88H2MoBqm4&e=

September 24, 2020: Guidance Regarding Lab Licensure Requirements for Licensees Performing COVID-19 Testing

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, September 24, 2020 11:55 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Guidance: Clinical Lab Licensure Requirements for COVID-19 Testing

The California Department of Public Health (CDPH) has issued <u>guidance</u> to clarify clinical lab licensure requirements for pharmacies, pharmacists and pharmacy technicians performing COVID-19 testing under the provisions of waivers issued by the Department of Consumer Affairs (DCA).

A link to the CDPH <u>Guidance for Pharmacies, Pharmacists, and Pharmacy Technicians</u> <u>Performing Waived, Point-of-Care COVID-19 Tests</u> is posted in the "COVID-19 Information" box on the Board of Pharmacy's homepage, <u>www.pharmacy.ca.gov</u>. The guidance also can be accessed in the right column of the <u>CDPH Laboratory Field Services COVID-19</u> <u>information page</u>.

October 8, 2020: Specific Pharmacy Law Waiver Set to Expire

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, October 8, 2020 2:27 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Pharmacy Law Waiver Set to Expire

The California State Board of Pharmacy reminds licensees that the following limited waiver previously issued pursuant to Business and Professions Code section 4062 will expire as indicated:

<u>Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System (ADDS)</u> - <u>Business and Professions Code sections 4119.11(a)(9) and BPC 4427.2(e)</u> – Effective through October 9, 2020.

Although the broad waiver is expiring, an individual or entity may request that the Board issue a site specific waiver. To submit a request, please follow the guidelines posted on the Board's website at <u>How to Request a Pharmacy Law Waiver</u>.

October 15, 2020: Specific Pharmacy Law Waiver Extended

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> **On Behalf Of** California State Board of Pharmacy **Sent:** Thursday, October 15, 2020 1:40 PM **To:** PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV **Subject:** Pharmacy Law Waiver Extended

In response to the Governor's emergency declaration and consistent with the authority of the Board to waive Pharmacy Law or the regulations adopted pursuant to it, the Board president, through his delegated authority, extends the following previously approved limited waiver through January 18, 2021:

Pharmacists to Intern Pharmacists and General Supervision - Immunizations - BPC section 4114.

Please use the link provided to review the conditions for use.

The Board reminds licensees that, although the broad waiver is set to expire January 18, 2021, an individual or entity may request consideration for a site-specific waiver. To submit a request, please follow the guidelines posted on the Board's website at <u>How to Request a Pharmacy Law Waiver</u>.

October 30, 2020: Specific Pharmacy Law Waiver Set to Expire

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Friday, October 30, 2020 1:19 PM To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV Subject: Pharmacy Law Waiver Set to Expire

The California State Board of Pharmacy reminds licensees that the following limited waiver previously issued pursuant to Business and Professions Code section 4062 will expire as indicated:

<u>Remote Processing (BPC section 4071.1(a))</u> – Effective through October 31, 2020.

Although the broad waiver is expiring, an individual or entity may request that the Board issue a site specific waiver. To submit a request, please follow the guidelines posted on the Board's website at <u>How to Request a Pharmacy Law Waiver</u>.

November 19, 2020: Pharmacy Law Waivers Reinstated – Quarterly Pharmacist Visits to Clinics; Remote Processing

From: General Board of Pharmacy Subscriber List <PHARM-
GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, November 19, 2020 9:21 AM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Waivers: Quarterly Consultant Pharmacist Visit to Clinics; Remote Processing

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with the provisions of Business and Professions Code section 4062, California State Board of Pharmacy (Board) President

Greg Lippe has authorized reinstatement of the following waivers of Pharmacy Law. Under the Board's policy, a waiver granted by the Board president is limited to 90 days.

Requirement for Consulting Pharmacist to Make Quarterly Visits to Clinic (BPC sections 4182(a) & (b) and 4192(a) & (b))

Waive the requirement for a consulting pharmacist to perform quarterly visits to a clinic under the following conditions:

The consulting pharmacist, using his or her professional judgment, determines that the quarterly inspection is not required during the declared emergency.

- When making such a determination, it may be appropriate to consider prior consultation report findings, potential impact to patients receiving care in the clinic, etc.
- A consulting pharmacist performs a desk audit of the clinic's procedures and records in lieu of the visit.
- A consulting pharmacist generates a report outlining any findings resulting from the desk audit and provides that report to the professional director or his or her designee.
- The consultant receives confirmation to his or her satisfaction that the corrections outlined in the findings of the audit have been made.

Effective: November 19, 2020

Expiration: January 16, 2021

Remote Processing (BPC section 4071.1(a))

For the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy as defined in Business and Professions Code (BPC) sections 4029 and 4037.

In addition to the provisions of BPC section 4071.1(a), pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under this waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The waiver does not include the dispensing of a drug or final product verification by remote processing.

Further, this waiver expands the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by

a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

Pharmacy and Pharmacist Remote Processing Waiver Conditions

Pharmacists are permitted to conduct remote processing as permitted by this waiver if in compliance with the following:

- The pharmacist must be a California-licensed pharmacist who either processes medication orders or prescriptions from a remote site or on the premises of a California licensed-pharmacy.
- A California-licensed pharmacy may allow staff to engage in remote processing provided the pharmacy has policies and procedures that outline the authorized functions to be performed. Policies and procedures must include methods for protecting the confidentiality and integrity of patient information and must expressly prohibit the printing or storage of protected health information on a device that is outside of the licensed pharmacy. Such policies must be readily retrievable and provided to the Board upon request (i.e. be able to be produced within three business days of request).
- A pharmacy utilizing remote processing shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order, prescription processing, and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy must ensure that any pharmacist performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site pharmacist has access to when the pharmacy is open.
- Each remote entry record must comply with all record keeping requirements for pharmacies, including capturing the positive identification of the pharmacist involved in the remote review and verification of a medication order or prescription.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

Pharmacy Intern and Pharmacy Technician Remote Processing Waiver Conditions

Pharmacy interns and pharmacy technicians are permitted to conduct **nondiscretionary tasks** related to remote processing as permitted by the waiver if in compliance with the following:

- The pharmacy intern or pharmacy technician who either enters medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy must be licensed by the Board.
- A pharmacy utilizing remote processing shall ensure that all pharmacy interns and pharmacy technicians providing such services have been trained on the pharmacy's policies and procedures relating to medication order or prescription processing and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy shall ensure that any pharmacy intern or pharmacy technician performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems to which an on-site pharmacy intern or pharmacy technician has access when the pharmacy is open.
- Each remote entry record must comply with all record keeping requirements for pharmacies.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

Effective: November 19, 2020

Expiration: January 16, 2021

COVID-19 Related Communications to Consumers

Twitter Messages and Subscriber Alerts





@CAPublicHealth to keep you and your customers safe: bit.ly/2LAJsq4.b

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California State Board of Pharmacy @CAPharmBoard · Jun 22 •••• **#Consumer** alert: **#FDA** advises do not use **#handsanitizer** products by Eskbiochem SA de CV due to the potential presence of toxic substance. Read a list of Eskbiochem products and the full FDA alert at bit.ly/3eourul.



FDA Advises Consumers Not to Use Eskbiochem Hand Sanitizers FDA Advises Consumers Not to Use Eskbiochem Hand Sanitizers due to the potential presence of methanol & fda.gov











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FDA Drug Information 🤣 @FDA_Drug_Info · Jul 31

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We've expanded our "list of hand sanitizers consumers should not use" to include subpotent hand sanitizers, in addition to hand sanitizers that are or may be contaminated with methanol:







California State Board of Pharmacy @CAPharmBoard · Aug 13 •••• El jabón es un arma muy poderosa contra el COVID-19. Lávate las manos con agua caliente y jabón durante al menos 20 segundos. #TusAccionesSalvanVidas covid19.ca.gov/es @CApublichealth





California State Board of Pharmacy @CAPharmBoard · Aug 21 Make sure you wash your mask by hand or in the washing machine after every use and help fight #COVID19. Learn more at covid19.ca.gov. #YourActionsSaveLives

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California State Board of Pharmacy @CAPharmBoard · Aug 27 •••• @CAPharmBoard warns #consumers to beware of alcohol-based #handsanitizer packaged in misleading containers - including food and drink containers and children's food pouches.

💿 U.S. FDA 🤣 @US_FDA · Aug 27

Beware of alcohol-based hand sanitizers packaged in containers that may appear as food or drinks. These products may put you and your family at risk of serious injury, or death, if ingested. fda.gov/news-events/pr... Show this thread

HAND SANTTIZER HAND SANTER



California State Board of Pharmacy @CAPharmBoard · Sep 3 Together, we can slow the spread of #COVID19. Wear face coverings when out in public—especially where physical distancing is difficult, like grocery stores. #YourActionsSaveLives covid19.ca.gov @CAPublicHealth



California State Board of Pharmacy @CAPharmBoard · Sep 13 •••• California's Blueprint for a Safer Economy builds on lessons learned from the last six months to create a new system for regulating movement and COVID-19 transmissions. Learn more at covid19.ca.gov/safer-economy #YourActionsSaveLives





California State Board of Pharmacy @CAPharmBoard · Sep 21 •••• Solo tres pequeños pasos lo ayudarán a mantenerse seguro y reducir la propagación del COVID-19: use una máscara, lávese las manos y mantén su distancia. Juntos Podemos #DisminuyeElContagio #TusAccionesSalvanVidas













March 23, 2020: Board of Pharmacy Office Closed to Public During COVID-19 Emergency

From: Board of Pharmacy News and Information <PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Monday, March 23, 2020 3:06 PM
To: PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Board of Pharmacy Office is Closed to Public During COVID-19 Emergency

Board of Pharmacy Office is Closed to Public During COVID-19 Emergency

Due to recommendations and guidance from local and state health officials to help prevent the spread of the Coronavirus (COVID-19), the California State Board of Pharmacy office building is closed to the public until further notice. If you would like to file a complaint, we strongly encourage you to do so by visiting or https://www.dca.ca.gov/consumers/complaints/consumer.shtml.

Individuals seeking to renew their license can do so online at <u>www.pharmacy.ca.gov</u> under "Quick Hits." If you need to make a payment, we encourage you to pay online or send a check or money order to: 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833. Our office remains open for employees.

The Board is exploring options for the public to participate at Board meetings through various platforms consistent with Governor Newsom's executive order. Information will be released as it becomes available on the Board's website and sent to "News and Information" subscribers.

During this time you may experience some delays in reaching staff. We appreciate your patience.

June 25, 2020: Board of Pharmacy Office Reopens to Public

From: Board of Pharmacy News and Information <PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy Sent: Monday, June 15, 2020 2:53 PM To: PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV Subject: An Update for Board of Pharmacy Stakeholders: Board of Pharmacy Offices Reopen to the Public

Dear Stakeholders -

In response to state and local stay at home orders to help reduce the spread of COVID-19, the Board of Pharmacy temporarily closed all offices to the public in March. Following a detailed risk assessment and implementation of a COVID-19 prevention plan, we reopened our offices to the public on June 15 with normal hours of operation Monday through Friday from 8:00 a.m. to 5:00 p.m.

