



California State Board of Pharmacy
1625 N. Market Blvd, N219
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



Notice of Meeting and Agenda Public Board Meeting May 7-8, 2019

DATES & TIMES: May 7, at 12:30 p.m.
May 8, at 9:00 a.m.

PLACE: Department of Consumer Affairs – First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

WEBCAST: <https://thedcapage.blog/webcasts>
Webcast will be available earliest at 12:30 p.m. on May 7, 2019. See notices below.

NOTE: Pharmacists and pharmacy technicians who attend in person may be awarded 6 hours of CE, in accordance with the Board's CE policy. Sign-in and sign-out on the day of the meeting will be required for the CE credit.

For questions or verification of the meeting, call Laura Hendricks at (916) 574-7918 or access the board's website at www.pharmacy.ca.gov. Meeting materials should be available on the board's website at www.pharmacy.ca.gov by May 1, 2019.

Important Notices to the Public: The meeting is open to the public and 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 Laura Hendricks at (916) 574-7917, by emailing laura.hendricks@dca.ca.gov or sending a written request to the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. 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 accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board are open to the public. 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. 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. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend at a physical location. Adjournment, if it is the only item that occurs after a closed session, may not be webcast.

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 Board President may, at his or her discretion, apportion available time among those who wish to speak. 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)).

Agenda

Call to Order

12:30 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 of the January 30-31, 2019 Board Meeting Minutes**

IV. **Approval of the March 22, 2019 Board Meeting Minutes**

V. **Approval of the April 16, 2019 Board Meeting Minutes**

VI. **Recognition and Celebration of Pharmacists Licensed in California for 50 Years and other Recognitions**

VII. **Board Officer Elections**

VIII. **Licensing Committee**

The board will review a summary of the committee's efforts at the April 3, 2019 meeting, as well as updates, for discussion and action as necessary.

- a. Presentation on Medication-Assisted Treatment and Discussion and Consideration of Proposal to Establish Authority for Pharmacist to Provide Non-Opioid Medication-Assisted Treatment
- b. Discussion and Consideration of Pharmacy Law Related to Collaborative Practice Agreements
- c. Post Implementation Review of the Advanced Practice Pharmacist Licensing Program including Licensing Requirements and Functions Authorized
- d. Discussion and Consideration of the Current Provisions of Pharmacy Law Governing Board Licensed Facilities either Impacted by Declared Disasters or Otherwise Destroyed
- e. Discussion and Consideration of Proposed Language Establishing Parameters and Fees for Inspections of Sterile Compounding Pharmacies as a Result of Remodeling of the Facility
- f. Licensing Statistics
- g. Future Committee Meeting Dates

IX. **Enforcement Committee**

The board will review a summary of the committee's efforts at the March 14, 2019 meeting, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Ethics Course Provisions in California Code of Regulations, Title 16, Section 1773.5
- b. Discussion and Consideration of Senate Bill 1442 (Weiner, Chapter 569, Statutes of 2018) Relating to Community Pharmacy Staffing
- c. Summary of a Presentation on the Board's Routine Pharmacy Inspections
- d. Update on and Discussion of Board's Citation and Fine Program
- e. Discussion and Consideration of Efforts to Reduce Investigation Times and Case Resolutions

- f. Discussion on Attorney General’s Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies
- g. Discussion and Consideration of AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction
 - 1. Consideration of Possible Regulations
 - 2. Consideration of Possible Statutory Changes
- h. Summary of a Presentation and Discussion on Disciplinary Guidelines
- i. Summary of a Presentation by the California Pharmacists Association on Proposal to Modify the Board’s Current Enforcement Process
- j. Review of Final Report Submitted by University of California San Diego’s Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)
- k. Discussion and Consideration of Proposed Changes to Self-Assessment Forms Incorporated by Reference in Title 16, California Code of Regulations, Sections 1715 and 1784
- l. Discussion and Consideration of Title 16, California Code of Regulations, Section 1715.6 Related to the Reporting of Drug Losses
- m. Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board’s Ask An Inspector Program
- n. Discussion and Consideration of Board’s Enforcement Statistics
- o. Future Committee Meeting Dates

X. Compounding Committee

The board will review a summary of the committee’s efforts at the February 20, March 13 and April 16, 2019 meetings, as well as updates, for discussion and action as necessary.

