

# California E-Pedigree Update

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# Statutory Mandate

Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions.

Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

*CA Business and Professions Code 4001.1*

# 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

# California's Requirements

## the law is really simple

- Unit Level Serialization
- Certification of Sales and Purchases
- Tracking of product information including lot level and expiration date
- All owners must append
- Nonproprietary and Interoperable
- Sanctions to cite and fine \$5,000 per transaction for violations

# Quick History Review

- 2004 First E-pedigree requirements established in CA starting 2007.
- 2006 E-pedigree law amended pushing back dates to 2009, and 2011 if supply chain documents need for a bit more time
- 2008 E-pedigree law amended pushing back implementation on a staggered basis to:

# California Law Today

- January 1, 2015: 50 percent of a manufacturers products sold in CA must be serialized
- January 1, 2016: remaining 50 percent must be serialized
- July 1, 2016: repackagers and wholesalers must be compliant
- July 1, 2017: distribution centers and pharmacies need to be compliant



# Regulations will be Needed for:

- Grandfathering
- Identification of how a manufacturer will establish the 50 percent
- Serialized numeric identifier
- Inference
- Certification
- Drop shipments

# The Regulation Process

Intended to encourage public input:

1. Identification of problem, develop solutions, alternative language
2. Formal rulemaking process
3. Review by outside administrative agencies

The process takes about one year

# Currently

- Board has drafted regulations needed to implement e-pedigree requirements
  - Serialized unique identifier
  - How mfg. are to report the 50 percent of compliant product on January 1, 2015
  - “Grandfathering”

*Copies are available from*

*<http://www.pharmacy.ca.gov> click under laws and regulations, then pending regulations*

*Final action expected by October 25, 2013*

# Serialized Numeric Identifier

- Regulation adopted as section 1747
- Shall conform to the FDA's SNI guidelines
- NDC plus 20 digit alpha numeric number

# Identification of 50 percent Serialized Product

- Section 1747.1
- Requires a list to be submitted to the board by December 31, 2014
- A Statement by someone authorized to bind the company
- A list of what products have been serialized, and how the 50 percent was calculated (SKU, unit volume, drug product family)

# 50 Percent

- A statement providing the calculations to reach the 50 percent
- A list and quantity of remaining drugs that are not yet serialized
- A statement describing what technology was used including platform, vendor, hardware, software and communications technology employed

# Remaining 50 Percent

- And due December 31, 2015, the same information for the remaining 50 percent.

# No Lists Submitted?

- Failure to provide the lists as specified by December 31, 2014 and December 31, 2015 are specifically defined as violations of pharmacy law.
- In addition to sanctions available to the board, products cannot be sold in CA



# “Grandfathering”

- Any manufacturer, wholesaler or repackager seeking to identify drugs it possesses as not serialized must submit to the board by July 31, 2016, a signed statement by someone authorized to bind the company:
  1. a list of drugs by name, SKU and NDC that it possessed BEFORE July 1, 2016
  2. a statement of how acquired
  3. a statement discussing how the drugs will be handled

# Grandfathering Part 2

- For pharmacies and pharmacy warehouses, by July 31, 2017, a list by someone authorized to bind the company according to the same criteria as for wholesalers and manufacturers

# The Board May . .

- The board may declare submissions as noncompliant, and can reject and require resubmissions until determined to be compliant for all declarations specified in this regulation section

# Where is the text of this regulation?

- [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)
- Click under “laws and regulations”
- Click under pending regulations

## CURRENT STATUS:

work and hearings completed by board,  
undergoing review by administrative agencies  
necessary to implement a regulation, final  
action due October 25, 2013

## Currently Under Development – More Regulations

- Drop shipments to e-pedigree

Status: Currently undergoing 45 days of public comment. Written comments to be submitted to board by October 28, 2013

Oral testimony before board on October 29, 2013

# Drop Shipments

For the purposes of Business and Professions Code section 4163.1, when a manufacturer utilizes the “drop shipment” method of sale as defined by that section, the data elements pertaining to transfers of ownership to and from the wholesaler distributor, including any certifications for receipt and delivery thereby, may be

## More text of drop shipment

omitted from the pedigree, in which case the manufacturer shall convey the pedigree directly to the pharmacy or other person authorized by law to dispense or administer the dangerous drug prior to or contemporaneous with delivery of the corresponding dangerous drug.

# Still Under Development by the Board

- Inference
  - Certification
  - Inspection
-



# New Regulations Under Development

- September 26, 2013

Proposed draft regulation text for inference and certification refined.

- See the text at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

Click under “about the board”

Enforcement Committee meetings, then

September 26, 2013, then

meeting materials

# What Type of Inference is Proposed?

- Homogeneous sealed case from manufacturer
- Advance receipt of pedigree record establishing eaches to case,
- Digital signature by responsible party
- The case remains unopened by wholesaler, and package shows no signs of tampering
- When case is opened, all its contents are immediately scanned

# Regulations in the Future

- Closure of Pedigree at end of life of product

# Get Involved!

- Meetings are public
- We are webcasting most meetings
- Join the subscriber alert
- Web section to be devoted to all things pedigree. Will include Qs and As

# Next E-Pedigree Meetings

December 10 – San Francisco

Thank You.