As we continue to monitor the COVID-19 situation, the Board of Pharmacy remains committed to updating our stakeholders and maintaining safe delivery of our programs and services. For additional information and updates, visit https://urldefense.proofpoint.com/v2/url?u=http-

3A__www.pharmacy.ca.gov&d=DwIFaQ&c=LHIwbLRMLqgNuqr1uGLfTA&r=2ykM7j3cEyKMb R6Jyy9zHSWNI2CvWOWnZeKnQ2Nqs2w&m=uysA61pO8kJhYjj08DCoD4AIhORNKiOGEsogkF xCX4Q&s=1EGWqbqZq1Sa6GSEovPfT3y9k8buenDxiFWpWIRHWBo&e=.

Thank you for your patience and understanding as we work under new protocols and procedures and continue to adjust to this ever-changing situation.

Sincerely,

Board of Pharmacy

August 27, 2020: News Release: FDA Warns Consumers Regarding Hand Sanitizers Packaged in Food and Drink Containers

From: Board of Pharmacy News and Information <PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV> On Behalf Of California State Board of Pharmacy
Sent: Thursday, August 27, 2020 9:33 AM
To: PHARM-NEWS@SUBSCRIBE.DCALISTS.CA.GOV
Subject: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

The California State Board of Pharmacy is providing the following news release from the U.S. Food and Drug Administration as an important warning to consumers about hand sanitizer products.

FDA NEWS RELEASE

COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

For Immediate Release: August 27, 2020

Silver Spring, MD — The U.S. Food and Drug Administration (FDA) is warning consumers about <u>alcohol-based hand sanitizers</u> that are being packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested. The agency has discovered that some hand sanitizers are being packaged in beer cans, children's food pouches, water bottles, juice bottles and vodka bottles. Additionally, the FDA has found hand sanitizers that contain food flavors, such as chocolate or raspberry.

"I am increasingly concerned about hand sanitizer being packaged to appear to be consumable products, such as baby food or beverages. These products could confuse consumers into accidentally ingesting a potentially deadly product. It's dangerous to add scents with food flavors to hand sanitizers which children could think smells like food, eat and get alcohol poisoning," said FDA Commissioner Stephen M. Hahn, M.D. "Manufacturers should be vigilant about packaging and marketing their hand sanitizers in food or drink packages in an effort to mitigate any potential inadvertent use by consumers. The FDA continues to monitor these products and we'll take appropriate actions as needed to protect the health of Americans."

In one recent example of consumer confusion, the FDA received a report that a consumer purchased a bottle they thought to be drinking water but was in fact hand sanitizer. The agency also received a report from a retailer about a hand sanitizer product marketed with cartoons for children that was in a pouch that resembles a

snack. Drinking only a small amount of hand sanitizer is potentially lethal to a young child, who may be attracted by a pleasant smell or brightly colored bottle of hand sanitizer.

Hand sanitizer can be toxic when ingested. The FDA continues to see an increasing number of adverse events with hand sanitizer ingestion, including cardiac effects, effects on the central nervous system, hospitalizations and death, primarily reported to poison control centers and state departments of health. For more information, consumers should refer to the FDA's guidelines on safe use of hand sanitizer as well as a question and answer page.

The FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's <u>MedWatch Adverse Event Reporting</u> program (please provide the agency with as much information to identify the product as possible).

The FDA continues to proactively work with manufacturers to recall potentially dangerous hand sanitizer products and is strongly encouraging retailers to remove these products from store shelves and online marketplaces. A <u>list of hand sanitizer</u> <u>products</u> the FDA urges consumers not to use, along with a description for consumers on how to use the list, has been posted to the agency's website, which is being updated regularly.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Media inquiries: Jeremy Kahn, 301-796-8671

Consumer inquiries: 888-INFO-FDA

Pharmacy Law Waivers

All current and expired <u>Pharmacy Law Waivers</u> are posted on the Board's website, <u>www.pharmacy.ca.gov</u>.

All Pharmacy Law Waivers – Updated 11/19/20

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code (BPC) section 4062, the California State Board of Pharmacy (Board) or the Board president through delegated authority has issued the following waivers.

The Board will make every effort to send a notice via a subscriber alert when the declaration of emergency has been lifted to signal the expiration of any waivers. The Board urges interested parties to <u>sign up to receive subscriber alerts</u> for the most up-to-date information.

Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision - Immunizations - BPC section 4114

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code (BPC) section 4062, the California State Board of Pharmacy (Board) or the Board president through delegated authority has issued the following waiver.

- The ratio of pharmacists to intern pharmacists may increase to allow for one additional intern pharmacist for each supervising pharmacist under the following conditions:
 - 1. The additional intern pharmacist is administering immunizations consistent with the provisions of Pharmacy Law.
 - 2. The pharmacy maintains a readily retrievable record documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver and the staff operating under the waiver. Records must be maintained for one year following the end of the declared emergency.
- Intern pharmacists providing immunizations under the provisions of this waiver may do so under the general supervision of a pharmacist at the discretion of the supervising pharmacist.

Effective: July 23, 2020

Expiration: January 18, 2021

Restoration of Retired or Canceled Pharmacist License – BPC section 4200.5(d), Related to Retired Licensees; BPC section 4402(b), Related to Canceled Pharmacist Licenses; and BPC section 4403, Related to Payment of Fees for Reissuance or Renewal of License

To allow for the restoration of a previously retired or canceled pharmacist license, the Board waives the provisions of Business and Professions Code sections 4200.5(d), 4402(b), and 4403 under the following conditions:

- 1. At the time of cancellation or transition to a retired status, the license was not subject to any disciplinary conditions or subject to any disciplinary proceeding.
- 2. The license has been in such a status no longer than five years.
- The individual applies for restoration by completing the required form <u>Application</u> to <u>Restore Your License</u> located on <u>the Board's website</u> under "COVID-19 Information."
 Upon processing of the application for restoring the license, the individual will receive email notification from the Board.

The Board has issued restored or reactivated pharmacist licenses for a maximum of six months. On September 17, 2020, the Department of Consumer Affairs (DCA) issued a waiver regarding license reactivation or restoration requirements subject to certain conditions. The September 17, 2020, DCA Waiver provides that a reactivated or restored license is valid until January 1, 2021, or when the State of Emergency ceases to exist, whichever is sooner. To align the validity dates of all restored or reactivated licenses required under pharmacy law with the September 17, 2020, DCA waiver, all restored or reactivated pharmacist licenses under the Board waiver will be valid until January 1, 2021, or until the State of Emergency ceases to exist, whichever is sooner.

Effective: November 19, 2020

Expiration: January 16, 2021

Remote Processing (BPC section 4071.1(a))

- For the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy as defined in Business and Professions Code (BPC) sections 4029 and 4037.
- In addition to the provisions of BPC section 4071.1(a), pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under

this waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The waiver does not include the dispensing of a drug or final product verification by remote processing.

• Further, this waiver expands the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

Pharmacy and Pharmacist Remote Processing Waiver Conditions:

- Pharmacists are permitted to conduct remote processing as permitted by this waiver if in compliance with the following:
- The pharmacist must be a California-licensed pharmacist who either processes medication orders or prescriptions from a remote site or on the premises of a California licensed-pharmacy.
- A California-licensed pharmacy may allow staff to engage in remote processing provided the pharmacy has policies and procedures that outline the authorized functions to be performed. Policies and procedures must include methods for protecting the confidentiality and integrity of patient information and must expressly prohibit the printing or storage of protected health information on a device that is outside of the licensed pharmacy. Such policies must be readily retrievable and provided to the Board upon request (i.e. be able to be produced within three business days of request).
- A pharmacy utilizing remote processing shall ensure that all pharmacists providing such services have been trained on the pharmacy's policies and procedures relating to medication order, prescription processing, and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy must ensure that any pharmacist performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site pharmacist has access to when the pharmacy is open.
- Each remote entry record must comply with all record keeping requirements for pharmacies, including capturing the positive identification of the pharmacist

involved in the remote review and verification of a medication order or prescription.

• A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

Pharmacy Intern and Pharmacy Technician Remote Processing Waiver Conditions:

- Pharmacy interns and pharmacy technicians are permitted to conduct **nondiscretionary tasks** related to remote processing as permitted by the waiver if in compliance with the following:
- The pharmacy intern or pharmacy technician who either enters medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy must be licensed by the Board.
- A pharmacy utilizing remote processing shall ensure that all pharmacy interns and pharmacy technicians providing such services have been trained on the pharmacy's policies and procedures relating to medication order or prescription processing and remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.
- A pharmacy shall ensure that any pharmacy intern or pharmacy technician performing remote processing shall have secure electronic access to the pharmacy's patient information system and to other electronic systems to which an on-site pharmacy intern or pharmacy technician has access when the pharmacy is open.
- Each remote entry record must comply with all record keeping requirements for pharmacies.
- A pharmacy utilizing remote processing is responsible for maintaining records of all medication orders and prescriptions entered into the pharmacy's information system.

Effective: November 19, 2020

Expiration: January 16, 2021

Requirement for Consulting Pharmacist to Make Quarterly Visits to Clinic (BPC sections 4182(a) & (b)/BPC 4192(a) & (b))

Waive the requirement for a consulting pharmacist to perform quarterly visits to a clinic under the following conditions:

• The consulting pharmacist, using his or her professional judgment, determines that the quarterly inspection is not required during the declared emergency.

- When making such a determination, it may be appropriate to consider prior consultation report findings, potential impact to patients receiving care in the clinic, etc.
- A consulting pharmacist performs a desk audit of the clinic's procedures and records in lieu of the visit.
- A consulting pharmacist generates a report outlining any findings resulting from the desk audit and provides that report to the professional director or his or her designee.
- The consultant receives confirmation to his or her satisfaction that the corrections outlined in the findings of the audit have been made.

Effective: November 19, 2020

Expiration: January 16, 2021

Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))

If the pharmacist-in-charge makes the determination that oral consultation, as required under Title 16, California Code of Regulations, section 1707.2(a), places the public and/or personnel at risk for exposure to COVID-19, in-person oral consultation may be waived under the following conditions:

- 1. The patient or patient's agent receives a verbal and prominently written notice of his or her right to request consultation by telephone.
- 2. The written notice includes the telephone number to call and the hours of availability during which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's records.
- 3. A pharmacist is readily available to speak to the patient or patient's agent during any regular hours of operation, unless additional hours of availability are provided and a return call is scheduled to occur within that time in the same business day, if acceptable to the patient. The pharmacist must make two good faith attempts to contact the patient by telephone and document the attempts or consultation. Documentation shall include the name of patient or prescription number, date, time and identification of pharmacist who provided consultation.
- 4. A pharmacist may provide oral consultation to the patient or patient's agent prior to the sale or delivery of a prescription.
- 5. The pharmacy has policies and procedures in place to ensure compliance with the requirements of this waiver prior to implementation.
- 6. A pharmacist may consult with patients or patients' agents using telephone, video chat or other method as acceptable to the patient.
- 7. If a pharmacist deems consultation is warranted in the exercise of his or her professional judgment or if there is an adverse drug therapy warning deemed necessary after the review as required by Title 16, California Code of Regulations,

section 1707.3, consultation must occur prior to the patient or the patient's agent receiving the prescription.

