



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

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.

At the February 2016 Board Meeting, the board considered a draft proposal to establish a registration requirement for pharmacies that operate automated delivery systems. During the meeting, the board discussed creating inventory requirements for the devices and the need to clarify some of the terminology used in the draft language. The board also heard public comment in which the board was asked to modify the requirements for hospitals that use the automated delivery systems. The board asked staff to modify the language and bring it back for further discussion. Subsequent to that meeting, staff worked with the board president and vice-president to refine the language.

The proposal was subsequently discussed during the April 27-28 Board Meeting. After discussion, the board referred the matter back to the Enforcement Committee to further refine the requirements.

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?

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.

At This Meeting:

To meet legislative deadlines, this matter is being brought to the board for consideration as a special meeting. During its discussion the board should review the final proposal as recommended by the Enforcement Committee. 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.

The proposed language from the Enforcement Committee is provided immediately following this memo.

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).*