Notice of Meeting and Agenda
Public Board Meeting
February 17, 2017

DATE(S): February 17, 2017, at 9:00 a.m.

& TIME(S):

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

WEBCAST:   http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml
(Webcast will be available earliest at 9:00 a.m. on February 17, 2017. 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 Debbie Damoth at (916) 574-7935 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 February 10, 2017.

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) 574-7935, by emailing debbie.damoth@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. 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)).
Call to Order

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. Comments from Senator Hernandez to the Board of Pharmacy

IV. Discussion and Consideration of the Proposed Regulation to Add Title 16 CCR Section 1746.5, Related to Travel Medications

V. Discussion and Consideration of the Proposed Regulation to Amend Title 16 CCR Section 1760, Related to Disciplinary Guidelines

VI. Automated Drug Delivery Systems (ADDS)
   1. Presentation(s) Regarding Systems and Features Currently Available
   2. Discussion of Current and Potential Circumstances Under which ADDS are Used and the Impact on Public Safety
   3. Discussion and Consideration of Next Steps by the Board

Lunch
A lunch break will be taken at some point during each day’s meeting.

VII. Closed Session
   a. Pursuant to Government Code section 11126(c)(3), the Board may Convene in Closed Session to Deliberate on Disciplinary Matters, Including Petitions, Proposed Decisions, Stipulated Decisions, Defaults, and Any Other Disciplinary Matters.
   b. Pursuant to Government Code section 11126(e), the Board may Convene in Closed Session to Discuss Pending Litigation

VIII. Reconvene Open Session

Adjournment
Upon conclusion of business
BOARD SETS SPECIAL MEETING ON AUTOMATED DRUG DELIVERY SYSTEMS

The California State Board of Pharmacy announces that it is holding a special meeting to discuss and consider possible changes in pharmacy laws to accommodate new technology and advances in the operation of automated drug delivery systems (ADDS) in a location that may be remote from the licensed pharmacy that provides oversight.

Background: Business and Professions Code sections 4105.5 and 4186, Health and Safety Code section 1261.6, and other provisions set specific requirements for pharmacies operating ADDS devices in licensed health facilities. Among other requirements, ADDS machines must “collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy and accountability.” Key provisions specify who is responsible for stocking an ADDS machine with medication and how restocking may be done.

Because many ADDS devices today offer features not addressed in pharmacy law, the board is inviting vendors to present information about available technological features and how the devices are affected by existing laws.

The board is seeking ways to allow pharmacies to provide better quality care and service to patients while maintaining security and protecting the public from diversion of controlled substances and other prescription drugs. The board’s focus during this meeting will be on reviewing ADDS technology that provides remote access to a health care professional (a nurse, anesthesiologist or other licensed provider).

Interested parties are invited to attend the board meeting at 9 a.m. Feb. 17, 2017, at 1625 N. Market Blvd., Sacramento, CA 95834. The meeting agenda is available on the board’s website here.

Those wishing to present at the meeting will be invited to speak after a board review of a questionnaire to determine the relevancy of the ADDS device to the board’s focus. If invited to speak, vendors will be advised to limit presentations to a brief demonstration or overview of their ADDS devices, focusing on inventory controls, security features and benefits to patient care. Vendors are asked to complete a questionnaire about their ADDS machines and to identify proposed changes to pharmacy law to more appropriately provide for use of such technology.

Vendors are asked to advise board staff no later than 5 p.m. Feb. 10 of their intent to present at the meeting; provide a copy of their presentation and responses to the ADDS questionnaire; and identify barriers that exist in current law. This will allow staff sufficient time to finalize the agenda and prepare materials for board members and the public.
To register or ask questions, please contact Debbie Damoth at (916) 574-7935 or debbie.damoth@dca.ca.gov.

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ADDS QUESTIONNAIRE

Vendor name ________________________________________________

Contact information __________________________________________

1. In what specific patient care settings would this ADD be used? What are the security requirements for the remote location to ensure that medication access is limited only to authorized providers?

2. How will the pharmacist review medication orders? Is there an interface or other method that allows for prospective review, or is review only retrospective?

3. What specific features are available through the technology to ensure that the correct medication was removed per the provider's medication order?

4. What are the security features of the technology? How is user access maintained and by whom? Who has the ability to remove medications?

5. How are remote devices restocked? If the medication is transported after being checked by the pharmacist, what features are available that provide for detection of a tampered container?

6. Can controlled substances be stocked? If so, what additional security features are available?
7. How would patient consultation occur?

8. How would the ADDS remote user interact with the pharmacist? What technology options exist?

9. How would the pharmacist detect drug diversion for medications stocked in the ADDS? What reports are available to allow the pharmacist to monitor safe use of ADDS technology? Please provide an example of these reports.

10. What specific law changes are recommended to support the use of this remote ADDS technology?

Please submit completed questionnaire to Debbie Damoth by fax at (916) 574-8618 or by email at debbie.damoth@dca.ca.gov by 5 p.m. Feb. 10.