8. Documentation required by this waiver shall be maintained and readily retrievable for one year following the end of the declared emergency.

Effective: April 1, 2020

Expiration: December 28, 2020

Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (Title 16, California Code of Regulations, section 1751.5)

Provisions of Title 16, California Code of Regulations, section 1751.5(a)(1)-(3) related to the requirement to don PPE garb (including masks, gowns, head, and shoe covers) when compounding in a compounding aseptic isolator or compounding aseptic containment isolator May be waived under the following conditions:

- 1. The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain garbing requirements established in the regulation.
- 2. The isolator manufacturer has provided written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required. This documentation must be readily retrievable by the licensed location.
- 3. A policy is developed that details the revised conditions for use of PPE for compounding pursuant to this waiver.
- 4. Applicable pharmacy staff are trained on the policy and the training is documented prior to implementation.
- 5. Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.
- 6. Surface sampling schedule will be reviewed for the possible need to increase the frequency.
- 7. Documentation indicating the duration of time the pharmacy is operating under the waiver approval is maintained.
 Note: This waiver not does extend to the requirements for the use of sterile gloves.

Effective: April 1, 2020

Expiration: December 28, 2020

Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5)

Waive the signature requirement for the receipt of the delivery of drugs as required in BPC section 4059.5 under the following conditions:

- The delivery personnel confirm that the employee accepting the delivery is a pharmacist.
- The delivery personnel input the pharmacist's name and license number conveyed to them by the pharmacist directly into their signature capture device in lieu of the pharmacist physically signing the tablet as part of the delivery process.

Note: This waiver applies only to the **signature** requirement for the pharmacist accepting delivery.

Effective: March 17, 2020

Expiration: December 21, 2020, or until the emergency declaration is lifted, whichever is sooner.

Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6))

Waive provisions related to the prohibition against a prescriber to dispensing medications to an emergency room patient if the medication dispensed is a short-acting, beta-agonist inhalation product.

Effective: March 27, 2020

Expiration: December 21, 2020, or until the emergency declaration is lifted, whichever is sooner.

USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8)

Waive USP <797> requirements related to the use of personal protective equipment (PPE) as related to Business and Professions Code section 4126.8, in that a PPE mask and gown may be reused by staff performing sterile compounding under the following conditions:

- The pharmacist-in-charge has made a determination that the current and potential stock of PPE on hand is insufficient to maintain the single-use provisions established in USP <797>.
- The pharmacy has developed a policy that details the conditions under which PPE may be reused. Such policies shall be consistent with standards of practice used during emergency situations.

- Documented training on the policy is provided to all staff.
- Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.
- Surface sampling schedule was reviewed for the possible need to increase the frequency.
- Documentation is maintained indicating the duration of time the pharmacy is operating under the waiver approval.

Effective: March 17, 2020

Expiration: December 21, 2020

Expired Waivers

Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System (ADDS) - Business and Professions Code sections 4119.11(a)(9) and BPC 4427.2(e)

A California licensed pharmacy applying for an ADDS license for a proposed location or relocation of an ADDS will not be subject to the required prelicensure inspection at the proposed location provided the pharmacy submits the following:

- 1. A description of the proposed ADDS location with pictures, video and/or a floor plan with the surrounding areas labeled and how the ADDS is secured.
- 2. A copy of the pharmacy's policies and procedures to operate the ADDS regarding security, safety, accuracy, accountability, patient confidentiality, maintenance, maintaining the quality, potency and purity of the dangerous drugs and devices, restocking, record keeping and quality assurance.
- 3. Proof of training or plans for training pharmacy staff and personnel at the pharmacy applying for the proposed ADDS location on the policies and procedures.
- 4. A statement that a copy of the policies and procedures will be maintained as required by BPC section 4427.3(c).

If the ADDS is an Automated Patient Dispensing System (APDS), the pharmacy must also provide the following with its application (see BCP section 4427.6):

 Policies and procedures that include all of the following: criteria used to determine which drugs are placed in the APDS; methods of ensuring patients are aware that consultation is available; a description of assignments of responsibility; training on using the APDS; plans for orienting participating patients; plans for ensuring delivery of drugs when the APDS is disabled or malfunctioning; and plans for handling of complaints, errors, omissions and other incidents with the use of the APDS.

- 2. A statement explaining how a written consent from participating patients is obtained and what means are used to identify the patient or patient's agent before releasing the drug.
- 3. A statement confirming the APDS has a two-way audio and video for consultation; records are maintained for all transactions; child resistant containers are used; drug warning labels are used for drugs causing risk of overdose, addiction, impairment while operating a vehicle, and risk if alcohol is consumed; a sign is prominently posted on the APDS with the pharmacy's name, address and phone number; the prescription label meets the patient-centered labeling requirements; and translation and interpretive services are available.

Effective: April 13, 2020

Expiration: October 9, 2020

Reassessment/Revalidation/Re-evaluation Requirements for Sterile Compounding Staff Competencies – Title 16, California Code of Regulations, sections 1751.6(e)(2) and 1751.7(b) and (d)

This waiver extends the reassessment, revalidation, or re-evaluation requirements in Title 16 CCR sections 1751.6(e)(2) and 1751.7(b) and (d) for up to an additional 90 days with respect to semi-annual and annual reassessment, revalidation, or re-evaluation requirements for individuals involved in sterile compounding under the following conditions:

- 1. The pharmacist-in-charge makes a determination that such a suspension in the reassessment, revalidation, or re-evaluation frequency is necessary and appropriate, balancing site-specific limitations and current staff competencies.
- 2. The pharmacist-in-charge ensures only properly trained persons are allowed to perform compounding.
- 3. Documentation is maintained identifying when reassessments, revalidations, or re-evaluations pursuant to this waiver were extended for each staff member involved in sterile compounding. Such documentation must be maintained for three years from the date of making.

Effective: April 15, 2020

Expires: August 12, 2020

Certification in Basic Life Support - Business and Professions Code section 4052.8(b)(2)

Waiver of Business and Professions Code section 4052.8(b)(2), requiring certification in basic life support (BLS) in order to initiate and administer immunizations, under the following conditions:

• The pharmacist held a BLS certification that expired on or after March 15, 2020.

Effective: April 6, 2020

Expiration: August 5, 2020

Use of Alcohol Sanitizer before Donning Sterile Gloves (Title 16, California Code of Regulations, section 1751.5(a)(5))

Waive Title 16, California Code of Regulations, section 1751.5(a)(5) to allow for hand cleaning with the use of non-persistent activity alcohol sanitizer prior to donning sterile gloves.

Effective: March 17, 2020

Expiration: July 24, 2020

Prohibited Acts involving Dangerous Drugs or Devices (BPC sections 4169(a)(1) and 4161(b))

A California-licensed pharmacy may receive dangerous drugs and dangerous devices from an unlicensed pharmacy, wholesaler, or third-party logistics provider located in another state to alleviate a temporary shortage of a dangerous drug or device that could result in the denial of health care under the following conditions:

- 1. The unlicensed location is appropriately licensed in its home state, and documentation of the license verification is maintained by the California pharmacy.
- 2. The pharmacy maintains documentation of the temporary shortage of any dangerous drug or device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
- 3. The pharmacy complies with all record-keeping requirements for each dangerous drug and device received from any pharmacy, wholesaler, or third-party logistics provider not licensed in California.
- 4. All documentation and records required above shall be maintained and readily retrievable for three years following the end of the declared emergency.
- 5. The dangerous drug or device was produced by an authorized FDA registered drug manufacturer.

Effective: March 21, 2020

Expiration: July 24, 2020, or until the emergency declaration is lifted, whichever is sooner.

Pharmacist Direct Supervision of Interns - Business and Professions Code section 4114

Waiver of the provision of Business and Professions Code section 4114(a) to allow for general supervision of an intern pharmacist **at the discretion of the supervising pharmacist** under the following conditions:

- The pharmacy documents the need for the supervision modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume, or limitation on staff availability because of shelter-in-place orders or quarantine.
- The intern pharmacist meets one of the following criteria:
- Enrolled in a recognized school of pharmacy with an anticipated graduation date in 2020; or
- Graduated from a recognized school of pharmacy; or
- Is certified by the Foreign Pharmacy Graduate Equivalency Committee.
- The pharmacy maintains a readily retrievable record documenting the intern pharmacists operating under the general supervision of a pharmacist under the waiver and justification of the need. Records must be maintained for one year following the end of the declared emergency.
- Under general supervision, the supervising pharmacist is generally aware of all activities performed by the intern pharmacist without direction from the pharmacist.

Effective: April 21, 2020

Expires: July 19, 2020

Intern Pharmacist Licenses (BPC section 4208)

The Board will automatically extend any intern pharmacist license with an expiration date on or before July 1, 2020, for an additional six months, if the intern pharmacist license is current and in good standing.

To verify your intern pharmacist license is extended, please visit the Board's website at <u>www.pharmacy.ca.gov</u> and select <u>License Search</u> under "Quick Hits" on the homepage.

Sterile Compounding Renewal Requirements for Facilities Located Within a Hospital (BPC sections 4127.1(c) & (d) and 4127.15(b))

A sterile compounding pharmacy whose license expires on or before July 1, 2020, may have its license renewed without being subject to the renewal requirements in BPC sections 4127.1(c) and (d) and 4127.15(b) under the following conditions:

- 1. The sterile compounding facility is located within a hospital or satellite location regulated by the California Department of Public Health and issued a General Acute Care Hospital License.
- 2. The compounding facility complies with all other provisions of Pharmacy Law as applicable, unless otherwise waived by the Board during this declared emergency.

Effective: March 21, 2020, modified March 27, 2020

Use of Sterile Disinfectant Agents – Title 16, California Code of Regulations, section 1751.4(d)(1)

Waiver of Title 16, California Code of Regulations, section 1751.4(d)(1) to allow for the use of a non-sterile alcohol-based disinfectant after cleaning on work table surfaces, carts, and counters under the following conditions:

- 1. The pharmacist-in-charge has made a determination that the current and potential stock of sterile alcohol (sIPA) on hand is insufficient to maintain the requirements established in the regulation.
- 2. The surface or equipment is NOT contained within an ISO Class 5 environment.
- 3. Surface sampling schedule is reviewed for the possible need to increase the frequency of cleaning and disinfection.
- 4. Documentation indicating the duration of time the pharmacy is operating under this waiver is maintained.

