

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

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www.pharmacy.ca.gov

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



Notice of Meeting and Agenda Public Board Meeting November 5-6, 2019

DATES & TIMES: November 5, at 3:00 p.m.

November 6, at 9:00 a.m.

PLACE: Department of Consumer Affairs

1625 N. Market Blvd. 1st Floor Hearing Room Sacramento, CA 95834

WEBCAST: https://thedcapage.blog/webcasts

Webcast will be available earliest at 3:30 p.m. on November 5, 2019. See notices below.

NOTE: Pharmacists and pharmacy technicians who attend in person on November 6, 2019, may be awarded 6 hours of CE, in accordance with the Board's CE regulations. 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 Debbie Damoth at (916) 518-3100 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 October 31, 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 Debbie Damoth at (916) 518-3100, 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 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 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. July 24-25, 2019
- b. September 13, 2019
- c. October 3, 2019
- d. October 14, 2019

IV. Recognition and Celebration of Pharmacists Licensed in California for 40 Years and other Recognitions

V. Board Election of Officers

VI. <u>Discussion and Consideration of Request from American University of Health Sciences, School of Pharmacy, for Board Recognition Pursuant to Title 16, California Code of Regulations Section 1719</u>

VII. Organizational Development Committee

- a. Budget Update/Report
- b. Board Member Attendance Information
- c. Update on Implementation of the Acceptance of Credit Cards for Renewal Payments
- d. Review and Consideration of Draft Sunset Report
- e. Personnel Update

VIII. Compounding Committee

The board will receive a summary of the committee's work at the September 5, 2019, September 24, 2019, November 5, 2019, meetings, as well as any updates, for discussion and action as necessary.

- a. Discussion and Consideration of Draft Policy Statement Regarding Applicability of Board Compounding Regulations and USP Compounding Chapters While Pending Appeals Before USP
- b. Discussion and Consideration of Timing of Formal Rulemaking for Proposed Regulations Relating to Pharmaceutical Compounding of Nonsterile Preparations (Note: Discussion will not address the text of the proposed regulation, only the timing of the rulemaking process.)
- c. Discussion of Timing of Committee's Recommendation to Initiate the Formal Rulemaking Process for Proposed Regulations Relating to Pharmaceutical Compounding of Sterile Preparations (Note: Discussion will not address the text of the proposed regulation, only the timing of the rulemaking process.)

IX. Discussion and Consideration of Board Approved Regulations, Comments Pending Review by the Board

- a. Proposed Amendments to Title 16 CCR Section 1707.2 Related to Mail Order Pharmacy Consultation
- b. Proposed Amendments to Title 16 CCR Section 1706.2 Related to Abandonment of Applications
- c. Proposed Addition to Title 16 CCR Section 1793.9 Related to Remote Dispensing Pharmacy Technicians

X. Enforcement Committee

The board will review a summary of the committee's work at the November 5, 2019, meeting, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Post Implementation Review of Inventory Reconciliation Requirements for Controlled Substances, Including Discussion and Consideration of Possible Amendments to Title 16, California Code of Regulations Section 1715.65
- b. Discussion and Consideration of Possible Amendments to Title 16, California Code of Regulations, Section 1715.6, Regarding Reporting Drug Losses to the Board
- c. Presentation on Routine Pharmacy Inspections
- d. Discussion and Consideration of Recently Enacted Legislation Impacting the Practice of Pharmacy
 - 1. AB 528 (Low, Chapter 677, Statutes of 2019) Controlled Substances: CURES Database
 - 2. AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019) Pharmacies: Relocation: Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications
 - 3. AB 973 (Irwin, Chapter 184, Statutes of 2019) Pharmacies: Compounding
 - 4. AB 1723 (Wood, Chapter 323, Statutes of 2019) Clinics: Purchasing Drugs at Wholesale
 - 5. SB 159 (Wiener, Chapter 532, Statutes of 2019) HIV Preexposure and Postexposure Prophylaxis
 - 6. SB 569 (Stone, Chapter 705, Statutes of 2019) Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency
 - 7. SB 655 (Roth, Chapter 213, Statutes of 2019) Pharmacy
- e. Discussion and Consideration of Board's Enforcement Statistics
- f. Future Committee Meeting Dates

