



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: January 27, 2021, 4:00 p.m.
January 28, 2021, 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 4:00 p.m. on January 27, 2021, and 9:00 a.m. January 28, 2021.

FOR PUBLIC COMMENT, PLEASE LOG ON TO THIS WEBSITE

January 27, 2021 - <https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=e8609b6f3cd16a1fbb77d12c7350e3c8c>

January 28, 2021 - <https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=e0dcab3c8c736e5e2622e6a7517add5f7>

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.

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

Discussion and action may be taken on any agenda item.

Wednesday, January 27, 2021

Call to Order

4:00 p.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. Update from the Department of Consumer Affairs

IV. Approval Board Meeting Minutes

- a. October 27-28, 2020, Board Meeting
- b. November 19, 2020, Board Meeting
- c. December 3, 2020, Board Meeting
- d. December 10, 2020 Board Meeting

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

- a. Consideration of Site-Specific Waiver
 1. CDPH Alternative Care Facility – Sacramento (Sleep Train Arena), HPE 57779
 2. LACC No 1 Pharmacy, PHY 57875
 3. McKesson Medical Surgical, Inc. NPL 1258

VI. Update on Pharmacist Licensure Examination Audit Performed by the Office of Professional Examination Services

VII. 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)

VIII. Reconvene Open Session, to Adjourn for the day

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.

IX. Licensing Committee Report

The Board will review a summary of the committee's work at its January 27, 2021, meeting, as well as updates for discussion and action as necessary.

- a. Summary of Presentation by University of California Schools of Pharmacy Related to Academic Dishonest
- b. Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacists to Order and Administer CLIA Waived Tests for Influenza and COVID
- c. Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacy Technicians to Administer COVID-19 and Influenza Vaccines.
- d. Discussion and Consideration of Board's Current Policy Related to Authority for Pharmacy Technicians to Administer Vaccines to Determine if Inclusion of Additional Vaccines is Appropriate
- e. Discussion and Consideration of Draft Pharmacist Workforce Survey
- f. Discussion and Consideration of Waiver Request of Business and Professions Code Section 4131(b) Related to the Location of the Supervising Pharmacy and Remote Dispensing Site Pharmacy
- g. Review and Discussion of Licensing Statistics
- h. Future Committee Meeting Dates

X. Enforcement and Compounding Committee Report

The Board will review a summary of the committee's work at its January 20, 2021, meeting as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Presentation on the Pharmacist Recovery Program
- b. Discussion and Consideration of Board Policy Related to Transparency Involving the Issuance of Citations and Fines
- c. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms
 - a. Community Pharmacy/Hospital Out-Patient Self-Assessment (17M-13)
 - b. Compounding Self-Assessment (17M-39)
 - c. Hospital Pharmacy Self-Assessment (17M-14)
 - d. Wholesaler Dangerous Drugs and Devices Self-Assessment (17M-26)
 - e. Automated Drug Delivery System Self-Assessment (17M-112)
- d. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model
- e. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substances Schedules
- f. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products

- g. Discussion and Consideration of FDA Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry
- h. Discussion and Consideration of the Compounding of Methylcobalamin
- i. Review and Discussion of Enforcement Statistics
- j. Future Committee Meeting Dates

XI. Communication and Public Education Committee Report

The Board will review a summary of the committee’s work at its January 27, 2021 meeting, as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Possible Changes to the Notice to Consumers Poster/Display
- b. Discussion and Consideration of Requirement for Pharmacies to Provide a Telephone Number on Prescription Labels
- c. Discussion and Consideration of Developing Information Materials about the Board of Pharmacy for Consumers
- d. Update on Communication and Public Education Activities by Staff
 - 1. The Script
 - 2. Board-provided Training
 - 3. Staff Outreach
 - 4. News Media
- e. Future Meeting Dates

XII. Legislation and Regulation Committee Update

The Board will receive an update from the Committee Chair.

- a. Board Adopted Regulations Approved by the Office of Administrative Law
 - 1. Proposed Regulation to Amend Title 16, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria
- b. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law
 - 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
 - 3. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers
- c. 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 Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112
- d. 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 Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
 - 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 Reporting Drug Losses
- e. 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 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 1704 Related to Address Change Notification
 3. Proposed Regulation to Add Title 16 Section 1708.1 Related to the Temporary Closure of Facilities
- h. Future Committee Meeting Dates

XIII. Organizational Development Committee Report

- a. Budget Update and Report
- b. Board Member Attendance Information
- c. Personnel Update
- d. Meeting Calendar for 2021

XIV. Discussion and Possible Board Action for the Increase in the Exempt Level and Salary of the Executive Officer Position

XV. Executive Officer Report

- a. Discussion of Board’s Response to COVID-19 Pandemic and Actions Taken by Other Agencies
- b. Update on Implementation of Controlled Substances Security Forms as required by Assembly Bill 149 (Statutes of 2019)

XVI. 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)

Reconvene Open Session, if necessary

XIV. Adjournment

Upon conclusion of business

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