

RFID Security Alliance

A resource for the RFID industry, driving market education and discussion about security and privacy issues surrounding the use of RFID technologies, solutions and applications.

www.RFIDSecurityAlliance.com

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SECURE RFID TRACKING OF DRUGS FROM A-Z INCLUDING MEDICINAL MARIJUANA



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Monthly calls announced on LinkedIn

Next: June 8th at 10 am Pacific

www.linkedin.com/groups?gid=62849

California Law-Epedigree

- The implementation compliance dates are:
 - 50 percent of a manufacturer's products by 2015;
 - The remaining 50 percent of the manufacturer's products by 2016;
 - Wholesalers and re-packagers must accept and forward products with the e-pedigree by July 1, 2016; and
 - Pharmacy and pharmacy warehouses must accept and pass e-pedigrees by July 1, 2017
- Reference
http://www.pharmacy.ca.gov/about/e_pedigree_laws.shtml

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)).

Interoperable=GSI Standards

“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

“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

Re-packaging

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)).

Data Elements

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.

The Marketplace

- The Rise and transformation of Supply Scape to Trace Link
- Very few small companies left in the market
- New Players are coming into the market from adjacent fields like rfXcel

Current Providers needed to be

1. Compliant with EPCglobal Ratifies Pedigree Messaging Standard which provided electronic XML Pedigrees among trading groups
2. Support Florida Department of Health Requirements, DH 2129, DH2135 as well as current electronic records standards and signatures

Medical Marijuana

- 14 States authorize the use of pot
- Dosages are a maximum of 2 ounces a day
- No state has an track and trace system in place
- City of Oakland leads the way in California
- Fear of Federal Intervention-Class I Drug

How to Keep RFID Data Secure

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