XI. Legislation and Regulation Committee

The Legislation and Regulation Committee will convene a meeting prior to the board meeting on November 5, 2019. The board will receive a summary of the committee's work, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Board Sponsored Legislation
 - 1. AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019) Pharmacies: Relocation: Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications
 - 2. AB 973 (Irwin, Chapter 184, Statutes of 2019) Pharmacies: Compounding
 - 3. SB 569 (Stone, Chapter 705, Statutes of 2019) Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency
 - 4. SB 655 (Roth, Chapter 213, Statutes of 2019) Pharmacy
- b. Discussion and Consideration of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations
 - 1. AB 528 (Low, Chapter 677, Statutes of 2019) Controlled Substances: CURES Database
 - 2. AB 1076 (Ting, Chapter 578, Statutes of 2019) Criminal Records: Automatic Relief
 - 3. AB 1264 (Petrie-Norris, Chapter 741, Statutes of 2019) Medical Practice Act: Dangerous Drugs: Appropriate Prior Examination

- 4. SB 159 (Wiener, Chapter 532, Statutes of 2019) HIV Preexposure and Postexposure Prophylaxis
- 5. SB 601 (Morrell, Chapter 854, Statutes of 2019) State Agencies: Licenses: Fee Waiver
- c. Discussion and Consideration of Board Approved Regulations Undergoing Final Review by the Office of Administrative Law
 - 1. Proposed Regulation to Amend Title 16 CCR Section 1749 Related to the Board's Fee Schedule
- d. Discussion and Consideration of Board Approved Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency
 - 1. Proposed Regulation to Ament Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet
- e. 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 1707 Related to Offsite Storage
 - 2. Proposed Regulations to Add Title 16 CCR Section 1717.5 Related to Automatic Refill Programs
 - 3. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements
 - 4. 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
 - 5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
 - 6. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers
 - 7. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
 - 8. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26
 - Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1813 Related to Use of an APDS, and Add Section 1715.1 Related to ADDS Self-Assessment Form 17M-112
 - 10. Proposed Regulations to Amend Title 16 CCR Sections 1769 and 1770 Related to Criminal Conviction Substantial Relationship and Rehabilitation Criteria
 - 11. Proposed Regulation to Add Title 16 CCR Section 1714.3 Related to Community Pharmacy Staffing
 - 12. Proposed Regulations to Amend Title 16 CCR Sections 1735 et seq. Related to Pharmaceutical Compounding of Nonsterile Preparations
- f. Future Committee Meeting Dates

XII. Licensing Committee

The board will review a summary of the committee's work at its September 25, 2019, and November 5, 2019, meetings, as well as updates, for discussion and action as necessary.

- a. Discussion and Consideration of Legislative Proposal to Amend the Requirements to Qualify for an Advanced Practice Pharmacist License in Business and Professions Code Section 4210.
- b. Discussion and Consideration of Legislative Proposal Regarding the Use of Automated Drug Delivery Systems
- c. Discussion and Consideration of Legislative Proposal to Amend Business and Professions Code

- section 4312 to Expand the Provisions to Apply to All Facility Licenses
- d. Discussion and Consideration of Amendments to Title 16 CCR Section 1709, to Specify Required Reporting Requirements for Individuals vested with Management and Control
- e. Discussion and Consideration of Legislative Proposal to Standardize the Requirements, including Qualifications, for all Designated Representative Licenses (Business and Professions Code Sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, & 4053.2)
- f. Discussion and Consideration of Proposal to Develop Intern Conferences for Students Recently Enrolled in a California School of Pharmacy and for Students Ready to Graduate from a California School of Pharmacy
- g. Discussion and Consideration of Committee's Strategic Plan Goals
- h. Discussion and Consideration of Draft Collaborative Practice Agreement: Pharmacist Protocol for Management of Opioid Use Disorders
- i. Review of Licensing Statistics

XIII. Update from the Department of Consumer Affairs

XIV. Petitions for Reinstatement of Licensure, Early Termination, or Other Reduction of Penalty 2:30 p.m., November 6, 2019

a. Glendora Medical Supply, PHY 47517 – Reduction of Penalty

XV. 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

Adjournment

Upon conclusion of business