



California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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



Notice of Meeting and Agenda Teleconference Public Board Meeting

DATES & TIMES: October 27, 2020, 4:00 p.m.
October 28, 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 4:00 p.m. on October 27, 2020 and 9:00 a.m. October 28, 2020.

FOR PUBLIC COMMENT, PLEASE LOG ON TO THIS WEBSITE

October 27, 2020 - <https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=e8d8bf46b826e9fc79e95987466610584>

October 28, 2020 - <https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=e191ee1e947816605bbcd0faf7364d31e>

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

Tuesday, October 27, 2020

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. Approval Board Meeting Minutes**
 - a. September 17, 2020, Board Meeting
- IV. Discussion and Consideration of designating all or portions of the decision, IV Solutions, Inc. v. Cal. Bd. of Pharmacy (Cal. App. B281845; LA2017604880) as Precedential pursuant to Government Code Section 11425.60**
- 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. Exela Pharma Sciences, BPC 4129.8 Temporary License
- VI. Organizational Development Committee Report**
 - a. Budget Update and Report
 - b. Board Member Attendance Information
 - c. Personnel Update
 - d. Meeting Calendar for Remainder of 2020
 - e. Proposed Meeting Calendar for 2021

VII. Communication and Public Education Committee Report

- a. Update on Communication Plan Regarding SB 159 Related to Furnishing HIV Preexposure and Postexposure Prophylaxis
- b. Update on Notice to Consumers Poster
- c. Update on The Script
- d. Quarterly Communications Report
- e. New Media Inquiries
- f. Public Outreach

VIII. 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)

IX. 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.

X. Discussion and Consideration of Comments on Board-Approved Regulations, Proposed Comment Responses, and Adoption of Regulations

- a. Proposed Regulations to Add Title 16 CCR Section 1717.5, Related to Automatic Refills
- b. Proposed Regulations to Amend Title 16 CCR Sections 1711 and 1713 and to Add Title 16 CCR Section 1715.1, Related to Automated Drug Delivery Systems

XI. Licensing Committee Report

The Board will review a summary of the committee's work at its October 20, 2020, meeting, as well as updates for discussion and action as necessary.

- a. Approval of July 8, 2020, Licensing Committee Meeting Minutes
- b. Discussion and Consideration of Proposal to Expand the Authority for Pharmacist to Administer CLIA Waived tests for Influenza and COVID-19
- c. Discussion and Consideration of Action Taken by the Accreditation Council of Pharmacy Education Related to California Health Sciences University's Loss of Accreditation Status
- d. Discussion and Consideration of Development of Mandatory Reporting Requirement for Schools of Pharmacy to Notify the Board of Licensees Engaged in Academic Dishonesty as part of the Student's Academics
- e. Discussion and Consideration of Authorized Duties of a Pharmacy Technician and Possible Expansion to allow for Administration of Influenza Vaccinations by Pharmacy Technicians
- f. Discussion and Consideration of Pharmacy Technician Application Requirements and Common Deficiencies
- g. Licensing Statistics
- h. Future Committee Meeting Dates

XII. Enforcement and Compounding Committee Report

The Board will review a summary of the committee's work at its October 27, 2020, meeting as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Recently Signed Legislation Impacting the Practice of Pharmacy
 - a. Assembly Bill 1710 (Wood, Chapter 123, Statutes of 2020) Pharmacy Practice: Vaccines
 - b. Assembly Bill 2077 (Ting, Chapter 274, Statutes of 2020) Hypodermic Needles and Syringes
 - c. Assembly Bill 2113 (Low, Chapter 186, Statutes of 2020) Refugees, Asylees, and Immigrants: Licensing
 - d. Assembly Bill 3330 (Calderon, Chapter 359, Statutes of 2020) Department of Consumer Affairs: Boards: Licensees: Regulatory Fees
 - e. Senate Bill 878 (Jones, Chapter 131, Statutes of 2020) Department of Consumer Affairs Licensing: Applications
 - f. Senate Bill 1474 (Committee on Business, Professions and Economic Development, Chapter 312, Statutes of 2020)
- b. Discussion and Consideration of Compounding Animal Drugs from Bulk Drug Substances, Including Federal Law and the FDA Draft Guidance, #256
- c. Discussion and Consideration of the Use of Peptides in Compounding Drug Products Under Section 503A of Federal Food, Drug, and Cosmetic Act (FD&C Act)
- d. Discussion and Consideration of Draft Information for Respondents Describing the Administrative Case Process
- e. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model
- f. Discussion and Consideration of Proposal of Board's Policy Encouraging Pharmacies to Report to Law Enforcement Acts Involving Drug Diversion by an Employee
- g. Discussion and Consideration of Disciplinary Cases and Incorporation of Ethics Program Requirement
- h. Review and Discussion of Enforcement Statistics
- i. Future Committee Meeting Dates

XIII. Legislation and Regulation Committee Report

The Board will review a summary of the committee's work at its October 27, 2020, meeting, as well as updates for discussion and action as necessary.

- a. Discussion and Consideration of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations
 1. Assembly Bill 1710 (Wood, Chapter 123, Statutes of 2020) Pharmacy Practice: Vaccines
 2. Assembly Bill 2028 (Aguiar-Curry) State Agencies: Meetings
 3. Assembly Bill 2077 (Ting, Chapter 274, Statutes of 2020) Hypodermic Needles and Syringes
 4. Assembly Bill 2113 (Low, Chapter 186, Statutes of 2020) 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, Chapter 131, Statutes of 2020) Department of Consumer Affairs Licensing: Applications
 10. Senate Bill 1474 (Committee on Business, Professions and Economic Development, Chapter 312, Statutes of 2020)
- b. Board Adopted Regulations Approved by the Office of Administrative Law
 1. Proposed Regulation to Add Title 16, Section 1714.3, Community Pharmacy Staffing

- c. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law
 - 1. Proposed Regulation to Amend Title 16, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria
 - 2. Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements
- d. 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, Section 1707, Off-Site Storage
- e. Discussion and Consideration of Board Adopted Regulations – Staff Drafting Final Rulemaking Documents for Final Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency
 - 1. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers
- 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 Regulation to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
 - 2. Proposed Regulation to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26
 - 3. Proposed Permanent Regulation to Add and Amend Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
 - 4. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation
 - 5. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses
- 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 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 1704 Related to Address Change Notification
 - 4. Proposed Regulation to Add Title 16 Section 1708.1 Related to the Temporary Closure of Facilities
- h. Future Committee Meeting Dates

XVI. Executive Officer Report

- a. Discussion of Board’s Response to COVID-19 Pandemic and Actions Taken by Other Agencies
- b. Update on the Sunset Review Process
- c. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

XVII. Update from the Department of Consumer Affairs

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(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.