California Prescription Drug Pedigree

Judith K. Nurse, Pharm D
Supervising Inspector
CA State Board of Pharmacy

Pedigree Overview Existing Law 2004 (cont)

- CA Board of Pharmacy may delay implementation of pedigree until 1/1/08
- CA legislature may delay implementation of pharmacy pedigree until 1/1/09

Pedigree Overview Existing Law 2004

- 2004 legislation passed
- 1/1/2005 legislation enacted & some sections implemented
- 1/1/2007 original pedigree implementation date

Pending Legislation On Governor's Desk

- 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

CAUTION

- If Governor does not approve this legislation, the information discussed in the next 16 slides WILL NOT become law.
- California then reverts to existing 2004 law, implementing pedigree 1/1/2007 unless Board takes action to extend implementation date to 1/1/2008

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

Pending Legislation Governor's Desk (cont)_

- Governor deadline to sign legislation 9/30/06. If signed effective 1/1/07
- 1/1/2009 pedigree implementation date
- CA Board of Pharmacy may delay implementation of pedigree until 1/1/11
- Application of pedigree in pharmacies subject to review during Board's sunset review

Pedigree Definition Pending 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

Prescription Drug Information

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

Electronic Pedigree Requirements

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

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

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

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 or wholesaler are documented on the same pedigree document as the transaction that resulted in receipt of the drug by the party returning it.

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

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

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 to 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 (cont)

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

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

Other restrictions

- Manufacturer/wholesaler may only furnish to an authorized person
- 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 dangerous drug without a pedigree

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

Or call us at (916) 574-7900