- a. Summary of a Presentation on the Current Proposed Revisions to USP General Chapter 795, Regarding Pharmaceutical Compounding – Nonsterile Preparations
- b. Summary of a Presentation on the Current Proposed Chapter Revisions to Pharmaceutical Compounding – Sterile Preparations, Chapter 797
- c. Summary of a Presentation on the Proposed USP Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings
- d. Future Committee Meeting Dates

XI. Organizational Development Committee

- a. Budget Update/Report
- b. Board Member Attendance Information
- c. Discussion and Consideration of Consolidation of Committee Meetings and Board Meetings
- d. Discussion and Consideration of designating all or portions of the decision, *In the matter of the Citation Against: ESI Mail Pharmacy, Inc. dba Express Scripts, Case No. CI 2009 44657; OAH Case No. 2011060384* as Precedential pursuant to Government Code section 11425.60
- e. Update on Implementation of the Acceptance of Credit Cards for Renewal Payments
- f. Discussion of Assembly Bill 434 Related to Accessibility Standards
- g. Sunset Report Update
- h. Personnel Update
- i. Update on the Relocation of Board Office
- j. Update on the Controlled Substance Utilization Review and Evaluation System (CURES)
- k. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists

(CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

- I. Discussion and Consideration of a Staff Request to Award Continuing Education to Pharmacists Who Complete the Job Analysis Questionnaire

XII. Closed Session Matters – Time Certain: May 8, 2019 at 9:00 a.m.

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

XIII. Communication and Public Education Committee

(Estimated Start Time 9:30 a.m.)

The board will review a summary of the committee’s efforts at the May 7, 2019 meeting, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Policy on Subscriber Alerts
- b. Staff Update on the “Ask an Inspector” Program
- c. Discussion and Consideration of Educational Materials for Consumers and Licensees during Declared Disasters
- d. Update on Communication and Public Education Activities by Board Staff
 1. The Script
 2. Projects
 3. News Media
 4. Public Outreach
- e. Review and Discussion of News or Journal Articles
- f. Future Meeting Dates

XIV. Petition from United Food & Commercial Workers Union (UFCW) for Rulemaking to Implement Business and Professions Code Section 4113.5 (SB 1442, Weiner) Regarding Pharmacist Assistance

XV. Legislation and Regulation Committee

The Legislation and Regulation Committee will convene a meeting immediately prior to the board meeting on May 7, 2019. The board will receive a summary of the committee’s efforts, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Board Sponsored Legislation
 1. AB 973 (Irwin) Pharmacies: Compounding
 2. SB 569 (Stone) Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency
 3. SB 655 (Roth) Pharmacy
- b. Discussion and Consideration of Legislation Impacting the Practice of Pharmacy, the Board’s Jurisdiction or Board Operations
 1. AB 312 (Cooley) State Government: Administrative Regulations Review
 2. AB 387 (Gabriel) Physician and Surgeons: Prescriptions
 3. AB 528 (Low) Controlled Substances: CURES Database
 4. AB 544 (Brough) Professions and Vocations: Inactive License Fees and Accrued and Unpaid Renewal Fees

5. AB 613 (Low) Professions and Vocations: Regulatory Fees
 6. AB 690 (Aguiar-Curry) Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications
 7. AB 1076 (Ting) Criminal Records: Automatic Relief
 8. AB 1131 (Gloria) Medi-Cal: Comprehensive Medication Management
 9. AB 1545 (Oberholte) Civil Penalty Reduction Policy
 10. SB 159 (Wiener) HIV Preexposure and Postexposure Prophylaxis
 11. SB 425 (Hill) Health Care Practitioners: Licensee's File: Probationary Physician's and Surgeon's Certificate: Unprofessional Conduct
 12. SB 476 (Stone) Pharmacist-in-Charge: Disciplinary Proceedings
 13. SB 601 (Morrell) State Agencies: Licenses: Fee Waiver
 14. SB 617 (Glazer) Pharmacy Technicians: Supervision
 15. SB 650 (Rubio) Unused Medications: Cancer Medication Recycling
- c. Discussion and Consideration of Board Approved Regulations Undergoing Public Comment Period
1. Proposed Regulations to Add Title 16 CCR Section 1793.9 Related to Remote Dispensing Technicians
 2. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet
 3. Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board's Fee Schedule
- 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. Regulations under Pre-Notice review by the Business, Consumer Services and Housing Agency
 - A. Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation
 2. Regulations under Pre-Notice review by DCA Legal Affairs
 - A. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage
 - B. Proposed Regulations to Add Title 16 CCR Section 1717.5 Related to Automatic Refill Programs
 - C. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications
 - D. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements
 3. Regulations under Pre-Notice review by DCA Legal Counsel
 - A. 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
 - B. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
 - C. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers
 - D. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
 - E. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26
- e. Discussion and Consideration of Board Approved Regulations Being Prepared by Board Staff to Initiate Pre-Notice Review

1. 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 Form 17M-112

f. Future Committee Meeting Dates

XVI. Executive Officer Recruitment – Update on Recruitment Efforts

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(a)(1), the Board May Convene in Closed Session to Consider the Employment of an Executive Officer, Including Updates on Actions by the Search Committee

Reconvene Open Session

Adjournment

Upon conclusion of business