

California State Board of Pharmacy

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Business, Consumer Services and Housing Agency Department of Consumer Affairs Gavin Newsom, Governor



Notice of Teleconference Meeting and Agenda Public Board Meeting

DATES & TIMES: April 19, 2023, 1:00 p.m.

April 20, 2023, 9:00 a.m.

Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided

FOR PUBLIC PARTICIPATION AND COMMENT, PLEASE LOG ON TO WEBEX AS SPECIFIED BELOW:

April 19, 2023 - To access the WebEx event, attendees will need to click the following link and enter a first name, last name, email, and the event password listed below:

https://dca-meetings.webex.com/dca-

meetings/j.php?MTID=m9ccb026bedfa2e728d246d55f32b33e4

If joining using the link above

Webinar number: 2491 235 8911 Webinar password: CSBP04192023

If joining by phone

+1-415-655-0001 US Toll

Access code: 249 123 58911

Passcode: 27270419

April 20, 2023 - To access the WebEx event, attendees will need to click the following link and enter their first name, last name, email, and the event password listed below:

https://dca-meetings.webex.com/dca-

meetings/j.php?MTID=me762c020a1c87031c584fa4107c745cc

If joining using the link above

Webinar number: 2490 809 9898 Webinar password: CSBP04202023

If joining by phone

+1-415-655-0001 US Toll

Access code: 249 080 99898

Passcode: 27270420

Members of the public participating via WebEx will be able to hear the meeting and provide public comment but may not be able to observe the meeting. 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.

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 in the following sample format: XXXXX@mailinator.com.

Important Notices to the Public: The Board of Pharmacy will hold a teleconference meeting via WebEx – access as provided above. General instructions for using WebEx are included in 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. 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 pursuant to Business and Professions Code section 4309(c), 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)). 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.

April 19, 2023

Call to Order 1:00 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. Recognition and Celebration of Pharmacists Licensed in California for 40 years and other Recognitions
- IV. Approval of Board Meeting Minutes
 - a. February 6-7, 2023, Board Meeting
 - b. March 15, 2023, Board Meeting
- V. <u>Update from the Department of Consumer Affairs</u>
- VI. Board Officer Elections
- VII. <u>Discussion and Consideration of Waiver of Pharmacy Law Provisions Consistent with the Authority in Business and Professions Code Section 4062 In Response to the Federal State of Emergency Related to COVID-19</u>
- VIII. <u>Discussion, Consideration and Possible Action Related to Proposed Regulations to Amend Title 16, California Code of Regulations Section 1715.1 and Automated Drug Delivery System Self-Assessment (Form 17M-112), Including Comments Received During 15-Day Public Comment Period</u>
- IX. <u>Discussion, Consideration and Possible Action Related to Proposed Regulations to Amend Title 16, California Code of Regulations Section 1707.6, Including Any Comments Received During the 45-Day Comment Period</u>
- X. Organizational Development Committee Report
 - a. Budget Update and Report
 - b. Board Member Attendance and Mail Vote Information
 - c. Personnel Update
 - d. Future Meeting Dates

XI. Medication Error Reduction and Workforce Committee

The Board will review a summary of some of the Committee's work at its March 8, 2023, meeting as well as updates for discussion and action as necessary.

- a. Summary of Presentation, Alliance for Quality Improvement and Patient Safety, on Patient Safety Organizations
- b. Discussion and Consideration of Pharmacist Well-Being Index State Report

XII. 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(c)(1), the Board Will Convene in Closed Session to Consider the Preparation, Approval, Grading or Administration of One or More Licensing Examination(s)

XIII. 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.

XIV. Enforcement and Compounding Committee Report

The Board will review a summary of the Committee's work at its January 23, 2023, February 15, 2023, March 23, 2023, and April 13, 2023, meetings as well as updates for discussion and action as necessary.

- a. Summary of Presentations of on US Pharmacopeia (USP) General Chapters including:
 - 1. USP Chapter 825 Regarding Radiopharmaceuticals
 - 2. USP Chapter 795 Pharmaceutical Compounding Nonsterile Preparations
 - 3. USP Chapter 797, Pharmaceutical Compounding Sterile Preparations
 - 4. USP Chapter 800, Hazardous Drugs Handling in Healthcare Settings
- b. Discussion, Consideration and Possible Action on Proposed Changes to Regulations as follows:
 - Proposed Addition to Title 16, California Code of Regulations Section 1738 –
 1738.14 Regulations Related to Radiopharmaceuticals
 - Amend Title 16 Article 4.5 and Repeal and Replace existing Sections 1735, 1735.1, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7 1735.8 and Adopt New Titles and Sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8, 1735.9, 1735.10, 1735.11, 1735.12, 1735.12, 1735.13 and 1735.14, Related to Pharmaceutical Compounding of Nonsterile Preparations
 - 3. Repeal Article 7 and Sections 1751-1751.10 and add new Article 4.6, Add New Titles and Sections 1736-1736.21, Related to Pharmaceutical Compounding of Sterile Preparations
 - 4. Add New Article 4.7 and Add New Titles and Sections 1737 1737.18 Related to

Hazardous Drugs

- c. Discussion and Consideration of Draft Statutory Proposal to Amend Business and Professions Code Sections 4081 and 4105
- d. Discussion and Consideration of Possible Action Regarding Proposal to Amend Title 16 California Code of Regulations Section Related to Compounding of Nonsterile and Sterile Preparations for Dispensing by Veterinarians to Animal Patients.
- e. Discussion and Consideration of Enforcement Statistics

XV. <u>Licensing Committee Report</u>

The Board will review a summary of the Committee's work at its April 5, 2023, Committee Meeting.

