



# California Prescription Drug Pedigree Requirement

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# Pedigree Overview

## First Law 2004

- SB 1307 (Figueroa) enacts CA's Law
- 1/1/2005 some sections implemented
- 1/1/2007 original pedigree implementation date, board could extend to 2008

# California Law Amendments in 2006

- Moved pedigree implementation date to 1/1/2009
- CA Board of Pharmacy may delay implementation of pedigree until 1/1/11
- Basic framework of pedigree law was not changed, but specificity was made to require unit-level serialization and interoperability.

## Throughout late 2007 & Early 2008

- Supply chain becomes highly concerned about inability to meet the January 1, 2009 implementation date
- Board of Pharmacy stands firm on date until March 25, 2008, when it agrees to move implementation date to January 2011 following receipt of “readiness letters” from supply chain members.

# California Law Amendments in 2008

- Established staggered implementation throughout supply chain (2015-July 2017)
- Added definitions to clarify provisions
- Added preemption for federal legislation or rulemaking

# 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

# 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.

# Pedigree Definition

- Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution

# 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

# Historical Context

- 1988 to 2008, 20 years under the PDMA does not stem diversion or counterfeiting  
Publication of final regulations implementing PDMA (as amended by the Prescription Drug Amendments of 1992 (PDA)) in 1999.  
Pedigree regulations stayed repeatedly.  
Rising concern over counterfeiting leads FDA Commissioner Mark McClellan to establish Counterfeit Drug Task Force in July 2003.

# Historical Context

- Beginning in 2003, states spurred to act  
Numerous contributing factors, including  
2003: Florida grand jury investigation reports  
2003: FDA Counterfeit Drug Task Force convened  
2003-2005: News reports on counterfeits and patient harm, including Washington Post series, segment of 60 Minutes, *Dangerous Doses*, events leading to "Tim Fagan's Law," and others  
Patients in CA among those potentially affected  
2003-2005: Nevada, Florida, and California

# Historical Context

- In 2004, published substantive Report of FDA Counterfeit Drug Task Force
  - Restated threat from recent increase in and sophistication of counterfeits/counterfeiters.
  - Among other findings, Report concluded that adoption and common use of reliable track and trace technology based on RFID tagging of products was feasible for use by 2007.
  - Encouraged use of electronic track and trace technologies and electronic pedigrees.

# Historical Context

- In 2005 and 2006, follow-up Reports by FDA Counterfeit Drug Task Force

Progress toward electronic track and trace and RFID adoption, but disappointment that industry had not voluntarily met 2007 projections for electronic track and trace, RFID implementation, mass serialization.

“We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps . . . and States that have championed this cause, such as California.” (2006 Update)

Recommended universal pedigree requirement (not just non-ADRs) to document all drug movements.

Recommended lifting PDMA regulations stay 12/06.

# Historical Context

- In 2006, as January 1, 2007 deadline drew near, California amended its law (SB 1476), extended date to January 1, 2009.

Primary motivation was to give more time.

Still no specification of particular technology, though interoperability, track and trace, and unique identifier requirements were added – made serialization requirement more explicit.

Gave Board of Pharmacy authority to extend deadline further, to January 1, 2011.

# Historical Context

- In 2007-2008, always close relationship between FDA and California draws closer on pedigree
- FDA repeatedly states support for the California model, including electronic track and trace, mass serialization with unique unit identifier, end-to-end universal pedigree (all drugs, all entities).  
FDA has said FDAAA standard-setting supports, does not deter, California pedigree compliance.

# Problem

- Of 4 billion US prescriptions in 2007, up to 40 million may have been filled with counterfeits, up to 10% in California; projected \$75 billion worldwide by 2010.
- FDA counterfeit drug cases: number opened 2004-2007 was more than double 2000-2003, while number opened in 2003 was itself five times that opened in 2000.  
In 2007, FDA counterfeit cases resulted in 71 arrests, 50 convictions, and \$26.5 million in fines and restitution.
- In April 2008 the FDA had 20 open counterfeiting cases from just one of two regional California offices.

# SB 1307 (2008 legislation):

Signed by the Governor on September 30, 2008

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

Percentages can be based upon:

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

# SB 1307 (2008 legislation):

## *Legislative Intent (SB 1307)*

California's electronic pedigree system will "provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

## **SB 1307 (2008 legislation):**

At the same time, it is recognized that the process of implementing serialized electronic pedigrees for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

# SB 1307 (2008 legislation):

## 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

# SB 1307 (2008 legislation):

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

# SB 1307 (2008 legislation):

“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

# SB 1307 (2008 legislation):

## Inference

- Board to establish regulations
- 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

# SB 1307 (2008 legislation):

## Grandfathering

- 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

# SB 1307 (2008 legislation):

## 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

# SB 1307 (2008 legislation):

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
  - Amgen
  - Arena Pharmaceuticals
  - Barr Pharmaceuticals
  - Baxter Healthcare
  - Bayer Healthcare
  - Biocom
  - CA Healthcare Institute
  - CA Pharmacists Association
  - CA Retailers Association
  - CA Society of Health-System Pharmacists

## 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

# Next Steps Forward

- Manufacturing off shore will continue to expand – supply chain needs security
- Work with FDA, GS1, and industry on standards/technologies.
- Formal and informal participation with FDA and federal legislators
- Expect to incorporate/use FDA standards.
- Continue working with industry on various initiatives to increase implementation Including GS1 standards-setting.
- Encourage technological development.

# What Vendors Have Told Us

- Many of the pieces are available now, but each company must develop its strategy.
- Actual pedigree record/transmission may be the easiest (and final) piece. Hardest piece may be serialization infrastructure.
- Many industry participants are working on outdated, non-integrated, legacy systems.
- Technology costs including RFID prices will continue to come down.

# Questions and for more information:

- [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)
- Click under information about e-pedigree
- Attend quarterly Enforcement Committee Meetings of the Board where E-Pedigree issues are scheduled.
- Work with your associations, GS1 and other interested groups.

*Thank you*

