



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

December 1, 2011

To: Members, California State Board of Pharmacy

Subject: Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Drugs

a. FOR INFORMATION: Presentation by Connie Jung, RPh, PhD, Acting Associate Director for Policy and Communications, Center for Drug Evaluation and Research, US Food and Drug Administration

Dr. Jung will provide a presentation on the FDA's activities regarding a track and trace system for prescription medication.

Time will be set aside to ensure a question and answer period.

b. FOR INFORMATION: Presentations and Questions from the Pharmaceutical Supply Chain Representatives on California's E-Pedigree Requirements

This portion of the meeting will offer an "open mike" for presentations by representatives of the supply chain, and an opportunity to address the board.

c. FOR DISCUSSION: Implementation Issues for California's E-Pedigree

Board staff will provide an overview of recent problems with counterfeit drugs discovered in California, and other supply chain issues investigated.

d. FOR DISCUSSION: Future Rulemakings to Implement California's E-Pedigree Requirements

California's e-pedigree law establishes a staggered implementation schedule:

- Manufacturers must serialize at least 50 percent of their product sold in California by January 1, 2015
- Manufacturers must serialize at least 50 percent of their product sold in California by January 1, 2016
- Wholesalers and repackagers have until July 1, 2016 to append and pass e-pedigrees for drugs they distribute into or through California
- Pharmacies and their distribution facilities have until July 1, 2017 to accept pedigrees for all drugs they acquire in California.

The board will have to promulgate regulations to implement some of the provisions in the law. Regulations will be required for:

- Inference
Inference allows a unique identifier to be applied to a case, pallet or other “aggregate” without individually reading each serialized unit. The law specifies that manufacturers, wholesalers and pharmacies distribute and receive electronic pedigrees, and verify and validate pedigrees at the unit level except where efficiency and safety can be secured through inference.
- Decommissioning
When the medication within a serialized container has been dispensed, there needs to be a process to close out the e-pedigree. Also involved in this is outdated medication or recalled medication that cannot be dispensed.
- Drop Shipment Pedigree
Drop shipping occurs when products are shipped from manufacturer directly to the pharmacy; however, ownership (and hence the need to append the pedigree) needs to track and certify ownership as it moves from the manufacturer to wholesaler to pharmacy, even though the wholesaler never possesses the medication. There will need to be a rule to describe what must occur in these situations.
- Linkage between invoice and shipping notice
Invoices are typically sent after drugs are delivered. Shipping notices accompany the shipment. The pedigree requires annotation to the pedigree before the product is sold to another entity – this could occur before the invoice arrives. However, documenting the sale is an important part of the chain of custody created with the e-pedigree system.
- Grandfathering Lists
The board is required to establish a process for manufacturers, wholesalers and pharmacies to designate drugs already in their possession when pedigree requirements kick in, and exempts these listed drugs from pedigree requirements. The law requires that the drugs be described in written lists submitted to board and specifies that these lists are confidential.

At this meeting, the board needs to discuss how the Enforcement Committee will initiate the development of the regulations.

e. FOR DISCUSSION: Future Meeting Dates of the Enforcement Committee (where e-pedigree implementation will be on the agenda)

The board has established the following meeting dates for 2012:

- March 13
- June 12
- Sept. 11
- Dec. 4

The March 13 meeting conflicts with an HDMA conference (representing large drug wholesalers) conference on the East Coast. Does the board wish to move this meeting date?