

Background and Summary of the California ePedigree Law

Problem: there is an increasing prevalence of counterfeit prescription drugs showing up in the US, intermingled with the legitimate drug supply. Counterfeit prescription drugs are a worldwide problem, reaching as high as 30 percent of the supply in some countries. The World Health Organization estimates that in developed countries, counterfeit drugs are less than 1 percent of the market.

To put this in perspective: 3.4 billion prescriptions were dispensed in the US in 2006. If 1 percent of this supply is counterfeit, this would mean that perhaps 34 million of these US prescriptions were filled with counterfeit medicine. In California, we have roughly 9 percent of the US prescription drug market, so this would indicate that perhaps 3 million prescriptions were filled and dispensed with counterfeit medicine in 2006.

In an attempt to prevent counterfeit medicine from entering the legitimate supply chain in California, in 2004 the state legislature passed anti-counterfeiting and anti-diversion legislation (SB 1307), including provisions pertaining to the licensure and qualifications of wholesalers, restrictions on furnishing, and the requirement of an electronic pedigree to accompany/validate drug distributions. Portions of the legislation were implemented in 2005 and 2006. In 2006, subsequent legislation (SB 1476) sponsored by the board moved the implementation date for the electronic pedigree component until 2009; the same legislation also augmented and clarified portions of the electronic pedigree requirements.

Under current law, as of 1/1/2009, no wholesaler or pharmacy may sell, trade or transfer a prescription drug at wholesale without providing, and no wholesaler or pharmacy may acquire any prescription drug without receiving, a pedigree.

The pedigree is a record in electronic form containing information regarding each transaction resulting in a change of ownership of the given prescription drug, including returns. The law specifies the particular data elements pertaining to the drug and to each of the ownership links in the chain of distribution that must be included in this record, and requires that the pedigree track each drug at the smallest package or immediate container (saleable unit). To implement this unit-level tracking requirement in an interoperable electronic system, requirements include a unique identifier (serialization number) placed on the smallest container saleable to a pharmacy, by the pharmaceutical manufacturer. Likewise, the manufacturer will also initiate the pedigree and pass that pedigree with the initial distribution; thereafter, the electronic pedigree will at all times accompany that particular container, appended by each successive owner to document each change of ownership of that particular container.

Simply put, the goal is for any owner/possessor of a prescription drug located at a licensed wholesaler, repackager, reverse distributor, or pharmacy in California, upon request, to have and keep electronic records that show the lineage of the drug from the manufacturer through to the current point in the drug distribution channel (wholesaler, repackager, pharmacy). The electronic pedigree must contain specific information required by statute, and must be made and passed in an "interoperable electronic

system,” an electronic track and trace system based on unique identification numbers (serialization) affixed at the point of manufacture.

The unique identifier or unique serialized number on each saleable container of prescription drugs will most likely be carried on either on a 2-D bar code or an RFID chip placed on the saleable unit by the manufacturer. The California Legislature has not mandated these specific technologies, but they are the two methods that have been identified that could meet the requirements of the legislation. The number on the serialized container could then be utilized to access the specific electronic pedigree for that individual container of prescription drug.

Industry participants have engaged in standards-setting work to develop industry standards necessary to interoperability and sharing of pedigree data and records. The primary standards-setting body for the industry that has been engaged in this work with industry participants has been EPCglobal, the same entity that developed the standards for the UPC bar code.

Requirements:

- ***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 and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drugs. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.”*** (California Business and Professions Code section 4034(a)).
- ***Interoperability:*** this is one of the augmentations to the legislation in 2006. With input from industry, we determined for this pedigree concept to work effectively, all parties at all levels of the supply chain needed to be able to access the pedigree information without having to purchase numerous types of hardware, software and middleware to be able to read whatever format a particular manufacturer chooses for their electronic pedigree. This will discourage companies from developing their own incompatible proprietary systems of electronic pedigrees, preventing a proliferation of systems and making it complex to read the pedigree by entities downstream (e.g., wholesalers and pharmacies). In January 2007, EPCglobal ratified a document-based pedigree messaging standard. Nearing finalization is a second EPCglobal standard, the EPCIS standard. The EPCIS standard would also allow the creation or appending of a pedigree, combined with a data storage and management system. This should be completed in several months.

“Interoperable electronic system” as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained

within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers and pharmacies for the pedigree of a dangerous drug. (California Business and Professions Code section 4034(i))

- Serialization at the unit level: this is the key to being able to enter, for instance, a pharmacy or wholesaler, to distinguish one container of prescription drugs from another, and to access the pedigree for each individual container. In addition, as long as the original container is available, the entire history of ownership for that specific container may be accessed. Specifically: ***“The pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy or another person furnishing administering or dispensing the dangerous drug”*** (California Business and Professions Code section 4034(d)).

With the California system, two containers of the same drug, same strength, same lot number and same expiration date, can be differentiated from each other. They each may have traveled very different supply chain routes to arrive at the same location. Only with the California serialized product can you tell each change of ownership for each container. The California process allows regulators to determine the origin of a container and be much more likely to identify when or if a product has been tampered with or if a counterfeit product has entered the supply chain.

- Repackaging: must be tracked on a single pedigree tracing back to the original manufacturer. Specifically: ***“a single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transactions to a pharmacy or other person for furnishing, administering or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number”*** (California Business and Professions Code section 4034(c)).
- Returns: must also be tracked on a single pedigree. ***“Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it”*** (California Business and Professions Code section 4034(e)).

The pedigree must contain (data elements):

1. The source of the dangerous drug, including the name, federal manufacturer’s registration number or a state license number as determined by the board, and principal address of the source.
2. The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, and the number of containers, the expiration dates, and the lot numbers.

3. The business name, address and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information including the name and address of each person certifying delivery or receipt of the dangerous drug.
4. 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.

California law also requires that pharmacies may not act as wholesalers, and

"A pharmacy may furnish dangerous drugs only to the following:

- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.**
- (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.**
- (3) A licensed wholesaler acting as a reverse distributor.**
- (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.**
- (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.**
- (6) A health care provider that is not a pharmacy, but that is authorized to purchase dangerous drugs**
- (7) To another pharmacy under common control. "** (California Business and Professions Code section 4126.5)

- Sanctions: ∓ In addition to other possible sanctions for non-compliance with pedigree requirements up to and including civil or criminal prosecutions, the board may cite and fine \$5,000 per occurrence (each saleable unit) or take formal discipline. Wholesalers must post a \$100,000 bond with the board as a condition of licensure, which provides a source to pay any fines assessed.
- Reporting to the board: a manufacturer, wholesaler or pharmacy with reasonable cause to believe a prescription medicine in or having been in its possession is counterfeit or subject of a fraudulent transaction shall notify the California Board of Pharmacy in writing within 72 hours of obtaining knowledge (only for drugs sold or distributed through California).
- Implementation Delay: the board can delay these requirements until 1/1/2011 if it determines, consistent with its public protection mandate, that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state.