



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



Notice of Meeting and Agenda Teleconference Public Board Meeting

DATES & TIMES: July 29, 2020, 10:00 a.m.
July 30, 2020, 9:00 a.m.

NOTE: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-29-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

INSTRUCTIONS FOR OBSERVATION:

WEBCAST: <https://thedcapage.blog/webcasts> Webcast will be available at 10:00 a.m. on July 29, 2020 and 9:00 a.m. July 30, 2020.

FOR PUBLIC COMMENT, PLEASE LOG ON TO THIS WEBSITE

July 29, 2020 - <https://dca-ca.webex.com/dca-ca/onstage/g.php?MTID=e310aafea199400d385dfb310bf52b72f>

July 30, 2020 - <https://dca-ca.webex.com/dca-ca/onstage/g.php?MTID=ed1a1ef3a00f6179eabb1635f0dabf536>

The preferred audio connection is via phone bridge. The phone number and access code will be provided as part of your connection to the meeting. General instructions for using WebEx can be found at the end of the agenda.

Important Notices to the Public: The Board of Pharmacy will hold a meeting via WebEx – access information is provided above. General instructions for using WebEx are attached to the agenda. The meeting is open to the public. Members of the public may but are not obligated to provide their names or personal information as a condition of observing or participating in the meeting. When signing into the WebEx platform, participants may be asked for their name and email address. Participants who choose not to provide their names will need to provide a unique identifier such as their initials or another alternative, so that the meeting moderator can identify individuals who wish to make public comment; participants who choose not to provide their email address may utilize a fictitious email address like in the following sample format: XXXXX@mailinator.com. The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Debbie Damoth at (916) 518-3090, by emailing debbie.damoth@dca.ca.gov or sending a written request to the Board of Pharmacy, 2720 Gateway Oaks Drive, Suite 100, Sacramento CA 95833. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Discussion and action may be taken on any item on the agenda. The time and order of agenda items are subject to change at the discretion of the Board President. In the event a quorum of the board is unable to attend the meeting, or the board is unable to maintain a quorum once the meeting is called to order, the members present may, at the president's discretion, continue to discuss items from the agenda and make recommendations to the full board at a future meeting.

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the Board or prior to the Board taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issues before the board, but the president may, at his discretion, apportion available time among those who wish to speak. If public comment is not specifically requested, members of the public should feel free to request an opportunity to comment. Individuals may appear before the Board to discuss items not on the agenda; however, the Board can neither discuss nor take official action on these items at the time of the same meeting (Government Code sections 11125, 11125.7(a)). The Board plans to webcast this meeting on its website at www.pharmacy.ca.gov. Webcast availability cannot, however, be guaranteed due to limited resources or technical difficulties. The meeting will not be cancelled if webcast is not available. Using the WebEx link will allow for participation and observation. Using the Webcast link will allow for observation with closed captioning. Adjournment, if it is the only item that occurs after a closed session, may not be broadcast in any medium.

Agenda

Wednesday, July 29, 2020

Call to Order

10:00 a.m.

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Approval Board Meeting Minutes

- a. June 18, 2020, Board Meeting

IV. Update from the Department of Consumer Affairs

V. Discussion and Consideration of Adoption of Board Approved Regulations, Comments Pending Review by the Board

- a. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

VI. Licensing Committee Report

The Board will review a summary of the committee's work at its July 8, 2020, meeting, as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Legislative Proposal to Expand Existing Authority for Pharmacists to Order and Administer Immunizations Approved by the FDA for the Prevention of Vaccine-Preventable Diseases
- b. Discussion and Consideration of Pharmacists' Authority to Perform CLIA Waived Tests for COVID-19
- c. Update on Implementation of SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis
- d. Discussion and Consideration of Proposal to Develop a Temporary Closure Status and Mandatory Notification Requirement for Board Licensed Sites

- e. Discussion and Consideration of Proposed Amendments to Title 16, California Code of Regulations Section 1704, Change of Address
- f. Licensing Statistics

VII. Enforcement and Compounding Committee Report

The Board will review a summary of the committee's work at its July 9, 2020, meeting as well as updates for discussion and action as necessary.

