



California Prescription Drug Pedigree

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Introductory Remarks

Pedigree Overview Existing Law 2004

- 2004 comprehensive anti-counterfeiting legislation passed
- 1/1/2005 legislation enacted & some sections implemented
- 1/1/2007 original electronic pedigree implementation date
- 1/1/2009 current electronic pedigree implementation date

California 2006 Pedigree Legislation

- Purpose
 - Response to industry request to delay
 - Allow technology to mature and continue to develop
 - Develop standards for interoperability and unique identifiers
 - Ensure system developed protects public safety
 - Clarification of original legislation

What is the problem , why state legislation?

- Counterfeit drugs entering legitimate pharmaceutical supply chain
- Inability to track source of counterfeits
- Obvious danger to health & safety of public
- Federal legislation implementation delayed

California regulation of prescription drugs

- Prescription drugs from manufacture through all stages of distribution until dispensed or administered to a patient by a pharmacy or prescriber are regulated in CA through required licensing of both the businesses and the individuals working in those businesses

California Licensing Scheme

- Businesses licensed
 - Manufacturer/ repackager located in CA
 - Wholesale drug distributor (both located in CA and out of state wholesaling into CA)
 - Brokering defined as wholesaling
 - Pharmacy (retail, hospital) (both located in CA and out of state dispensing to CA residents)

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.

Addition to Pedigree Definition 2006 Legislation

- 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 Document Requirements

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

Prescription Drug Information

- Drug name – trade or generic
- Quantity
- Dosage form
- Strength
- Container size
- Number of containers
- Expiration dates
- Lot numbers

Transaction and Source Information

- Business name
- FDA manufacturing registration number or state license number as determined by the Board
- Principal address of the source
- Date of transaction
- Sales invoice number

Ownership Information

- For each prior owner of the drug the pedigree must contain:
 - Prescription drug information
 - Source information
 - Transaction information
 - Name & address of each person certifying delivery or receipt of prescription drug

Pedigree Certification

- A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate

Pedigree tracking

- Pedigree tracks each prescription drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy.

Drug Returns

- Prescription drugs returned to the manufacturer, wholesaler or reverse distributor are documented on the same pedigree document as the transaction that resulted in receipt of the drug by the party returning the drug.

Repackaging-a part of original pedigree

- Single pedigree includes every change of ownership from initial manufacturer through the final transaction to a pharmacy or other person for furnishing, administering or dispensing the prescription drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number

Transactions not requiring a pedigree

- Samples –provision of prescription drug samples by a manufacture’s employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge

Transactions not requiring a pedigree (cont)

- Injectable prescription drugs delivered directly by manufacturer to an authorized prescriber directly responsible for the administration of the injectable
 - may not be dispensed to a patient or patient’s agent for self administration
 - Must be administered to patient by prescriber or other authorized entity receiving drug directly from manufacturer
 - Exemption expires 1/1/10 unless industry requests extension and Board grants to 1/1/11

Reporting requirement

- Manufacturer, wholesaler or pharmacy with reasonable cause to believe a prescription drug in, or having been in, its possession is counterfeit or subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify CA Board in writing within 72 hours of obtaining knowledge.
 - Applicable only if drugs sold or distributed in or through the state of California

Related Existing Law

- All wholesalers selling into or located in CA must be licensed in CA (effective 1/1/05)
- Surety bond required for all licensed wholesalers
- Restrictions on pharmacy furnishing, manufacturers and wholesalers (effective 1/1/05)
- Wholesaler or pharmacy may not purchase, sell, trade or transfer a prescription drug without receiving or issuing a pedigree (effective 1/1/09)

Pharmacy Furnishing Restrictions

- Pharmacy may only furnish prescription drugs to:
 - Wholesaler/manufacturer from whom the drug acquired
 - Pharmacy/wholesaler of common control – drugs may only be transferred to wholesaler by pharmacy if drugs originally purchased from commonly controlled wholesaler
 - Licensed wholesale reverse distributor
 - Pharmacy or wholesaler in sufficient quantity to alleviate a specific shortage

Pharmacy furnishing restrictions (cont)

- Patient or pharmacy pursuant to a prescription
- Health care provider authorized to purchase prescription drugs
- Pharmacy under common control

Other restrictions

- Manufacturer/wholesaler/pharmacy may only furnish prescription drugs to a licensed business or prescriber
- Acquire prescription drugs only from a manufacturer or licensed wholesaler
- Effective 1/1/09, a wholesaler or pharmacy may not receive, sell, trade or transfer a prescription drug without a pedigree

Enforcement/Investigation

- Adulterated, Misbranded, Countereit
 - Manufacturer container
 - Prescription container
- Recall
- Repackaging
- Drug returns

What do we do to prepare for 1/1/09

- Develop interoperability standards
- Develop unique identifier standards
- Participate in public CA Board of Pharmacy quarterly pedigree workgroup meeting
- Participate at pharmacy, wholesaler and manufacturer levels to assure compliance by 1/1/09



Questions?

Visit our Web site at
www.pharmacy.ca.gov

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