Effective: April 3, 2020

Expiration: July 1, 2020

Inventory Reconciliation Report of Controlled Substances (Title 16, California Code of Regulations, section 1715.65(c))

A pharmacy or clinic must complete the required inventory reconciliation report specified in Title 16, California Code of Regulations, section 1715.65(c) at least once every six months rather than every three months if determined to be necessary by the pharmacist-in-charge or professional director to ensure continuity of direct patient care activities that would otherwise be impacted. Effective: March 24, 2020

Expiration: June 22, 2020

Staffing Ratio of Pharmacists to Intern Pharmacists (BPC section 4114(b))

The ratio of pharmacists to intern pharmacists may increase to allow for one additional pharmacy intern for each supervising pharmacist under the following conditions:

- 1. The pharmacy documents the need for the ratio modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume or limitation on staff availability because of quarantine.
- 2. The additional intern pharmacist meets one of the following criteria:
 - a. Enrolled in a recognized school of pharmacy with an anticipated graduation date in 2020; or
 - b. Graduated from a recognized school of pharmacy; or
 - c. Is certified by the Foreign Pharmacy Graduate Equivalency Committee.
- 3. The pharmacy maintains a readily retrievable record documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver, the staff operating under the waiver, and justification of the need. Records must be maintained for one year following the end of the declared emergency.

Effective: March 20, 2020

Expiration: June 24, 2020, or until the emergency declaration is lifted, whichever is sooner.

Staffing Ratio of Pharmacists to Pharmacy Technicians (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations, section 1793.7)

The ratio of pharmacists to pharmacy technicians may increase to allow for one additional pharmacy technician for each supervising pharmacist under the following conditions:

- 1. The pharmacy documents the need for the ratio modification due to the COVID-19 public health emergency. Examples of documentation may include, but are not limited to, an increased prescription volume, limitation on staff availability because of quarantine.
- 2. The supervising pharmacist, exercising their professional judgment, may refuse to supervise the additional pharmacy technician and provide the pharmacist-in-

charge of their determination. When making such a determination, the supervising pharmacist must specify the circumstances of concern with respect to the pharmacy and patient care implications. Under such circumstances, the ratio may not increase.

• The pharmacy must maintain a readily retrievable record, documenting the date(s) and time(s) when the ratio is increased pursuant to this waiver and the staff operating under the waiver, and justification of the need. Records must be maintained for one year following the end of the declared emergency.

Effective: March 19, 2020

Expiration: June 24, 2020, or until the emergency declaration is lifted, whichever is sooner.

Guidance Documents

COVID-19 FREQUENTLY ASKED QUESTIONS

1. Are pharmacies still required to get the patient's signature when picking up or delivering medications to the patient due to the risk of spreading the COVID-19 virus?

Please review Board regulation, <u>Title 16, CCR section 1713</u>, Receipt and Delivery of Prescriptions and Prescription Medication. Current pharmacy law does NOT require the patient to sign for picking up or the delivery of a prescription. But there may be insurance or pharmacy policies that require this information. You may wish to contact your insurance administrator or consult your pharmacy's policies about waiving this provision.

2. Is a pharmacy allowed to compound hand sanitizer because the products are no longer readily available?

The Board does not have jurisdiction over over-the-counter (OTC) products such as hand sanitizers. The Food and Drug Administration (FDA) has recently published guidance on compounding hand sanitizer. Please consult the FDA guidance, "Policy for Compounding of Certain Alcohol-Based Hand Sanitizers Products During the Public Health Emergency."

3. Can my pharmacy compound hydroxychloroquine and chloroquine if we can get the ingredients?

Please see Board regulation, <u>Title 16, CCR 1735.2</u>, Compounding Limitations and Requirements. In particular, section 1735.2(d)(3) prohibits the compounding of a drug preparation that is a copy or essentially a copy of a commercially available drug UNLESS that drug product appears on the ASHP or FDA lists of drugs that are in short supply at the time of compounding and dispensing.

- <u>ASHP Drug Shortages</u>
- FDA Drug Shortages

4. Are there any changes in telehealth/telemedicine laws regarding controlled substance prescriptions due to the COVID-19 emergency?

Please see the <u>Drug Enforcement Administration (DEA) website</u> and contact the <u>Medical Board of</u> <u>California</u> for complete details and updates regarding telehealth/telemedicine.

The DEA, in consultation with the Department of Health and Human Services (HHS), <u>announced</u> that as of January 31, 2020, it will allow DEA registered practitioners to begin

issuing prescriptions for controlled substances to a patient for whom they have not conducted an in-person medical evaluation. DEA-registered practitioners may continue this telemedicine practice for as long as the designation of the public health emergency is in effect provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose.
- The telemedicine communication is conducted using an audio-visual, real time, twoway interactive communication system.
- The practitioner is acting in accordance with applicable federal and state laws.
- In addition to the above federal requirements, the Medical Board of California requires a physician to be licensed in the state of California (see BPC section 2290.5) but does not require the patient to have an in-person contact with the prescriber.

5. Do I need to notify the Board of Pharmacy if I want to temporarily change my pharmacy hours due to the COVID-19 crisis? What if I want to temporarily close the pharmacy?

There is no requirement to notify the Board when a pharmacy changes its hours. But see <u>BPC</u> <u>section 4312</u>, Voiding a Permit, if the pharmacy wants to TEMPORARILY close. This section requires a pharmacy to engage "in the ordinary activity for which the license was issued for at least one day each calendar week during any 120-day period." If it does not, the Board may review the circumstances of closure before cancelling the license. If the pharmacy wants to PERMANENTLY close, Title 16 <u>CCR section 1708.2</u>, Discontinuance of Business, requires the pharmacy to notify the Board PRIOR to selling/transferring the dangerous drug inventory. Additionally, <u>BPC section 4333</u> requires all prescription and other records be moved to and maintained at a Board-licensed facility for at least three years.

You must submit a request if you need a waiver to temporarily close your pharmacy. Send your request to <u>amber.dillon@dca.ca.gov</u>.

6. Can a pharmacy refill a prescription without the prescriber's authorization during the COVID-19 crisis? What about a controlled substance or Schedule II prescription?

<u>BPC section 4064</u> allows a pharmacist to refill a dangerous drug or device prescription without the prescriber's authorization if the prescriber is unavailable to authorize the refill AND if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have an adverse effect on the patient's well-being. The pharmacist must:

- Make a reasonable effort to contact the prescriber PRIOR to refilling the prescription and make an appropriate record, including the basis for proceeding.
- Inform the patient the prescription was refilled pursuant to this section.
- Inform the prescriber within a reasonable time that the refill was provided.

The prescriber does not incur any liability as a result of refilling a prescription pursuant to this section.

HSC section 11200(c) prohibits a prescription for Schedule II substance being refilled. HSC section 11201 allows a pharmacist to refill a prescription for a controlled substance (other than Schedule II) if the prescriber is unavailable to authorize the refill AND if, in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist shall:

- Make every reasonable effort to contact the prescriber prior to refilling a prescription pursuant to this section.
- Refill only a reasonable amount sufficient to maintain the patient until the prescriber can be contacted.
- Note on the reverse side of the prescription the date and quantity of the refill and that the prescriber was not available and the basis for his or her judgment to refill the prescription without the prescriber's authorization.
- Inform the patient that the prescription was refilled without the prescriber's authorization, indicating that the prescriber was not available and that, in the pharmacist's professional judgment, failure to provide the drug might result in an immediate hazard to the patient's health and welfare or might result in intense suffering.
- Inform the prescriber within a reasonable period of time.

The prescriber shall not incur any liability resulting from refilling a prescription pursuant to this section.

7. How can I apply for a waiver of Pharmacy Law, and how long is the waiver effective?

Pursuant to <u>BPC section 4062</u>, during a declared federal, state or local emergency, the Board has the ability to waive provisions of Pharmacy Law. Under the Board's policy, waivers granted by the Board's president are limited to 90 days. For information on how to request a waiver for any provision of Pharmacy Law, please go to <u>the Board's website</u>, <u>www.pharmacy.ca.gov</u>, and click on How to Request a Pharmacy Law Waiver in the COVID-19 Information box.

8. My pharmacy is having trouble findings certain drugs at my regular wholesaler due to the COVID-19 emergency, but the hospital down the street has the drug available. Can my pharmacy purchase this drug from the hospital during this emergency?

Yes. Although <u>Business and Professions Code section 4380</u> in general prohibits the resale of drugs acquired at preferentially low prices (or bid price merchandise) permitted under federal law because of the Nonprofit Institutions Act (15 U.S.C. section 13c), there is an

exception for the "occasional emergency situation" where no other drug sources are readily available in the community to meet the emergency need.

9. Is there a limit on the amount of a controlled substance that can be prescribed on a prescription? Is there a limit on the amount of a controlled substance that can be dispensed to the patient?

Federal and California pharmacy laws are silent on the amount of a controlled substance that can be prescribed. If the prescription is uncertain, erroneous or irregular, <u>California Code of Regulations, title 16, section 1761(a)</u> requires the pharmacist contact the prescriber to obtain the information needed to validate the prescription. But CCR section 1761(b) prohibits a pharmacist from dispensing a controlled substance that was not prescribed for a legitimate medication purpose even if validated by the prescriber.

Although there is no quantity limit on the original controlled substance prescription dispensed, <u>Health and Safety Code section 11200</u> limits the quantity of a controlled substance dispensed as a refill for Schedule III or IV drugs to a 120-day supply. Furthermore, all controlled substance prescriptions must be filled and refilled within six months of the date written. Schedule III and IV drugs cannot be refilled more than five times. No prescription for Schedule II drugs can be refilled.

10. I have several out-of-state patients and students who have sheltered in place or been quarantined in California due to COVID-19. Is the pharmacy able to fill their out-of-state Schedule II prescriptions?

Please refer to the article "Q&A: Out-of-state e-scripts for Schedule II medications" on page 16 of the July 2018 issue of The Script and Health and Safety Code (HSC) section 11164.1(a)(1) on filling out-of-state Schedule II prescriptions.

Here are some other suggestions to take care of patients who come from out-of-state with prescriptions issued by out-of-state prescribers:

- Have the patient go to urgent care or a California prescriber to obtain a new Schedule II prescription.
- Contact the out-of-state prescriber for an alternative non-Schedule II controlled substance medication, which can be filled by the California pharmacy per <u>HSC section</u> <u>11164.1(b)</u> and 16 <u>CCR section 1717</u>.

11. Many patients are requesting their controlled substances refills early due to the COVID-19 emergency. How early can I fill these controlled substances prescriptions?

The pharmacist should use professional judgment, exercise corresponding responsibility, and review the patient's CURES Report. If warranted, the pharmacist should contact the prescriber to advise the prescriber of the patient's request for an early refill and discuss if an early refill is appropriate and/or legitimate in this situation. Only then can the pharmacist determine whether and when the prescription should be refilled. See <u>HSC section 11153</u> and 16 <u>CCR section 1761</u> for complete law. The pharmacy may also wish to contact the insurance company regarding payment guidelines for early refills.

12. Due to COVID-19 pandemic, does the Board require my pharmacy staff to wear personal protective equipment (PPE) while working in the pharmacy? Can the pharmacy require the customers to wear PPE?

On June 18, 2020, Governor Newsom announced that Californians are now **required** to wear face coverings in public spaces – particularly indoors or when physical distancing is not possible.