- a. Summary of Presentation and Discussion on the Administrative Case Process
- b. Summary of Presentation and Discussion on the Board's Citation and Fine Program
- c. Summary of Presentation and Discussion on Inspections Performed by the Board
- d. Enforcement Statistics

VIII. Communication and Public Education Committee Report

The board will review a summary of the committee's work at its July 8, 2020, meeting as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Communication Plan Regarding SB 159 (Wiener, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis
- b. Discussion and Consideration of Providing Information about Possible Consequences of DUI Conviction on License Renewal Notices
- c. Update on Communication and Public Education Activities by Staff
 - 1. *The Script*
 - 2. Projects
 - a) Online registry of services
 - b) Notice to Consumer poster
 - c) Disciplinary Case Summaries
 - 3. Board-provided Training
 - 4. News Media
 - 5. Public Outreach

IX. Legislation and Regulation Committee Report

The Board will review a summary of the committee's work at its July 8, 2020, meeting, as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Petition Submitted to the Board for Interpretative Ruling or Policy Statement Regarding Mandatory Reporting Provision of Penal Code Section 11160 and its Applicability to Community Pharmacists
- b. Discussion and Consideration of Pharmacy Security Requirements
- c. Discussion and Consideration of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations
 - 1. Assembly Bill 1710 (Wood) Pharmacy Practice: Vaccines
 - 2. Assembly Bill 2028 (Aguilar-Curry) State Agencies: Meetings
 - 3. Assembly Bill 2077 (Ting) Hypodermic Needles and Syringes
 - 4. Assembly Bill 2113 (Low) Refugees, Asylees, and Immigrants: Licensing
 - 5. Assembly Bill 2549 (Salas) Department of Consumer Affairs: Temporary Licenses
 - 6. Assembly Bill 2983 (Holden) Pharmacies: Automatic Refills
 - 7. Assembly Bill 3045 (Gray) Department of Consumer Affairs: Boards: Veterans
 - 8. Assembly Bill 3342 (Bauer-Kahan) Child Day Care Facilities: Epinephrine Auto Injectors
 - 9. Senate Bill 878 (Jones) Department of Consumer Affairs Licensing: Applications

- 10. Senate Bill 1474 (Committee on Business, Professions and Economic Development)
 - d. Board Adopted Regulations Approved by the Office of Administrative Law
 - 1. Proposed Regulation to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1707.2 Related to Duty to Consult
 - e. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law
 - 1. Proposed Regulation to Add Title 16, Section 1714.3, Community Pharmacy Staffing
 - 2. Proposed Regulation to Amend Title 16, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria
 - f. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumers Affairs or the Business, Consumer Services and Housing Agency
 - 1. Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements
 - 2. Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage
 - g. Discussion and Consideration of Board Approved Regulations Undergoing Public Comment
 - 1. Proposed Regulations to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of Receipt and Delivery of Prescriptions and Prescription Medications, and Add Section 1715.1 Related to ADDS Self-Assessment Form 17M-112
 - 2. Proposed Regulation to Add Title 16 CCR Section 1717.5 Related to Automatic Refill Programs
 - h. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency
 - 1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
 - 3. Proposed Regulation to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26
 - 4. Proposed Permanent Regulation to Add and Amend Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
 - 5. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation
 - 6. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses
 - i. Discussion and Consideration of Board Approved Text to Initiate Rulemaking –Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency
 - 1. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

X. Organizational Development Committee Report

- a. CE policy for attendance at Committee and Board Meetings
- b. Budget Update and Report
- c. DCA Annual Pro Rata Report
- d. Board Member Attendance Information
- e. Personnel Update
- f. Meeting Calendar for Remainder of 2020
- g. Proposed Meeting Calendar for 2021

XI. Executive Officer's Report

- a. Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies
- b. Update on the CURES System and implementation of AB 149 (Cooper, Chapter 4, Statutes of 2019)
- c. Updates on National Issues
 1. FDA Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products
 2. Summary of the Annual Meeting of the National Association of Boards of Pharmacy

XII. Review of Policy Granting President Discretion to Waive Provisions of Pharmacy Laws Pursuant to Business and Professions Code section 4062, Including the Authority to Extend Waivers

XIII. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code section 4062

- a. Consideration and Possible Extensions of Waivers
 1. Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5)
 2. Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6))
 3. Requirement for Consulting Pharmacist to Perform Visits to Clinic (BPC section 4182(a) & (b) and section 4192(a) & (b))
 4. USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8)
 5. Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (Title 16, California Code of Regulations, section 1751.5)
 6. 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)
 7. 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
 8. Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))
 9. Remote Processing (BPC section 4071.1(a))

XIV. Presentation, Discussion and Consideration of Published Research, Examining Students' Attitudes toward Academic Dishonesty in California Pharmacy Schools

XV. Discussion and Consideration for Board Approval of Proposed Board Provided Training Program as Required by SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

XV. Closed Session Matters

- a. Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters, Including Proposed Decisions, Stipulated Decisions, Defaults, Petitions for Reductions in Penalty, and Any Other Disciplinary Matters
- b. Pursuant to Government Code Section 11126(e), the Board Will Convene in Closed Session to Discuss Pending Litigation
- c. Pursuant to Government Code Section 11126(c)(1), the Board Will Convene in Closed Session to Consider the Preparation, Approval, Grading or Administration of One or More Licensing Examination(s)

XVI. Reconvene Open Session

Adjournment

Upon conclusion of business

Due to technological limitations, adjournment will not be broadcast. Adjournment will immediately follow closed session, and there will be no other items of business discussed.