

Automated Drug Dispensing

by Gerry Hinkley, Caitlin Stulberg, Jamin Agosti

California regulators have read new limitations into state statute that would bar the exchange of automated drug dispensing system “pockets” by health care facility staff.

Introduction

Despite its plain text, the California Board of Pharmacy (the “**BoP**”) has adopted an interpretation of state statute requiring stocked removable pockets for automated drug dispensing systems (“**ADDs**”) to be transported to and inserted into an ADDs by pharmacy staff. The California Department of Public Health (“**CDPH**”) has publicly stated that it will follow the BoP’s interpretation.¹ While the continued use of non-pharmacy staff to transport or insert stocked ADDs pockets carries the risk of enforcement actions from these agencies, the BoP’s interpretation requires legislative actions to formally implement.

Background

Historically, intermediate care and nursing facilities have relied on pharmacies to fill patient-specific prescription orders and non-patient specific emergency supplies kits (“**ekits**”), which were transported to and stored in the facilities.² Modern ADDs, on the other hand, are sophisticated storage and inventory systems designed to store and dispense emergency and first dose drugs at the point of care, allowing facility staff to access a larger volume and variety of drugs all under the supervision of a pharmacist.³ Drugs are tracked using

TAKEAWAYS:

The California Board of Pharmacy has adopted a position contrary to the plain text of state statute, putting pharmacy operators of ADDs in a tight spot.

Pharmacists and health care facilities using non-pharmacy staff to exchange stocked ADDs pockets may be at risk of enforcement action.

To properly enforce its interpretation, the Board of Pharmacy will need legislative action.



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¹ Meeting of Board of Pharmacy Enforcement and Compounding Committee at 2:22:34, Jan. 4, 2017, <https://youtu.be/670A1MZ3gOg?t=8554>.

² Guidance on the Interdisciplinary Safe Use of Automated Dispensing Cabinets, Institute for Safe Medication Practices 1 (2008), https://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf.

³ *Id.*

barcode and chip-based inventorying technologies to prevent selection and dosing errors and to identify and prevent drug diversion. While the array of ADDS in the market incorporates a variety of technologies, ADDS generally combine various security methods to identify and prevent unauthorized access, such as passcodes, fingerprint scanning, and video recording.⁴ Transitioning from manual point of care drug storage, such as an ekit or first dose system, to an ADDS has been shown to reduce medication administration errors by up to 53 percent.⁵

As drugs within ADDS are dispensed or expire, or as new drugs become available, ADDS need to be replenished with additional non-patient specific unit dose drugs. Today, ADDS are refilled by pharmacy staff who replenish the system's removable, secure tamper-evident "pockets" with non-patient specific unit dose drugs at the pharmacy. The filled pockets are then delivered and inserted into the ADDS. ADDS are programmed to receive drugs safely and securely by electronically recognizing the type, dose, and expiration date of drugs within each pocket, as described above.

Discussion

In California, ADDS and the pharmacies and facilities that employ them are regulated by statute, the BoP, and the CDPH. Under this regulatory system, ADDS located within skilled nursing and intermediate care facilities ("in-facility ADDS")⁶ must be owned and supervised by a pharmacist.⁷ Section 4119.1(b) of the California Health and Safety Code expressly deems drugs stored within ADDS to be pharmacy inventory.⁸ Accordingly, a pharmacist is required to ensure such drugs are stored safely and securely, which

includes mandatory monthly in-person service inspections by pharmacy personnel.⁹ While the law requires the pharmacist to restock an ADDS by filling pockets or other secure containers, the law is clear that the pharmacist is not required to physically place the containers in an ADDS. However, there is a conflict between the law and the BoP's interpretation of the law regarding the pharmacist's required role with respect to placing pockets in the in-facility ADDS.

Section 1261.6(g) of the California Health and Safety Code makes clear that ADDS "stocking" may only be performed by pharmacy personnel¹⁰. However, for ADDS using "removable pockets, cards, drawers, or similar technology," the statute provides that "the stocking system may be done outside of the facility and be delivered to the facility" so long as:

- (i) the task of filling the pockets is performed by pharmacy staff at the pharmacy;
- (ii) the pockets are transported to the ADDS in secure tamper-evident containers; and
- (iii) the facility and pharmacy establish policies and procedures for proper placement of the pockets into the ADDS.¹¹

Thus, for ADDS using removable pockets, the "stocking" that must be performed by pharmacy personnel only applies to the refilling of the pockets outside of the facility.

Nonetheless, the BoP Enforcement and Compounding Committee (the "Committee") interprets section 1261.6(g) to also require that the insertion of stocked ADDS pockets

4 *Id.* at 14.