The California Department of Public Health has released guidance requiring the use of face coverings in high-risk situations as follows:

- Inside or in line to enter any indoor public space.
- Obtaining services from the health care sector in settings including but not limited to a hospital, pharmacy, medical clinic, laboratory, physician or dental office, veterinary clinic, or blood bank.
- Waiting for or riding on public transportation or paratransit or while in a taxi, private car service, or ride-sharing vehicle.
- Engaged in work, whether at the workplace or performing work off-site, when:
 - Interacting in person with any member of the public;
 - Working in any space visited by members of the public, regardless of whether anyone from the public is present at the time;
 - Working in any space where food is prepared or packaged for sale or distribution to others;
 - Working in or walking through common areas, such as hallways, stairways, elevators, and parking facilities;
 - In any room or enclosed area where other people (except for members of the person's own household or residence) are present when unable to physically distance.
- Driving or operating any public transportation or paratransit vehicle, taxi, or private car service or ride-sharing vehicle when passengers are present. When no passengers are present, face coverings are strongly recommended.

• While outdoors in public spaces when maintaining a physical distance of 6 feet from persons who are not members of the same household or residence is not feasible.

Additionally, in May 2020, the California Department of Public Health published <u>COVID-19</u> <u>Guidance for Pharmacies and Pharmacy Staff</u>. See <u>www.cdph.ca.gov</u> for complete details. Some of the recommendations:

For pharmacy staff:

- Ensure staff engage in frequent hand hygiene (i.e., routinely washing hands with soap and water for at least 20 seconds), and avoid touching eyes, nose, and mouth.
- Ensure staff self-monitors for illness (fever, cough, shortness of breath). Staff with flu-like symptoms should stay at home or should go home.
- Staff should wear facemasks or cloth face covering while in the pharmacy.
- Encourage prescribers to submit telephone or electronic prescriptions.
- Avoid touching items handled by customers such as insurance or credit cards, and wash hands or use hand sanitizer if these items are touched.
- Minimize physical contact with customers. As much as possible, maintain a 6-foot distance.
- Point-of-care services (e.g., immunizations, blood pressure measurements) should be avoided if a patient has respiratory symptoms, or if the service is not urgent for a patient who is asymptomatic. If point-of-care service is provided, the pharmacy staff should wear proper PPE and practice hand hygiene.

13. Can a California pharmacist provide COVID-19 testing? What about an advanced practice pharmacist?

Effective May 12, 2020, California Governor Gavin Newsom signed <u>Executive Order N-39-20</u> allowing pharmacists to participate in COVID-19 testing. <u>Guidance for pharmacists ordering and</u> <u>collecting specimens for COVID-19 tests</u> is posted in the COVID-19 Information box on the Board's website.

The DCA and the Board encourage pharmacists to <u>contact their partner laboratories</u> to obtain information about reporting requirements, specimen handling, transportation requirements, and reimbursements.

Additional Resources

Please <u>sign up for subscriber alerts</u> and monitor the Board's website for regular updates and additional resources related to COVID-19, including:

- Pharmacy Law Waivers
- Important Information for Licensees 3/24/20
- Ask an Inspector

For additional information about COVID-19, please also visit the following websites:

- <u>Governor's Office</u>
- Medical Board of California
- <u>CDPH</u>
- <u>DEA</u>
- <u>FDA</u>
- <u>CDC</u>
- U.S. Postal Service

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Attachment C

Board Publications

The Script - Newsletter

CALIFORNIA STATE BOARD OF PHARMACY

THE SCRIPT BE AWARE & TAKE CARE: Talk to your pharmacist!

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New year brings changes in pharmacy laws for 2020



Gov. Gavin Newsom has signed a variety of bills adding or amending laws that govern the practice of pharmacy in California. Unless specified otherwise, the new laws take effect Jan. 1, 2020.

Many of the key provisions are summarized below. Click on the bill number to read the full text for a more complete explanation of each new law.

<u>AB 528</u> Controlled Substances: CURES Database

(Low, Chapter 677, Statutes of 2019)

Effective January 1, 2021, this law expands the CURES reporting requirements to include Schedule V drugs and reduces the reporting deadline to one business day from the date the prescription was released to the patient.

<u>AB 690</u> Pharmacies: Relocation: Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications

(Aguiar-Curry, Chapter 679, Statutes of 2019)

Effective upon signing by the

PRESIDENT'S MESSAGE



By Gregory Lippe, President, **Board of Pharmacy**

Happy new year! As the newly elected president, I want to extend best wishes to all for a healthy and safe 2020 on behalf of the California State Board of Pharmacy.

The Board is happy to begin the new year with the appointment of Anne Sodergren as its new executive officer. Ms. Sodergren has over 25 years of experience with the Board, most recently as interim executive officer.

As I am sure you are aware, in October the Board invalidated a CPJE taken by almost 1,400 pharmacist applicants. The Board took this action after receiving credible information that the validity and reliability of the CPJE had been compromised. Evidence indicated widespread subversion by applicants who shared information about the exam questions through electronic communications.

This issue continues to be a top priority for the Board. The investigation is ongoing, and Board staff is coordinating efforts with investigators within the Department of Consumer Affairs. I encourage anyone with relevant information to come forward.

Applicants who took the invalidated CPJE were allowed to retake the exam November 16 and 17. Since then, the CPJE has been administered several times, resulting in the issuance of more than 1,240 licenses to new California pharmacists.

The Board is also focused on patient protection. The **Compounding Committee** worked actively in 2019 to review proposed revisions to USP chapters and to incorporate comprehensive changes into California regulations on pharmaceutical compounding. Late last year, however, the Board voted to delay rulemaking on compounding preparations pending USP's postponement of chapters 795, 797, and 825. A policy statement regarding California compounding regulations is posted on the Board's website.

The Board encourages licensees and interested groups to participate in the rulemaking process and to comment on proposed regulations. To ensure you are notified about the rulemaking process and comment period, be sure you have signed up to receive news subscriber alerts. To sign up, go to the Board of Pharmacy Email **Registration** page and follow the instructions to receive News and Information email notices.

Thank you for participating in the rulemaking process. Your efforts help the Board carry out its mission to protect and promote the health and safety of Californians by pursuing the highest quality of pharmacist care and the appropriate use of pharmaceuticals.

For other updates, please subscribe to News and Information alerts and follow us on Twitter.

The Board's Mission

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.
New laws

Continued from page 1

governor, this law creates a limited exemption to the licensure transferability requirements for a pharmacy to relocate because of damage caused by a declared disaster. The law also establishes specific requirements for a pharmacy technician working in a remote dispensing site pharmacy.

AB 973 Pharmacies: Compounding

(Irwin, Chapter 184, Statutes of 2019)

This law requires that compounding of drug preparations by a pharmacy must be done consistent with the relevant compounding chapters of the United States Pharmacopeia-National Formulary (USP).

The Board released a <u>policy statement</u> regarding California legal requirements for compounding pharmacies pending information from USP regarding implementation of chapters 795, 797, and 800. The policy statement is available on the Board's website.

AB 1723 Clinics: Purchasing Drugs at Wholesale

(Wood, Chapter 323, Statutes of 2019)

This law increases the maximum hours of operation for a primary care community clinic or free clinic from 20 hours to 40 hours per week.

<u>SB 159</u> HIV Preexposure and Postexposure Prophylaxis

(Wiener, Chapter 532, Statutes of 2019)

Effective July 1, 2020, this comprehensive law authorizes pharmacists to furnish HIV preexposure and postexposure prophylaxis under specific conditions.

Key provisions of the law require the Board of Pharmacy, in consultation with the Medical Board of California (MBC), to approve training programs that pharmacists must complete before furnishing either preexposure or postexposure prophylaxis. In addition, the law specifies guidelines issued by the federal Centers for Disease Control and Prevention (CDC) that the Board of Pharmacy must use to establish the drug or drug combinations to be furnished:

- For HIV preexposure prophylaxis: "2017 <u>Preexposure Prophylaxis for the Prevention</u> <u>of HIV Infection in the United States – 2017</u> <u>Update: A Clinical Practice Guideline</u>," or any subsequent guidelines published by the CDC.
- For HIV postexposure prophylaxis: "<u>Updated</u> <u>Guidelines for Antiretroviral Postexposure</u> <u>Prophylaxis After Sexual, Injection Drug</u> <u>Use, or Other Nonoccupational Exposure to</u> <u>HIV–United States, 2016</u>," or any subsequent guidelines published by the CDC.

The law also requires the Board of Pharmacy to consult with the MBC in developing emergency regulations to be adopted by July 1, 2020, to implement the law. The Board adopted emergency regulations and approved initiating a regular rulemaking on January 29, 2020.

<u>SB 569</u> Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency

(Stone, Chapter 705, Statutes of 2019)

This law authorizes a pharmacist to fill a prescription for a controlled substance that does not conform to the controlled substances security form requirements under specific conditions.

SB 655 Pharmacy

(Roth, Chapter 213, Statutes of 2019)

This law makes technical and other conforming changes to Pharmacy Law on a variety of matters, including externship hours for pharmacy technician trainees; reverse distributors acquiring drugs from an unlicensed source; validity of CPJE or NAPLEX scores following occupational analysis; inactivation of advance practice pharmacist license by the Board; and application and renewal payments for government applicants and licensees.

Medication errors top list of citations

Medication errors ranked as the top reason for a citation issued by the Board of Pharmacy during most of the last quarter of fiscal year 2018-19.

A total of 63 citations were issued for medication errors from April 1, 2019, through June 25, 2019. The citations were issued for violations of California Code of Regulations (CCR), title 16, <u>section 1716</u> (Variation from Prescriptions).

Medication error cases also may include other types of violations. For example, printing the wrong information on a prescription label could also result in citation for violation of <u>section 1764</u> (Unauthorized Disclosure of Prescriptions).

Examples of medication errors cited by staff include:

- Prescription was written for glyburide 10mg, but pharmacist filled it with glipizide 5mg.
- Pharmacist dispensed ear drops (Debrox) instead of artificial tears eye drops as prescribed.
- Prescription label read to take prescription four times daily instead of three times daily as prescribed.
- Pharmacy mistakenly dispensed Naproxen to a patient who was not prescribed this drug.

Staff also reported examples of unauthorized disclosure or prescriptions:

- Pharmacy shipped patient A's prescription to patient B, disclosing patient A's prescription information to patient B.
- Nonresident pharmacy incorrectly dispensed prescription for Prolensa for patient G to patient K, disclosing patient G's protected health information.
- During an inspection, patients' drug names were visible on finished prescriptions from the pickup counter. Exposing patient names and drug information without authorization is a violation.

