



California Prescription Drug Pedigree Requirements

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Today's Messages:

- ❑ Envisioning a track and trace system for the supply chain has been a long time coming – more than 20 years at the federal level, more than 7 years in California
- ❑ In California, firm deadlines of 2015-17 for manufacturers, wholesalers, pharmacies
- ❑ The serialization requirement is not easy, takes time to perfect. There will be no further extensions of time.

More Messages

- ❑ The law applies to nearly all prescription drugs intended for sale in California
- ❑ This track and trace system is still needed due to ongoing problems being discovered in supply chain

Purpose of Pedigree

- The pedigree is an important part of a series of provisions intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated or diverted drugs. The overall intent is to secure the drug distribution system and sustain and increase confidence in authenticity of prescription drugs in California by creating a track and trace system.

Pedigree Definition

- “Pedigree” means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drug.

Interoperable electronic system defined

- ❑ Electronic track and trace system for prescription drugs
- ❑ Uses unique identification number
- ❑ Established at point of manufacture
- ❑ Contained within standardized non-proprietary data format and architecture
- ❑ Uniformly used by manufacturers, wholesalers and pharmacies

Electronic Pedigree Requirements

- ❑ Prescription Drug Information
- ❑ Transaction and Source Information
- ❑ Ownership Information
- ❑ Certification

CA's Requirements

Sequenced implementation -- the compliance timeline has been moved out

▣ **Manufacturers (generic and brand) must pedigree:**

- 50 percent of their products by 2015,
- the remaining 50 percent by 2016

Percentages can be based upon:

- Unit volume
- Product package (SKU) type
- Drug product family

Sequenced Implementation

- ❑ Wholesalers and repackagers must accept and pass pedigrees by July 2016
- ❑ Pharmacies and pharmacy warehouses must accept pedigrees by July 2017

Exemptions

- ❑ Radiologic drugs
- ❑ Drugs labeled “for veterinary use only”
- ❑ Compressed medical gases
- ❑ Solutions:
 - IV solutions for replenishment
 - IV solutions used to maintain equilibrium of water and minerals (dialysis)
 - Solutions for irrigation or reconstitution
- ❑ Surgical kits containing a device and medical supplies, sealed by the Mfg.
- ❑ Kits containing a drug/device, biologic/device, drug/biologic/device that are physically or chemically or combined as produced as single entity
- ❑ Kits containing two or more products packaged together in a single package comprised of a drug and device or biologic and device
- ❑ Drugs received by a state or local government agency from a federal govt. agency

Expanded or New Definitions

- ❑ Manufacturer includes NDA, ANDA, and BLA holders; contract Mfgs
- ❑ “Smallest package or immediate container” which must be pedigreed is further defined as the smallest unit made by the mfg. “for sale to the pharmacy”
- ❑ Third party logistics provider: a licensed wholesaler who takes possession of, but not ownership of, drugs. Does not need to append pedigree but must maintain copies of it.
- ❑ Invoice Annotation to Pedigree: allows a customer-specific shipping number referenced to the sales invoice number in place of invoice number

Repackagers Included

“Repackager” added to various sections to clarify that repackagers:

- Are a manufacturer that must pedigree repackaged items
- Must reference original pedigree information on repackaged products
- Must create a unique identification number for pedigree of repackaged items

Inference

- ❑ Board will need to establish regulations to allow
- ❑ Allows a unique identifier to be applied to a case, pallet or other “aggregate” without individually reading each serialized unit
- ❑ Specifies intent that Mfgs, 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

Grandfathering of Existing Product

Establishes process for mfgs., wholesalers and pharmacies to designate drugs already in their possession when pedigree requirements kick in

- ❑ Exempts from pedigree requirements drugs described in written lists submitted to board
- ❑ These lists are confidential
- ❑ Board may establish requirements for the lists -- regulations

Drop Shipment

- ❑ Provides definition: Products shipped from Mfg to Pharmacy; Ownership/Pedigree goes from Mfg to wholesaler to pharmacy
- ❑ Regulations may be developed to establish alternative pedigree

Preemption

Preemption of CA law, if:

- ❑ Federal legislation or federal regulations are enacted addressing pedigree or serialization measures for dangerous drugs
 - Within 90 days board must publish notice of inoperation of pedigree requirements
 - Within 90 days board must adopt emergency regs stating inoperation of requirements
- ❑ If FDA enacts any rules or takes action inconsistent with any provision of CA law, that CA provision is inoperative
 - Within 90 days board must publish notice of inoperation
 - Within 90 days board must adopt emergency regs stating inoperation of specific requirements

