



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: April 29, 2021, 3:00 p.m.
April 30, 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 3:00 p.m. on April 29, 2021, and 9:00 a.m. April 30, 2021.

FOR PUBLIC COMMENT, PLEASE LOG ON TO THIS WEBSITE

April 29, 2021 - <https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=ef141b2725f76a123ab84f657c387aad8>

April 30, 2021 - <https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=e1f84aa9bbc6fc7b33786fdd0ec964f4b>

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.

Thursday, April 29, 2021

Call to Order

3:00 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. Approval Board Meeting Minutes

- a. January 27-28, 2021, Board Meeting
- b. March 18, 2021, Board Meeting
- c. October 27-28, 2020, Board Meeting, Correction to Previously Approved Minutes

IV. Update from the Department of Consumer Affairs

V. Board Officer Elections

VI. Organizational Development Committee Report

- a. Budget Update and Report
- b. Board Member Attendance Information
- c. Update to the Board Member Procedure Manual
- d. Personnel Update
- e. Meeting Calendar for 2021
- f. Proposed Meeting Calendar for 2022

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. Communication and Public Education Committee Report

The Board will review a summary of the committee's work at its April 29, 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 Self-Assessment Process
- c. Update on Communication and Public Education Activities by Staff
 - 1. The Script
 - 2. Staff Outreach
 - 3. News Media
- d. Future Meeting Dates

X. Licensing Committee Report

The Board will review a summary of the committee's work at its April 21, 2021, meeting, as well as updates for discussion and action as necessary.

- a. Summary of Presentation by the Accreditation Council for Pharmacy Education on Academic Dishonesty Including Accreditation Standards
- b. Summary of Presentation, Discussion and Consideration of California Schools of Pharmacy Policies Related to Academic Dishonesty and Code of Conduct
- c. Summary of Presentation, Discussion, and Consideration of Report by the Office of Professional Examination Services Documenting Results of Audits of the NAPLEX and CPJE Examinations
- d. Summary of Presentation by the National Association of Boards of Pharmacy on the Multistate Pharmacy Jurisprudent Examination (MPJE)
- e. Discussion and Consideration of Pharmacist Licensure Examinations as required by Business and Professions Code Section 4200
- f. Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacists to Order and Perform Tests
- g. Discussion and Consideration of Draft Pharmacist Workforce Survey
- h. Discussion and Consideration for Approval, Changes to Proposed Board Provided Training Program. Pursuant to Business and Professions Code Sections 4052.02(b), 4052.03(b)(3) Related to Furnishing HIV Preexposure (PrEP) and Postexposure (PEP) Prophylaxis
- i. Review and Discussion of Licensing Statistics
- j. Future Committee Meeting Dates

XI. Enforcement and Compounding Committee Report

The Board will review a summary of the committee's work at its February 18, 2021 and April 22, 2021, meetings as well as updates for discussion and action as necessary.

- a. Summary and Discussion on the Informational Meeting on "White Bagging"
- b. Summary of Presentation on the National Association of Boards of Pharmacy, Compounding Data Sharing Project
- c. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products
- d. Discussion and Consideration of Compounding with Components or Other Materials that Could Result in Insanitary Conditions as Established in the FDA Insanitary Conditions at Compounding Facilities Guidance for Industry
- e. Discussion and Consideration of Opportunities to Improve Naloxone Accessibility through Auxiliary Labels for Opioid Prescriptions
- f. Discussion and Consideration of Assembly Bill 2789 (Wood, Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission
- g. Discussion and Consideration of Federal Food and Drug Administration Final Rule Related to Importation of Certain Canadian Prescriptions Drugs
- h. Summary of Presentation by the Office of the Attorney General on the Annual Report to the Legislature Pursuant to Business and Professions Code Section 312.2
- i. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model
- j. Review and Discussion of Enforcement Statistics
- k. Future Committee Meeting Dates

XII. Legislation and Regulation Committee Update

The Board will review a summary of the committee's work at its April 29, 2021 meeting, as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Assembly Bill 5 (Gonzalez, Chapter 296, Statutes of 2019)
- b. Discussion and Consideration of Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations
 1. Assembly Bill 2 (Fong) Regulations: Legislative Review: Regulatory Reform
 2. Assembly Bill 29 (Cooper) State Bodies: Meetings
 3. Assembly Bill 69 (Kiley) State of Emergency: Termination After 60 Days
 4. Assembly Bill 107 (Salas) Licensure: Veterans and Military Spouses
 5. Assembly Bill 225 (Gray) Department of Consumer Affairs: Veterans: Spouses
 6. Assembly Bill 527 (Wood) Controlled Substances
 7. Assembly Bill 646 (Low) Department of Consumer Affairs: Boards: Expunged Convictions
 8. Assembly Bill 657 (Bonta) State Civil Service System: Personal Services Contracts
 9. Assembly Bill 671 (Wood) Medi-Cal: Pharmacy Benefits
 10. Assembly Bill 846 (Low) Controlled Substances: CURES Database
 11. Assembly Bill 1064 (Fong) Pharmacy Practice: Vaccines: Independent Initiation
 12. Assembly Bill 1236 (Ting) Healing Arts: Licensees: Data Collections
 13. Assembly Bill 1328 (Irwin) Clinical Laboratory Technology and Pharmacists
 14. Assembly Bill 1430 (Arambula) Pharmacy: Dispensing Controlled Substances
 15. Assembly Bill 1533 (Assembly Business and Professions Committee) State Board of Pharmacy:

Appointment Removal

16. Senate Bill 306 (Pan) Sexually Transmitted Disease: Testing
 17. Senate Bill 362 (Newman) Community Pharmacies: Quotas
 18. Senate Bill 409 (Caballero) Pharmacy Practice: SARS-CoV-2 and Influenza Testing
 19. Senate Bill 524 (Skinner) Health Care Coverage: Patient Steering
 20. Senate Bill 731 (Durazo) Criminal Records: Relief
- c. Board Adopted Regulations Approved 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 Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers
- d. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law
1. Proposed Regulation to Amend Title 16 Section 1707, Off-Site Storage
 2. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs
 3. 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
- e. 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 Permanent Regulation to Add and Amend Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
- f. 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 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
 3. Proposed Regulation to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
 4. Proposed Regulation to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26
 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
 7. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification
 8. Proposed Regulation to Add Title 16 Section 1708.1 Related to the Temporary Closure of Facilities
- g. 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 1735.2 to Update the Compounding Self-Assessment Form 17M-39
- h. Future Committee Meeting Dates

XIII. Executive Officer Report

- a. Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies

- b. Appointment to Advisory Committee on Examinations (ACE)
- c. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacist Licensure Examination (NAPLEX)

XIV. Closed Session Matters

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- 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

XV. 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.