The top 10 types of citations issued April 1 through June 25, 2019, were:

Code violation	Description	Total number of violations
<u>CCR 1716</u>	Medication error	63
<u>CCR 1714(b)</u>	Pharmacy security/drug loss	39
<u>BPC 4081(a)</u>	Records kept open for inspection for three years	27
BPC 4301(l)	Unprofessional conduct – conviction of a crime	27
<u>BPC 4301(h)</u>	Unprofessional conduct – self administration	27
<u>CCR 1764</u>	Unauthorized disclosure of prescriptions	16
<u>CIV 56.10</u>	Disclosure of protected health information	14
<u>CCR 1718</u>	Current inventory defined	10
<u>CCR 1711(d)</u>	Quality assurance program – develop pharmacy systems and workflow processes	8
<u>HSC 11165(d)</u>	Failure to report to CURES	8

Tips, resources to prevent drug errors

According to the Food and Drug Administration (FDA), the most common causes of medication errors are:

- Poor communication.
- Ambiguities in product names, directions for use, medical abbreviations or writing.
- Poor procedures or techniques.
- Patient misuse because of poor understanding of the directions for using the product.

One of the most important ways to prevent errors is for pharmacists to provide patients with proper consultation when dispensing prescriptions. <u>CCR</u> <u>section 1707.2</u> requires pharmacists to provide consultation to patients:

- Upon request.
- Whenever the pharmacist deems it warranted in his or her professional judgment.

- Whenever a prescription medication has not been previously dispensed to the patient.
- Whenever a prescription medication is dispensed in a new dosage form or strength or with new written directions.

The Institute for Safe Medication Practices (ISMP) offers many resources and tools to help health care professionals and patients prevent medication errors. ISMP also provides a section on reporting medication errors with information for health care professionals regarding trends in medication errors and how to prevent or correct them.

In addition, <u>FDA MedWatch</u> provides an <u>online</u> <u>reporting form</u> and phone number – (800) FDA-1088 – for pharmacists and other health care providers to report medication errors or adverse drug side effects.

Applicants can pay for pharmacist license online

Pharmacist applicants who have passed both the CPJE and the NAPLEX can submit a <u>Request for Issuance</u> <u>of Pharmacist License</u> 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.

Did you know...

Facilities, pharmacists, pharmacy technicians, intern pharmacists and designated representatives are required to register for email notifications from the Board of Pharmacy within 60 days of obtaining a license or at the time of license renewal. In addition, licensees must update their registration within 30 days of changing their email address. The process is easy! To register your email address and receive email notifications from the board, click <u>here</u> or visit the board's <u>website</u> and subscribe to the email notification list under Quick Hits. Email addresses are confidential and not posted on the board's online license verification system.

Report recalls, adverse drug reactions

Timely reporting of recalls and adverse drug reactions (ADR) to the Board of Pharmacy and the FDA MedWatch program is critical to protecting public health and safety. Reports to the Board of Pharmacy should be emailed to compounding.report@dca.ca.gov.

The following sections of the California Business and Professions Code (BPC) establish reporting requirements for compounding pharmacies and outsourcing facilities under specific conditions:

- <u>BPC 4126.9</u>
- <u>BPC 4127.1</u>
- <u>BPC 4127.2</u>
- <u>BPC 4127.8</u>
- <u>BPC 4129.1</u>
- <u>BPC 4129.2</u>

For nonsterile compounding pharmacies:

 BPC 4126.9(a) – requires recalls be reported to the Board within 12 hours if use of the product may cause serious adverse health consequences or death, or if the product was dispensed or intended for use in California. BPC 4129.9(c) – requires ADR be reported to MedWatch within 72 hours of the pharmacy learning of the event.

For in-state, sterile compounding pharmacies:

- BPC 4127.1(e)(3) /4127.8

 require recalls be reported to the Board within 12 hours.
- BPC 4127.1(f) requires ADR be reported to the Board and MedWatch within 12 hours.

For out-of-state, sterile compounding pharmacies:

- BPC 4127.2(e)(3)/4127.8 require recalls be reported to the Board within 12 hours.
- BPC 4127.2(f) requires ADR be reported to the Board and MedWatch within 12 hours.

For in-state, outsourcing facilities:

 BPC 4129.1(e)(2) – requires recalls be reported to the Board within 24 hours.

- BPC 4129.1(e)(3) requires a copy of any clinically related complaint involving the outsourcer's compounded products be reported to the Board within 72 hours.
- BPC 4129.1(e)(4) requires ADR be reported to the Board within 24 hours.

For out-of-state, outsourcing facilities:

- BPC 4129.2(e)(2) requires recalls be reported to the Board within 24 hours.
- BPC 4129.2(e)(3) requires a copy of any clinically related complaint involving the outsourcer's compounded products be reported to the Board within 72 hours.
- BPC 4129.2(e)(4) requires ADR be reported to the Board within 24 hours.



Case study: Pharmacist failure to verify compounding ingredients



Situation:

A pharmacy technician mislabeled a stock bottle of fludrocortisone powder as fluticasone, a look-alike, soundalike ingredient. The active pharmaceutical ingredient (API) was subsequently entered into the pharmacy computer system and affixed with a bar code for fluticasone. No pharmacist was involved in this process.

During compounding, the pharmacy technician retrieved the API and scanned the bar code. The computer system identified the API as fluticasone. The pharmacy technician compounded the preparation. The pharmacist did not review the compounded medication in the compounding room. Instead, using a computer in another part of the pharmacy, the pharmacist reviewed only the electronic compounding record, which was auto populated as to the drugs used based on the bar code affixed to the API container. The pharmacist performed the final check/signed off on the drug preparation without visually reviewing the API bottle to confirm the APIs used in compounding.

The error:

Fluticasone was entered into the computer system, resulting in the wrong bar code being issued and affixed to the API stock bottle, which contained fludrocortisone. The API was used in a triturate (starting compounded drug) that was then used as an ingredient in another formulation. The pharmacists who signed off on the subsequent compounded drug preparation assumed the starting compounded drug was compounded correctly. These compounding errors went on for approximately six months, until a pharmacist noted the error and alerted the pharmacist-incharge. The pharmacy notified the patient and patient's doctor of the error.

The fix:

Short-term fix: The pharmacy has a pharmacist visually confirm the container of API has been bar-code labeled correctly before it is used.

Long-term fix: In addition to the pharmacist visually confirming the API is bar-code labeled correctly, a camera system was to be installed in the compounding area and record every API manufacturer label and pharmacy generated bar code. This will allow the pharmacist to view both prior to signing off on the compounded drug preparation.

Discussion:

Although technology may provide efficient ways to compound drugs, it does not always provide checks and balances needed to prevent an error from reaching a patient. Please continue to evaluate your compounding processes to identify where errors can occur. It may be helpful to ask compounding staff to come up with ideas to make the compounding process safer.

Case study: Monitor will call area, verify returned pills to prevent losses

California Code of Regulations, title 16, <u>section 1714(b)</u> requires that pharmacies maintain their "facilities, space, fixtures and equipment so that drugs are safely and properly prepared, maintained, secured and distributed." The regulation also requires that pharmacies be "of sufficient size and unobstructed area to accommodate the safe practice of pharmacy."

Besides the stock shelves in the back of the pharmacy, section 1714(b) applies to the will call area and workspace near the front counter where filled prescriptions are stored for patients to pick up.

Recently, the Board of Pharmacy investigated a California retail pharmacy that reported losing more than 100 hydrocodone/ acetaminophen tablets. An internal investigation by the pharmacy revealed that a series of shortages had occurred during a three-month period.

According to the internal investigation, an unlicensed



pharmacy clerk pilfered the tablets from filled prescriptions left in the will call bin, which was obstructed by a barrier and not clearly visible to pharmacists and other staff. The pharmacy found that eight to 21 tablets were lost per each incident. On two occasions, customers reported their prescriptions had been shorted; other times, prescriptions were not double counted upon their return to stock. A Board of Pharmacy inspection found the pharmacy and the pharmacist-in-charge violated section 1714(b) by failing to maintain security over controlled substances within the pharmacy.

Besides maintaining and monitoring spaces in the pharmacy, it is important for pharmacists to keep accurate count of pills returned to stock. This will help prevent shortages that can add up to major drug losses and diversion cases.

Check out CPJE dates for 2020 online

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

Avoid errors in reporting data to CURES

By Lisa Henry

Did you know there are now more than 550 million prescription records in the CURES database? In 2019, an average of 3.1 million dispensations were uploaded to California's prescription drug monitoring program every month.

Currently, the CURES reporting process starts with dispensers submitting data to Atlantic Associates Inc. (AAI). AAI checks the information and notifies dispensers to correct any reporting errors, including missing data and incorrect file formats. Once it is validated, AAI forwards the data to the California Department of Justice (DOJ) to update the CURES database.

Despite the validation process, data reported to CURES may still contain errors. This means some CURES information may not be as helpful or accurate for dispensers and prescribers, which in turn could have an impact on patients.

The Board of Pharmacy's <u>CURES webpage</u> includes information on reporting data to CURES. Below are some reminders and tips to help dispensers submit proper and accurate data.

Items to check:

- Non-controlled substances and over-thecounter drugs do not need to be reported.
- Ensure the NDC code is entered correctly and is in the 11-digit format.
- Look for prescriber names that are the same or similar but are different people. (Check their DEA numbers.)
- Verify patient names are entered correctly.

- Ensure dates entered are not future dates.
- Pharmacy license numbers and DEA numbers are not interchangeable. Use the Board of Pharmacy's full license designation with letters and numbers (e.g., PHY12345) for the state license number. Do not use the pharmacy's DEA number (e.g., AB1234567) in this field.

Helpful Resources:

- The <u>DEA's Controlled Substance Schedules</u> lists Schedule II–IV drugs required to be reported. This page also includes information on exceptions for some controlled substances. See also <u>California</u> <u>Health and Safety Code section 11165(d), et</u> <u>seq.</u>
- <u>AAI's Direct Dispense Application</u> <u>Instruction Manual</u>
- The FDA's National Drug Code Directory
- NDC searchable database

For more information or assistance reporting CURES data, please contact:

- <u>Atlantic Associates Inc.</u> Phone: (800) 539-3370 Email: <u>data@aainh.com</u>
- <u>California Department of Justice CURES</u> Phone: (916) 210-3187 Email: <u>CURES@doj.ca.gov</u>

www.pharmacy.ca.gov

Corresponding responsibility is critical in filling controlled substances scripts

By De'Bora White, Board of Pharmacy Inspector

A growing number of consumers are filing complaints with the Board of Pharmacy about difficulty getting opioid prescriptions filled. However, as many communities battle an epidemic of opioid abuse, it is important that pharmacists exercise their legal obligations in filling controlled substances prescriptions.

Pharmacists are often the last line of defense in the battle against prescription drug abuse. As licensed professionals, they must weigh their calling to serve patients against their obligation to prevent controlled substances from getting into the wrong hands.

Corresponding responsibility

Under <u>Health and Safety Code section 11153</u>, a pharmacist has a corresponding responsibility to ensure a prescription for a controlled substance is for a legitimate medical purpose. The law requires pharmacists to use professional judgment to determine whether a prescription is suspicious.

In an important disciplinary case, <u>In the Matter</u> of the Accusation Against Pacifica Pharmacy; <u>Thang Tran</u>, the Board of Pharmacy revoked the licenses of a Huntington Beach pharmacy and its pharmacist for failing to exercise corresponding responsibility in filling numerous questionable prescriptions for opioid medications. The case identified "red flags" that should alert the pharmacist and prompt questions about a prescription.

