



**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 Enforcement and Compounding Committee Meeting

**DATES & TIMES:** Wednesday, January 20, 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 earliest at 9:00 a.m. on January 20, 2021. While the Board intends to webcast this meeting, it may not be possible to webcast the entire meeting due to technical difficulties or limitations on resources. If you wish to participate or to have a guaranteed opportunity to observe, please plan to participate via the WebEx option listed below.

**FOR OBSERVATION AND PUBLIC COMMENT, PLEASE LOG ON TO THIS WEBSITE** <https://dca-meetings.webex.com/dca-meetings/onstage/g.php?MTID=e9e70f138e82a05baa00a1ad782799a26>

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.

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.

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**Important Notices to the Public:** The Enforcement and Compounding Committee 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 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) 518-3090, by emailing [debbie.damoth@dca.ca.gov](mailto: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 Committee Chair. 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 Chair'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 Committee or prior to the Committee taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issues before the Committee, but the chair may, at his or her 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 Committee to discuss items not on the agenda; however, the Committee 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 Committee plans to webcast this meeting on its website at [www.pharmacy.ca.gov](http://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 will not be broadcasted in any way.

## Agenda

### **DISCUSSION AND ACTION MAY BE TAKEN ON ANY ITEM ON THE AGENDA.**

Wednesday, January 20, 2021

Call to Order

9:00 a.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 October 27, 2020, Enforcement and Compounding Committee Meeting Minutes
- IV. Presentation on the Pharmacist Recovery Program
- V. Discussion and Consideration of Board Policy Related to Transparency Involving the Issuance of Citations and Fines
- VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms
  - a. Community Pharmacy/Hospital Out-Patient Self-Assessment (17M-13)
  - b. Compounding Self-Assessment (17M-39)
  - c. Hospital Pharmacy Self-Assessment (17M-14)
  - d. Wholesaler Dangerous Drugs & Devices Self-Assessment (17M-26)
  - e. Automated Drug Delivery System Self-Assessment (17M-112)
- VII. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model
- VIII. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substances Schedules and its Impact on Healthcare Services
- IX. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products

X. Discussion and Consideration of FDA Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry

XI. Discussion and Consideration of the Compounding of Methylcobalamin

XII. Review and Discussion of Enforcement Statistics

XIII. Future Committee Meeting Dates

XIV. Adjournment

Upon conclusion of business