5 Etienne Cousein et al., Effect of automated drug distribution systems on medication error rates in a short-stay geriatric unit, 20 *Journal of Evaluation in Clinical Practice* 678 (June 2014), <http://onlinelibrary.wiley.com/doi/10.1111/jep.12202/pdf>.

6 Facilities licensed under California Health and Safety Code sections 1250(c) and (d).

7 Cal. Bus. & Prof. Code § 4119.1(a).

8 Cal. Bus. & Prof. Code § 4119.1(b).

9 *Id.*; Cal. Health & Saf. Code § 1261.6(h).

10 Cal. Health & Saf. Code § 1261.6(g).

11 *Id.*

be performed by pharmacy personnel.¹² The Committee notes that stocked ADDS pockets remain pharmacy inventory and, therefore, should remain the responsibility of the pharmacist. However, subsections (ii) and (iii) of section 1261.6(g) provide requirements with regard to transportation and placement, respectfully, of the stocked ADDS pockets, but do not include any requirement that pharmacy personnel do such transporting or placement.¹³

Additionally, the BoP cannot support such a limitation by citing the general statement that drugs stored in ADDS “shall be part of the inventory of the pharmacy.”¹⁴ It is a well-established canon of statutory construction that the specific prevails over the general.¹⁵ Section 1261.6(g) specifically regulates in-facility ADDS, and more specifically subsections (ii) and (iii) specifically regulate the transportation and placement of pockets into in-facility ADDS. These subsections state that the pockets must be transported in secure tamper-evident containers and that the facilities and pharmacies must establish policies and procedures for the proper placement of the pockets into the ADDS. Here, the California State Legislature could have, but did not, prescribe who must transport the stocked pockets and place them into the ADDS. In fact, it is evident that pharmacies and facilities are meant to develop their own policies and procedures addressing proper placement of such pockets, and this would logically include who may do the placing.

The Committee also analogizes ADDS stocking to “restocking of the emergency kits in [skilled nursing facilities],”¹⁶ which must be returned to the pharmacy

for inventory, restocking and recordkeeping after any medication is removed.¹⁷ After pharmacy personnel inventory and restock the ekit, however, it may be transported to and placed in a facility for storage by facility staff.¹⁸ The Committee notes it relied on ekit regulations when concluding that ADDS pockets may be transported only by pharmacy personnel. However, the ekit requirements more closely align with *permitting* transportation and insertion of stocked ADDS pockets by facility staff than they do with prohibiting them from doing so. Just as ekits may be transported to and stored in a cabinet within a facility by facility staff, it would follow that stocked ADDS pockets may similarly be transported to a facility and placed in ADDS.

CDPH, which licenses intermediate care and skilled nursing facilities, has indicated that it intends to defer to the BoP’s interpretations of ADDS stocking requirements.¹⁹

Conclusion

The statutory interpretation on this matter is clear. If the Board of Pharmacy wants to change the requirements for ADDS in intermediate care and skilled nursing facilities, doing so will require an amendment of the statute, which is the purview of the California State Legislature. Nonetheless, due to the BoP’s erroneous interpretation, there is risk that the BoP or CDPH may bring an enforcement action against individuals or entities that permit non-pharmacy personnel to transport stocked ADDS packets or insert stocked packets into ADDS. Individuals or entities that face an enforcement action of this kind would have a defensible position under the law.

12 Enforcement and Compounding Committee Report, California Board of Pharmacy, Page 4, http://www.pharmacy.ca.gov/meetings/agendas/2017/17_jan_bd_mat_enf.pdf (Jan. 4, 2017) (“BoP Committee Report”); Meeting of Board of Pharmacy Enforcement and Compounding Committee at 2:33:45, Jan. 4, 2017, <https://youtu.be/670A1MZ3g0g?t=9225>. The BoP echoed the Committee’s interpretation of this statute during its January 24, 2017 meeting.

13 *Id.*

14 Cal. Bus. & Prof. Code § 4119; Cal. Code Regs. tit. 22, § 72377(b).

15 *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992); *Wood v. Cty. of San Joaquin*, 4 Cal. Rptr. 3d 340, 347-48 (Ct. App. 2003), as modified (Sept. 5, 2003); Cal. Civ. Code § 3534.

16 BoP Committee Report at 4.

17 *Id.*; Cal. Bus. & Prof. Code § 4119; Cal. Code Regs. tit. 22, § 72377(b).

18 Cal. Bus. & Prof. Code § 4119(a).

19 Meeting of Board of Pharmacy Enforcement and Compounding Committee at 2:22:34, Jan. 4, 2017, <https://youtu.be/670A1MZ3g0g?t=8554>.

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