What are red flags?

Red flags that may prompt a pharmacist to question a prescription include:

- The prescription has irregularities on its face.
- The patient's demeanor is nervous.
- The patient's age or presentation is unusual

(e.g., youthful patient seeking chronic pain medications).

- Multiple patients provide the same address.
- The patient has multiple prescribers for duplicate therapy.
- The patient offers cash payment for the medication.
- The patient seeks early prescription refills.
- The prescription is written for an unusually large quantity of drugs.
- The initial prescription is for strong opioids.
- The patient lives far away from the area served by the pharmacy or the prescriber.
- The prescription is written outside the prescriber's medical specialty.
- The prescription has no logical connection to the patient's illness or condition.

What's a pharmacist to do?

HSC section 11153 requires pharmacists to use their professional judgment in deciding whether a prescription is suspicious. To help make that determination, a pharmacist may:

- Contact the prescriber to clarify or adjust a prescription.
- Discuss with the prescriber other medications the patient is taking or other health care practitioners the patient is seeing.
- Ask for documentation of a patient's medical condition, diagnosis or treatment plan.

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Board designates precedential case

The Board of Pharmacy has adopted as precedential portions of an administrative law decision clarifying that nonresident pharmacies are bound by California laws because they do business in California pursuant to a California license.

The decision was issued *In the matter of the Citation Against ESI Mail Pharmacy Inc., dba Express Scripts* (Case No. CI 2009 44657; OAH Case No. 2011060384). The Board adopted portions of the decision as precedential on May 8, 2019.

The case involves a challenge to a citation alleging ESI Mail Pharmacy Inc., dba Express Scripts, obstructed a patient in obtaining legally prescribed drugs. Among other issues, ESI Mail Pharmacy argued that the Board lacked authority to issue the citation because ESI Mail Pharmacy's home state is Arizona, which lacks a law providing for discipline based on obstruction of dispensing a legally prescribed medication.

The Board adopted as precedential a specific finding in the case that the Board has authority to discipline ESI Mail Pharmacy because the Board had issued a nonresident pharmacy license to the company, and therefore the company must comply with California law. In addition, Arizona pharmacy law allows administrative action based on California law relating to prescription drugs.

Under the Administrative Procedure Act, a decision that contains a significant legal or policy determination of general application that is likely to recur may be designated as precedential (Government Code section 11425.60). The Board of Pharmacy may rely on a precedential decision, and parties may cite it in argument to the Board and courts.

The decision in the ESI Pharmacy case, including the portions adopted a precedential, is posted on the <u>Precedential Decisions webpage</u> on the Board's website.

Brochure explains inspection process

A new brochure to help licensees understand and prepare for Board of Pharmacy inspections is now available on the Board's website.

"<u>Pharmacy Inspections by the California State</u> <u>Board of Pharmacy</u>" includes a list of documents that pharmacies are required to have readily available for inspectors to review. In addition, other items that an inspector will check are listed.

The brochure describes what happens if an inspector orders a correction or suspects a violation of pharmacy law. It also explains how to provide feedback about an inspection to the Board and how to file anonymous comments or a complaint with the Board's parent agency, the Department of Consumer Affairs.

To download the brochure, go to <u>www.pharmacy.</u> <u>ca.gov</u>. Click the "Licensees" tab at the top of the homepage and go to Important Information for Licenses > Publications > Pharmacy Inspections.

Renew license online fast with credit card

Most individual licensees can now renew their licenses and pay by credit card on the Board's website, <u>www.pharmarcy.ca.gov</u>.

To renew online, click the "Licensees" tab at the top of the homepage and go to "<u>Personal License</u> <u>Information/Renewal</u>." Click on the appropriate link to renew licenses online for pharmacists, pharmacy technicians, advanced practice pharmacists, and designated representatives.

For questions about renewing a license either online or by mail, contact <u>renewalstatus@dca.</u> <u>ca.gov</u>. To confirm your license expiration date, name and address of record, click on "License Search" under "Verify a License" on the website <u>homepage</u>.

Program assists pharmacists, interns with substance abuse, mental illness

Pharmacists are among the most highly educated and trained health care providers in America. Even so, pharmacists and intern pharmacists are no more immune to substance abuse or mental illness than the general public.

In fact, their access to prescription drugs and other work-related factors may place pharmacists and interns at special risk. Without treatment, substance abuse or mental illness can impair their professional judgment and jeopardize their career – or worse, a patient's life.

Fortunately, treatment is available through the Pharmacist Recovery Program established by the California State Board of Pharmacy. The program is operated under contract by Maximus Inc., a provider of health and human services programs for many local, state and federal government agencies.

The program's purpose is help pharmacists and interns recover and, if possible, return to their workplace and profession. Licensed or certified experts evaluate participants to identify the nature and severity of their chemical dependence or mental illness; develop a treatment plan; monitor

Corresponding responsibility

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- Consult medical reference materials regarding the dosing, indication or appropriateness of the prescribed medication.
- Review the patient's medication profile in CURES.
- Consider the number of pharmacies or prescribers a patient is using and the distances between those locations.
- Consider the prescriber's specialty scope of practice and the amount of medication prescribed.

their participation; and provide encouragement and support.

The Pharmacist Recovery Program accepts voluntary self-referrals. Pharmacist or interns who are experiencing alcohol or drug abuse or have a mental illness can seek treatment on their own anytime. Families, employers, friends and professional colleagues also may call the program for information and assistance.

Voluntary requests for assistance are confidential. However, confidentiality may be compromised if participants pose a threat to themselves or the public or do not improve or comply with the program; or if a case is misdiagnosed or mismanaged.

If you have a problem or work with a pharmacist or intern who does, call the Pharmacist Recovery Program toll-free number 24 hours a day: **1-800-522-9198**. Information is also available online under "<u>Important Information for Licensees</u>" on the Board's website, <u>www.pharmacy.ca.gov</u>.

<u>Read more: "Pharmacist Recovery Program – A</u> <u>Personal Experience," The Script – December 2018</u> (page 17)

• Consider the prescriber's standing with his or her licensing Board.

For more information

To learn more, visit the <u>corresponding</u> <u>responsibility page</u> on the Board's <u>website</u>: Go to Licensees > Important Information for Licensees > Corresponding Responsibility. The page includes links to a <u>corresponding responsibility brochure</u>, a <u>training video</u>, and a link to the <u>Pacifica Pharmacy</u> <u>decision</u>, which the Board has designated as precedential.

CE webinars on law, ethics are online



The Board of Pharmacy has developed and posted two continuing education (CE) webinars online to enable pharmacists to meet a new requirement for CE courses in law and ethics.

California Code of Regulations, title 16, section

<u>1732.5(b)</u> requires that at least two of the 30 hours of CE required for renewal of a pharmacist license be completed by participating in a law and ethics course provided by the Board of Pharmacy. The requirement applies to pharmacists whose licenses expire on or after July 1, 2019.

Pharmacists can find these video webinars on the <u>Law and Ethics Webinar page</u> at the Board's website, <u>www.pharmacy.ca.gov</u>. Each webinar can be viewed anytime; registration is not required. At the completion of each program, viewers are directed to download and fill out a certificate as evidence of completing the course.

The ethics webinar guides viewers through important concepts and presents scenarios reflecting ethical issues facing pharmacists in the daily practice of their profession. The law webinar is being updated to include important pharmacy laws and regulations taking effect in 2020.

For general questions about CE requirements for California pharmacists, visit the <u>Continuing</u> <u>Education Information webpage</u> on the Board's website.

Free take-back bins, disposal service are available for pharmacies

California pharmacies are eligible to receive free drug takeback bins and paid disposal service through a federally funded program intended to combat the opioid epidemic and reduce the misuse of medications.



The <u>California</u> <u>Statewide Drug</u> <u>Take-Back Program</u>

is expected to expand options for consumers to safely dispose of unused, unwanted or expired medications – including controlled substances – for humans and pets. The program is funded by the state <u>Department of Health Care Services</u> (DHCS) and administered by the <u>California</u> <u>Product Stewardship Council (CPSC)</u>.

California licensed pharmacies, hospitals and other agencies approved by the Drug Enforcement Administration can apply to receive free collection bins. The program will pay for the cost of the bins, disposal service through 2020, technical assistance, and promotion of bin locations.

For more information, including a program FAQ sheet and instructions on how to apply for a drug take-back bin, visit the California Statewide Drug Take-Back Program website at <u>www.</u> takebackdrugs.org.

Beware, protect yourself from scam calls

The Board of Pharmacy recently has issued warnings about licensees receiving scam phone calls.

How does the scam work?

Callers give themselves a fake name and claim to be Board inspectors or to be "calling from the state Board of Pharmacy." They typically claim the licensee is under investigation by the Board, the DEA, the FBI, or another government agency. The caller also may warn the licensee will face discipline unless the licensee pays a "fine."

In some cases, callers warn the licensee not to report the call to anyone "or else you will jeopardize the investigation." They also may give a fake call-back number or ask for the licensee's cell phone number.

These calls are scams – attempts to extort money from licensees.

The Board of Pharmacy has emailed subscriber alerts and posted <u>information about scam calls</u> online. The Department of Consumer Affairs (DCA) also has reported <u>attempted fraud schemes</u> <u>targeting its licensees.</u>

What can you do to protect yourself?

Licensee security is an important matter. How can you be sure anyone who contacts you on behalf of the Board of Pharmacy or any government agency is legitimate? Here are some important tips from the Board and DCA:

- A Board inspector will never call to ask you to pay a fine to the inspector.
- If you have doubts or any questions about a Board inspector's identity, contact the California State Board of Pharmacy at (916) 518-3100.
- If someone claims to be a Board inspector, ask to see the inspector's badge and business card issued by the Board of Pharmacy.
- Contact the DCA at (800) 952-5210 to find out if an official investigation is being conducted.



- If the caller claims to represent the DEA or the FBI, report the call to the <u>DEA's</u> <u>Extortion Scam reporting program</u> or the <u>FBI's Internet Crime Complaint Center</u>.
- If the caller's phone number appears to be a Board of Pharmacy or DCA telephone number, report the scam using the <u>Federal</u> <u>Communications Commission's consumer</u> <u>complaint form.</u>

A reminder about your address of record:

Licensed individuals are required to provide an address of record to the Board of Pharmacy. (The address of record does not have to be a home address, although you must also separately provide the Board with your home address.) In addition, <u>Business and Professions Code section</u> <u>4100</u> requires licensees to notify the Board of any change of address of record or change of name within 30 days.

Addresses of record do not appear in a public search of license records on the Board's website. The Board decided in July 2019 to remove this information from online view in the interest of protecting licensees in their homes from privacy violations.

<u>However, addresses of record are public</u> <u>information by law</u> and disclosable upon request pursuant to the California Public Records Act.

Board welcomes new leaders, members

In recent months the Board of Pharmacy has chosen new leadership and welcomed two new members following the departure of several others.