- a. Discussion and Consideration of Provisions for Remote Processing
- b. Discussion and Consideration of Changes to the Board's Sample CPA Related to MAT to Remove the Data 2000 Waiver Reference
- c. Discussion and Consideration of Possible Regulations to Implement Government Code Section 16.5 Related to Digital Signatures and Development of Policy Statement to Facilitate Implementation of Digital Signatures of Applications and Other Notices
- d. Discussion and Consideration of Licensing Statistics

XVI. Legislation and Regulation Committee

The Board will review a summary of the Committee's work at its April 19, 2023, Committee Meeting.

- a. Discussion and Consideration of Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations
 - 1. Assembly Bill 317 (Weber) Pharmacist Service Coverage
 - 2. Assembly Bill 602 (Pellerin) California State Board of Pharmacy: Emergency Refills: Report
 - 3. Assembly Bill 663 (Haney) Pharmacy: Mobile Units
 - 4. Assembly Bill 913 (Petrie-Norris) Pharmacy Benefit Managers
 - 5. Assembly Bill 1060 (Ortega) Health Care Coverage: Naloxone Hydrochloride
 - 6. Assembly Bill 1286 (Haney) Pharmacy
 - 7. Assembly Bill 1341 (Berman) Public Health: COVID-19 Testing and Dispensing Sites: Oral Therapeutics
 - 8. Assembly Bill 1557 (Flora) Pharmacy: Electronic Prescriptions
 - 9. Assembly Bill 1619 (Dixon) Pharmacists: Drug Disclosures: Cannabis or Cannabidial Interactions
 - 10. Senate Bill 339 (Weiner) HIV Preexposure Prophylaxis and Postexposure Prophylaxis
 - 11. Senate Bill 345 (Skinner) Health Care Services: Legally Protected Health Care Services
 - 12. Senate Bill 427 (Portantino) Health Care Coverage: Antiretroviral Drugs, Devices and Products

- 13. Senate Bill 524 (Caballero) Pharmacists: Testing and Treatment
- 14. Senate Bill 544 (Laird) Bagley-Keene Open Meetings Act: Teleconferencing
- 15. Senate Bill 826 (Rubio) Crimes: Criminal History Information: Subsequent Arrest
- 16. Senate Bill 873 (Bradford) Prescription Drugs: Cost Sharing
- Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency
 - 1. Proposed Regulation to Add Title 16 CCR Section 1706.6 Related to Military Spouses and Partners Temporary Licensure
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1709.1 Related to the Designation of Pharmacist-in-Charge
 - 3. Proposed Regulation to Add Title 16 CCR Section 1750 & 1750.1 Related to Outsourcing Facilities
 - 4. Proposed Regulation to Amend Title 16 CCR Section 1746.3 Related to Opioid Antagonist
- c. Discussion and Consideration of Board Approved Regulations Board Staff Reviewing Comments Provided by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency
 - Proposed Regulation to Amend Title 16 CCR Section 1760 Related to the Disciplinary Guidelines
- d. Discussion and Consideration of Board Approve Regulations Board Staff Drafting Rulemaking Documents
 - 1. Proposed Regulation to Amend Title 16 CCR Section 1732.5 and Add Section 1732.8 Related to Continuing Education
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1708.2 Related to Discontinuance of Business
 - 3. Proposed Regulation to Add Title 16 CCR Section 1746.6 Related to Medication Assisted Treatment Protocol
 - 4. Proposed Regulation to Amend Title CCR Section 1711 Related to Quality Assurance
- e. Update on Board Authorized Section 100 Regulations Board Staff Drafting Section 100 Documents
 - Proposed Regulation to Amend Title 16 CCR Sections 1715 and 1785 Related to the Community Pharmacy, Hospital Pharmacy, and Dangerous Drug Distributor Self-Assessment Forms

XVII.Executive Officer Report

- a. Changes to CURES System
- b. Update on Presentations Provided During the Quarter
- c. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacist Licensure Examination

XVIII. 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(c)(1), the Board Will Convene in Closed Session to Consider the Preparation, Approval, Grading or Administration of One or More Licensing Examination(s)
- c. Pursuant to Government Code Section 11126(e)(1), the Board Will Convene in Closed Session to Confer with its Legal Counsel Regarding Pending Litigation
 - Absolute Pharmacy LLC dba Absolute Pharmacy LLC; Andreas Dieter Dettlaff v. California Board of Pharmacy, et al., Los Angeles Superior Court, (Case No. 22STCP04253).

Reconvene Open Session, if necessary

XIX. Adjournment

Upon conclusion of business

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