Senator Ridley-Thomas' Letter to the Senate Journal (8/25/08)

- ❑ Commemorating agreements that the amendments incorporated in SB 1307 by all involved parties to operate in good faith to implement the requirements as soon as possible and by the dates established in the bill. Writing in support are:
 - ❑ Abbott Laboratories Biocom
 - ❑ Amgen CA Healthcare Institute
 - ❑ Arena Pharmaceuticals CA Pharmacists Association
 - ❑ Barr Pharmaceuticals CA Retailers Association
 - ❑ Baxter Healthcare CA Society of Health-System
Pharmacists
 - ❑ Bayer Healthcare

Entities in Support (cont)

- CA State Association of Counties
- Cardinal Health
- Compressed Gas Association
- Council on Radionuclides and Radiopharmaceuticals
- Daiichi-Sankyo
- Genentech
- Generic Pharmaceutical Association
- Gray Panthers
- Healthcare Distribution Management Association
- Hospira
- Johnson and Johnson
- McKesson Corporation
- Merck, Inc.
- Mylan, Inc.
- National Association of Chain Drug Stores

Entities in Support (cont)

- National Coalition of Pharmaceutical Distributors
- Novartis Pharmaceuticals
- Pfizer
- Pharmaceutical Research and Manufacturers of America
- Rite Aid
- Sandoz, Inc.
- Teva Pharmaceuticals, USA
- Walgreens
- Wyeth

2011

- Sometime during 2011, most likely in the fall, the board will resume work on pedigree requirements. This will most likely include regulations to specify:
 - Inference
 - Pedigree requirements for drop shipments
 - Linkage between shipping order and invoice
 - Decommissioning

Where e-pedigrees would have helped

- Heparin 2008 --Five separate recalls of heparin from mfgs between January and March

Hospital Inspections Initiated

- ❑ 533 hospitals
- ❑ Personal inspections by Board of Pharmacy staff
- ❑ Between April 15 and July 1, 94 had recalled heparin located by board in non-quarantined areas
- ❑ Numerous notices to licensees over the three months that recalled heparin had been found in health care facilities and search to remove it
- ❑ 7,000 patients in CA exposed after recalls initiated

Perfect Storm of Problems with these recalls

- ❑ Repeated notices by different manufacturers in short time, and FDA alert released several weeks later (“I have already seen this”)
- ❑ Recall notice identifies recalled drugs by lot number – this number does not appear on invoices
 - No easy way to ID if hospital, especially large hospitals, have them
 - Some hospitals purchase drugs outside of pharmacy premises and have deliveries made to warehouses
 - Recall notices from wholesalers shipped in totes with new drugs and filed away, not provided to pharmacy director

Perfect Storm

- ❑ Use of the word “voluntary” on recall notice
- ❑ Heparin found and stashed all over hospitals, outside of control of pharmacy
- ❑ Some returned heparin to wholesalers, who did not recognize it as recalled, and reshipped it to new pharmacies (3 of these documented by the Board)

Resolution:

- ❑ Citations and fines for pharmacies and pharmacists-in-charge
- ❑ Statutory changes in California law (7/2009) to require all licensed sites to join Board's subscriber alert to enable immediate contact of licensees
- ❑ *Recall Best Practices* for hospitals developed in series of meetings with stakeholders
- ❑ Will share and route recalls

Recalls

Ever increasing number: Between February 4 and 14, 2011, there were seven notices of recalls sent to the board. One was to the consumer level, the other six to the retail level.

Manufacturers recall by lot number, but pharmacies and wholesalers currently don't often track it.

Other Needs/Uses for E-Pedigree:

- ❑ Significant recent thefts of drugs, \$75 M, \$37 M, \$8 M – drugs may re-enter supply
- ❑ Recalls, returns, drug take-backs will be greatly facilitated by electronic track and trace, will help end fraud

Reporting Counterfeits in CA

- If a manufacturer, wholesaler or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify the Board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or throughout CA

CA Business & Prof Code 4034(h)

Takeaway(s)

- ❑ Problems exist in supply chain
- ❑ Additional time has enabled vendors and standards organizations to step into the space to provide possible solutions
- ❑ Increasing press interest in this subject
- ❑ Federal solution modeled on California law is very likely – timing still uncertain
- ❑ E-pedigree is coming. If you have not yet made any progress during last 7 years, 5 years to effective date will go by in a flash

Thank you