Members elected Greg Lippe as president and Debbie Veale as vice president in November 2019. Mr. Lippe succeeded Victor Law, who resigned from the Board as president in July. The new officers will serve the remainder of terms that expire in 2020.

In January 2020, the Board announced the appointment of Anne Sodergren as executive officer. Ms. Sodergren, who has more than 25 years of service with the Board, previously served as interim executive officer since the retirement of Virginia Herold in December 2018.

The Board also has welcomed two licensee members appointed by Governor Gavin Newsom in February – Seung Oh of San Diego and Jignesh "Jig" Patel of Roseville.

Mr. Oh, 32, has been pharmacist-in-charge at Vons Pharmacy in Liberty Station, San Diego, since 2014. He was owner and founder of Oh Creative Solutions from 2015 to 2016, a staff pharmacist at Safeway Pharmacy in 2014, and a pharmacist and director of operations at Rainbow Pharmacy from 2013 to 2014. Mr. Patel, 42, has been a division pharmacy manager for Safeway NorCal Division since 2006. He has held several positions at Safeway since 1999, including pharmacy manager, pharmacist, intern pharmacist, and pharmacy technician.

Meanwhile, three other members have recently left the Board in addition to Mr. Law, a licensee who served since 2012.

Stanley C. Weisser's term expired in June 2019. Mr. Weisser, a licensee, served 12 years on the board, including five terms as president. In 2016, the National Association of Boards of Pharmacy presented Mr. Weiser with its highest honor, the Lester E. Hosto Distinguished Service Award, for his commitment to protecting public health.

Amjad Mahmood Khan, a public member who joined the Board in 2017, resigned in August 2019. Mr. Khan is a lawyer in Los Angeles and also an adjunct professor at UCLA Law School.

Valerie Muñoz resigned from the Board in February 2020. Ms. Muñoz, a public member who joined the Board in 2016, is a City Council member and former mayor of La Puente.

Board moves to new Sacramento office

On July 1, 2019, the California State Board of Pharmacy moved to a new location in Sacramento that consolidates most of its staff into a single suite while providing space for possible future expansion.

The new address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833. The main phone number is (916) 518-3100. The main fax number remains unchanged, (916) 574-8618. The office is open from 8 a.m. to 5 p.m. Monday through Friday, excluding state holidays.

Contact information can be found on the Board's website, <u>www.</u> <u>pharmacy.gov</u>. Click on the <u>Contact Us</u> link at the bottom of the homepage for a map with directions to the new office.



Board consolidates meeting schedule to coincide with committee dates

The Board of Pharmacy is consolidating its Board and committee meeting schedules to better streamline operations.

Instead of setting independent meeting dates throughout the year, most committees will meet on the first day of quarterly two-day Board meetings. The second day will be devoted to meetings of the entire Board, including a report and discussion of information from the previous day's committee meetings.

One committee meeting annually will be scheduled independently of the Board meeting. At these meetings, each committee will establish its policy goals – which will support the Board's strategic plan

 for the upcoming year. At each subsequent committee meeting, staff will report on the progress of policy goals.

In addition, a committee may occasionally schedule independent meetings if



necessary to handle its workload.

Dates, agendas, materials and other information about <u>Board</u> <u>and committee meetings</u> are posted under "Meetings" on the Board's website, <u>www.pharmacy.</u> <u>ca.gov</u>.

Stay informed about the Board sign up for news, information alerts

The Board of Pharmacy has begun sending subscriber alerts about Board activities and events to a new email listserv called News and Information. Subscribers will receive notifications about Board and committee meetings, Board activities, rulemakings, new laws and regulations, press releases, consumer tips, and other general news and information.

The Board will no longer send this type of information to facilities, in an effort to reduce the volume of subscriber alerts received by pharmacies and other licensed sites. However, notices of drug product recalls and other relevant notifications will continue to be sent to facilities. Anyone may register an email address to receive News and Information subscriber alerts. To sign up, visit the <u>Board of Pharmacy Email Registration</u> page at <u>www.pharmacy.ca.gov</u>.

Reminder to licensees: As required by regulations, all <u>facilities</u>, <u>pharmacists</u>, <u>intern</u> <u>pharmacists</u>, <u>pharmacy technicians</u> and <u>designated representatives</u> MUST register their email address for subscriber alerts. Licensees may sign up for email alerts by license type on the Board's email registration webpage.

Board congratulates pharmacists for four decades of active service

The Board of Pharmacy proudly celebrates its licensed pharmacists who have dedicated 40 or more years of service to California consumers. The Board gratefully acknowledges their decades of contributions to the pharmacy profession.

In honor of their service, the names of <u>pharmacists who have been on active status for at least 40 years</u> are posted on the Board's website. In addition, these pharmacists will receive certificates and invitations to be recognized at Board meetings.

Pharmacists recognized at recent Board meetings include:



Donna Wong Ouchida



Fredrick Lloyd Meister



Gene Tsukamoto



Helen Mizrahie-Jonah



Joseph Grasela



Philip Kai-Kwong Zia



Robert S. Rashkow



Steven Jay Thompson

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California State Board of Pharmacy



Attend board, committee meetings to earn CE credit, participate in public policy

Want to learn about the California State Board of Pharmacy and participate in making policy? Attend a meeting!

Information about all <u>board and</u> <u>committee meetings</u> – including dates, locations, agendas and materials that include background information for agenda items – is available at the <u>Board of</u> <u>Pharmacy website</u>.

Board meeting agendas are posted at least 10 days before meetings. Background materials for agenda items typically are available online about five days before meetings.

For most Board meetings, pharmacists and pharmacy technicians who attend a full-day meeting on the designated date may be awarded six CE hours per renewal period. To receive CE credit, licensees must sign in and out on an attendance sheet at the meeting. Check the Board's agenda to determine which dates are eligible for CE hours.

Pharmacists and pharmacy technicians who sign in and out also may earn two hours of CE credit for attending a full committee meeting per renewal period.

To stay informed about all meeting schedules, agendas, and materials, sign up to receive <u>News</u> and Information subscriber alerts from the Board.

Board meetings scheduled in 2020:

- May 6-7 Department of Consumer Affairs hearing room, 1625 N. Market Blvd., Sacramento, CA 95834.
- June 18 Location to be determined.
- July 29-30 Location to be determined.
- September 17 California State Board of Pharmacy hearing room, 2720 Gateway Oaks Drive, Sacramento, CA 95833.
- October 27-28 Department of Consumer Affairs hearing room, 1625 N. Market Blvd., Sacramento, CA 95834.
- **December 3** Location to be determined.

When feasible, board meetings are webcast at the <u>Department of</u> <u>Consumer Affairs webcast page</u>.

Contact <u>The Script</u>

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.

UNION LABEL

Attachment D

Other Information

Case Summaries

Application Type TCH	<u>Description</u> Applicant was convicted on multiple occasions for driving under the influence of two (twice), domestic violence, and grand theft within a two year period.
ТСН	Applicant was convicted on two occasions for receiving stolen property and
ТСН	Applicant was convicted on multiple occasions for tampering with a vehicle, public intoxication, trespassing, and driving unde rthe influence of drugs.
ТСН	Applicant was arrested for using a stolen credit card to make fraudulent purchases. The applicant completed a diversion and the criminal case was
ТСН	Applicant was convicted on multiple occasions for possession and being under the influence of a controlled substance (methamphetamine) and theft.
ТСН	Applicant's previous license was voluntarily surrendered following a conviction for assault with a deadly weapon. Upon reapplication, the applicant was evaluated by a clinical psychologist and found to have an impaired abililty to
RPH	Applicant was convicted in another state of driving with a blood alcohol concentration of .20. The applicant's out-of-state license was revoked, in part, for the applicant's failure to cooperate with the other state's investigation.
ТСН	Applicant was convicted of driving under the influence of alcohol and Xanax. The applicant's blood alcohol concentration of .20
TCH	Applicant was convicted of sexual battery.
ТСН	Applicant's pharmacy technician registration was revoked by another state based on the applicant's passing of a forged prescription for Xanax. The applicant admitted to developing a dependence to alcohol, benzodiazapines,
ТСН	Applicant was convicted of driving under the influence of alcohol on two occasions. The applicant's blood alcohol concentrations were .22 and .15.
ТСН	Applicant was convicted of acquiring a credit card by fraud, and burglary. Applicant admitted to using a stloen credit card to buy merchandise which was then returned for cash and used to purchase methamphetamine. The applicant
TCH	Applicant was convicted of theft and admitted to stealing to support his opioid
ТСН	Applicant was convicted on multiple occasions for driving under the influence of alcohol (BAC .17), possession of a controlled substance, and possession of
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
ТСН	Applicant was convicted of conspiracy to commit wire fraud and ordered to pay over \$8 million in restitution.
ТСН	Applicant was convicted twice of driving under the influence of alcohol. The applicant's blood alcohol concentrations were .20 and .22.

INT	Applicant was convicted of driving under the influence of alcohol. The applicant's blood alcohol concentration was .20.
PHY	Application was denied on grounds the sale was not a good faith, arms-length
LSC	Application was denied on grounds the sale was not a good faith, arms-length
LSC	Application was denied based on a pending investigation against another pharmacy with common ownership.
ТСН	Applicant was convicted of driving under the influence of alcohol. The applicant's blood alcohol concentration was .21.
RPH	Application was denied due to the submission of fraudulent intern hours.
ТСН	Applicant was convicted of driving under the influence of alcohol. The applicant's blood alcohol concentration was .32.
ТСН	Applicant was convicted of lewd conduct.
ТСН	Applicant was convited of driving under the influence and hit and run. The applicant's blood alcohol concentration was .20. This conviction was not
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
RPH	Applicant was convicted of driving under the influence of alcohol on three occasions. In addition, the applicant's license in another state was placed on probation following an admission to diverting controlled substances for self use.
ТСН	Application was denied due to submission of a fraudulent high school transcript.
ТСН	Applicant was convicted on two occasions for carrying a loaded firearm and driving under the influence of alcohol. The applicant's blood alcohol
ТСН	Applicant was convicted of conspiracy and submitted a fraudulent insurance
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
OSF	Application was denied based on a pending investigation against another pharmacy with common ownership.
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.

WLS	Application was denied based on a pending investigation against another pharmacy with common ownership.
RPH	Application was denied based on allegations of examination misconduct.
ТСН	Applicant was convicted on two occasions of being under the influence of a controlled substance and possession of carrying a concealed weapon while
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
OSF	Application was denied based on a failed outsourcing facility inspection.
ТСН	Applicant was convicted of driving under the influence of alcohol on three occasions. The applicant's blood alcohol concentrations were .15 and .25 (no
ТСН	Applicant was convicted on two occasions of grand theft and embezzlement of
ТСН	Application was denied based on the submission of a fraudulent PTCB certificate.
ТСН	Applicant was convicted of driving under the influence of alcohol. The applicant's blood alcohol concentration was .36
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
РНҮ	Application was denied based on a pending investigation against another pharmacy with common ownership.
РНҮ	Application was denied based on applicant pharmacy's failure to engage in normal activity during the period the temporary license was in effect.



CALIFORNIA STATE BOARD OF PHARMACY