



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

DATE & TIME: January 23, 2023, 9:00 a.m.

Note: Pursuant to the provisions of Government Code section 11153, neither a public location nor teleconference locations are provided.

INSTRUCTIONS FOR OBSERVATION:

Livestream: <https://thedcapage.blog/webcasts> Livestream will be available the earliest at 9:00 a.m. on January 23, 2023. While the Board intends to livestream this meeting, it may not be possible to livestream the entire meeting due to technical difficulties or limitations on resources. The meeting will not be cancelled if livestream is unavailable. If you wish to participate or to have a guaranteed opportunity to observe, please plan to participate via the WebEx option listed below.

FOR PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION, PLEASE LOG ON TO WEBEX:

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=m98d1375b7baeddb165e3f7ffe327e04f>

If joining using the link above

Webinar number: 2485 936 5552

Webinar password: CSBP01232023

If joining by phone

+1-415-655-0001 US Toll

Access code: 248 593 65552

Passcode: 27270123

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.

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 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 Committee is unable to attend the meeting, or the Committee 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)).

Agenda

Discussion and action make be taken on any agenda item.

January 23, 2023

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 Committee 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. Discussion, Consideration and Approval of Draft Minutes from the October 4, 2022, Enforcement and Compounding Committee Meeting

IV. Discussion and Consideration and Possible Action on Self-Assessment Forms

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- a. Community Pharmacy/Hospital Out-Patient Self-Assessment (17M-13)
- b. Hospital Pharmacy Self-Assessment (17M-14)
- c. Wholesaler/Third-Party Logistics Provider Self-Assessment (17M-26)
- d. Automated Drug Delivery System Self-Assessment (17M-112)

V. **Discussion and Consideration of Barriers to Timely Case Resolutions**

VI. **Overview on Federal Requirements for Compounding Under Provisions of 503A**

Note: The intended purpose of this agenda item is to provide education on the federal requirements governing compounding.

VII. **Presentation on USP General Chapter 825, Regarding Radiopharmaceuticals**

Note: The intended purpose of this agenda item is to provide education on the requirements of the new chapter

VIII. **Discussion, Consideration and Possible Action on Proposed Addition to Title 16, California Code of Regulations Section 1738 Related to Radiopharmaceuticals**

IX. **Review and Discussion of Enforcement Statistics**

X. **Future Committee Meeting Dates**

XI. **Adjournment**

Upon conclusion of business