



**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SPECIAL PUBLIC BOARD MEETING
MINUTES**

DATE: June 8, 2016

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

BOARD MEMBERS PRESENT: Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Gregory Lippe, Public Member
Stanley Weisser, RPh
Albert Wong, PharmD
Allen Schaad, RPh
Lavanza Butler, RPh
Ramon Castellblanch, Public Member

BOARD MEMBERS NOT PRESENT: Ryan Brooks, Public Member
Gregory Murphy, Public Member
Ricardo Sanchez, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Lori Martinez, Staff Manager
Debbie Damoth, Staff Manager
Laura Hendricks, Staff Analyst

Special Board Meeting

Call to Order

12:35 p.m.

I. Call to Order, Establishment of Quorum, and General Announcements

President Gutierrez called the Special Board Meeting to order at 12:35 p.m. Board members present: Lavanza Butler, Victor Law, Gregory Lippe, Stanley Weisser, Deborah Veale, Amy Gutierrez, Allen Schaad, Albert Wong and Ramon Castellblanch.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

There were no comments from the board or from the public.

III. Finding of Necessity for Special Meeting

Ms. Freedman explained that the board must first determine the necessity of holding the Special Board Meeting. The board determined that in order to meet legislative deadlines, action must be taken on the proposed amendments to SB 1193 (related to automated drug delivery systems).

There were no comments from the public.

Motion: Taking action on the proposed amendments to SB 1193 (related to automated drug delivery systems) is necessary and requires the board to convene a Special Board Meeting.

M/S: Veale/Lippe

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

IX. Proposed Legislation Relating to Registration of Automated Drug Delivery Systems

President Gutierrez explained that as part of the board's Sunset Report, the board identified several issues, including the need to be advised of the locations of automated delivery systems used by pharmacies.

President Gutierrez reported that the language was discussed at both the February and April 2016 Board Meetings. At the April Board Meeting, the board referred the matter back to the Enforcement Committee to further refine the requirements.

President Gutierrez stated that during its June 2, 2016, meeting, members of the Enforcement Committee discussed several aspects of the proposal including:

1. Should the board specify inventory requirements?
2. Should the board impose a mile radius restriction between the pharmacy and the delivery system it operates?
3. Should hospitals be exempt from some of these requirements?

President Gutierrez reported that ultimately the committee determined that other provisions of pharmacy law detail inventory requirements, and as such, additional specificity is not required. Further, the committee determined that a mile radius restriction should not be required, and that a hospital should not need to register systems used for administration in the hospital.

President Gutierrez explained that to meet legislative deadlines, this matter is being brought to the board for consideration as a special meeting. President Gutierrez stated that as part of its discussion the board should review the final proposal as recommended by the Enforcement Committee. She noted that depending on the outcome of the board's discussion and action, board staff will work to secure amendment of the language into the board's sunset bill, SB 1193.

Note: The proposed language from the Enforcement Committee is provided below.

Proposal to Add Section 4105.5

- (a) For purposes of this section, an automated drug delivery system includes a device as defined in Health and Safety Code Section 1261.6(a)(1).
- (b) Every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall provide the board in writing with the location of each device within 30 days of installation of such a device, and on an annual basis as part of the license renewal. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.
- (c) Every pharmacy that uses such a system may only do so if all of the following conditions are satisfied.
 1. Use of the device is consistent with legal requirements.
 2. Policies and procedures include appropriate security measures and monitoring of the inventory to prevent thefts and diversion.
 3. Drug losses from the device are reported to the board as required by law.
 4. The pharmacy license is unexpired and not subject to disciplinary conditions.
- (d) The board may prohibit a pharmacy from using a system if it determines that the

conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal such a decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

- (e) A system used in a licensed hospital for doses administered in the hospital is exempt from the registration requirements in subdivision (b).

President Gutierrez reviewed the language provided above and noted that the Enforcement Committee took considerable time at its meeting to review and refine the language.

Ms. Veale spoke in support of the language and thanked the Enforcement Committee for its work.

Mr. Law asked to clarify if a drug delivery device located in an outpatient location needed to be registered. President Gutierrez explained that a device located in an outpatient facility would need to be registered.

Dr. Castellblanch asked why the language was not brought before the Legislation and Regulation Committee. It was clarified that at the April Board Meeting, the board motioned to send the language to the Enforcement Committee for further review and development.

Dr. Castellblanch asked why the board was going to exempt hospitals from the registration requirements. Robert Stein, pharmacist, noted that hospitals should be exempt from certain aspects of the registration requirements due to the sheer volume of drug delivery systems in hospitals. He added that the devices were all owned by the hospital and are operated by hospital staff.

Ms. Butler asked why the Enforcement Committee had removed the 75-mile radius requirement that had been in previous versions of the language. It was clarified that placing a limit on the miles a device could be located from a pharmacy could negatively impact rural areas in California.

Ms. Herold explained that the language was intended to create a simple registration program so that the board is aware of where the drug delivery devices are located and who owns the machines. Dr. Castellblanch spoke in support of the need to gather registration information.

Dr. Wong asked if the board has seen these machines in use. Members of the Enforcement Committee noted that at one of their committee meetings, the members had seen demonstrations of the machines and their capabilities. President Gutierrez stated that perhaps staff could help coordinate field trips to locations using the drug delivery devices for interested board members.

Karen Nishi, representing Cubex, briefly described how its drug delivery systems operate.

Lori Hensic from Kaiser thanked the board for its work on the language. However, she expressed concern that the definition of a "licensed hospital" in section e may be confusing. The board discussed various ways to clarify the language in section e. Robert Stein, pharmacist, suggested the language below. The board agreed with Dr. Stein's suggested language.

- (e) A system operated by a licensed hospital pharmacy as defined in section 4029 for doses administered in a facility operated under a consolidated license under Health and Safety Code section 1250.8 shall be exempt from the registration requirements of subdivision (b).

A long term care pharmacist thanked the board for removing the 75 mile radius requirement from the language and spoke in support of the registration of these devices.

Motion: Vote down the committee recommendation.

M/S: Lippe/Weisser

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Motion: Approve the amended language as provided below.

Proposal to Add Section 4105.5

- (a) For purposes of this section, an automated drug delivery system includes a device as defined in Health and Safety Code Section 1261.6(a)(1).
- (b) Every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall provide the board in writing with the location of each device within 30 days of installation of such a device, and on an annual basis as part of the license renewal. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.
- (c) Every pharmacy that uses such a system may only do so if all of the following conditions are satisfied.
 - 1. Use of the device is consistent with legal requirements.
 - 2. Policies and procedures include appropriate security measures and monitoring of the inventory to prevent thefts and diversion.
 - 3. Drug losses from the device are reported to the board as required by law.
 - 4. The pharmacy license is unexpired and not subject to disciplinary conditions.
- (d) The board may prohibit a pharmacy from using a system if it determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal such a

decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

- (e) A system operated by a licensed hospital pharmacy as defined in section 4029 for doses administered in a facility operated under a consolidated license under Health and Safety Code section 1250.8 shall be exempt from the registration requirements of subdivision (b).

M/S: Weisser/Lippe

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

President Gutierrez adjourned the Special Board Meeting 2:04 p.m.