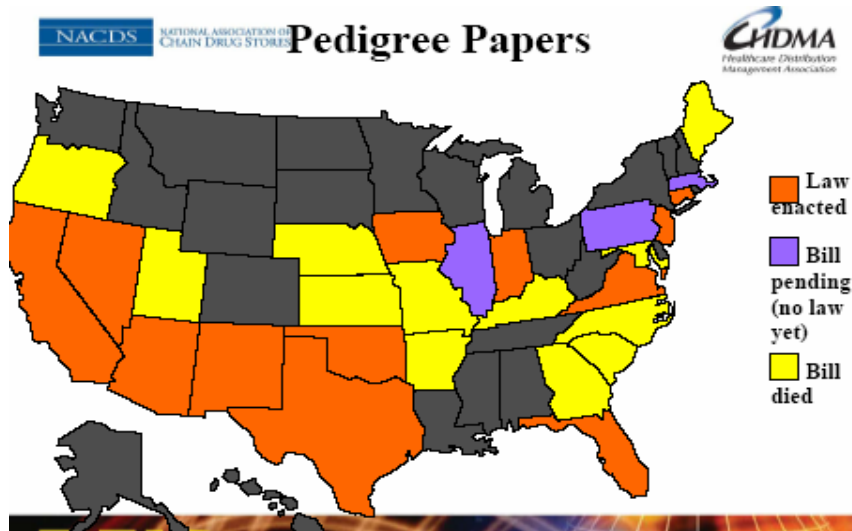


## RX Tracking Regulations - Active State Pedigree Laws (As of 10/17/05)



Sources:

- NACDS RFID Health Care Industry Adoption Presentation By Diane L. Darvey, Director, Pharmacy Regulatory Affairs
- Anti-Counterfeit Drug Initiative Workshop and Vendor Display Response Letter By John Patrick Oroho, Counsel to the PDMA Alliance, Inc.

\*\*\*Note: None of the states specifically refer to the impact their legislation will have on reverse logistics, with the exception of recommendations of appropriate methods of disposal.

### Common Features of All State Programs:

- Use of Pedigrees
- Increased licensing requirements
- Bonds required for wholesalers
- Financial/criminal background checks for wholesalers
- Wholesalers must designate a representative
- Increased inspections
- Accreditation of wholesalers required by Nat'l accreditation body

| State | Summary of Law   |
|-------|--|
| AZ    | <p>Paper or Electronic Pedigree with EVERY wholesale distribution IF drug leaves normal chain of distribution</p> <p>Exemptions for manufacturer, intercompany transfers, and other transfers</p> <p>Each recipient must provide certification that they have authenticated the pedigree</p> |

| State | Summary of Law   |
|-------|--|
| CA    | <p>Electronic record of transactions resulting in a change of ownership of the drug<br/> Each recipient must provide certification that they have authenticated the pedigree<br/> Non-resident wholesalers must have \$100,000 surety bond to be licensed.</p> <p><b>Program applies to any company that takes possession or transfers possession of RX drugs.</b><br/> Program will be implemented in 2008.</p>   |
| CT    | <p>Paper/e-Pedigree of each distribution from manufacturer to distributor to pharmacy<br/> Working on pedigree authentication program</p>  |
| FL    | <p>Paper/e-Pedigree of each wholesale distribution of drug. Effective July 2006, must be approved by dept of Health<br/> Each recipient must provide certification that they have authenticated the pedigree<br/> As of July 2006, FL will not recognize/exempt authorized distributors of record. EVERYONE must give/receive pedigree (except patient).<br/> Criminal liability for noncompliance<br/> Two exemptions from requirement to provide pedigree: 1. manufacturer when selling to distributing its own drugs, 2. an affiliated group of 50+ retail pharmacies, warehouses, or repackagers who distribute among the group.</p> <p><b>Only wholesalers doing business in Florida will be required to participate in the tracking process.</b></p> |
| IN    | <p>Paper/e-Pedigree approved by Board of Pharmacy for all drugs that leave the normal chain of distribution<br/> Wholesaler can't deliver a "legend drug" without a current pedigree.<br/> Wholesalers must submit surety bond.<br/> <b>Applies only to wholesalers and secondary wholesalers, and those who sell product to wholesalers.</b></p>  |
| IA    | <p>Record all transactions between manufacturer and wholesaler.</p>  |
| NV    | <p>Paper/e-Pedigree for all RX drugs before 1/1/07. After 1/1/07, only e-Pedigrees.<br/> Must be certified by wholesaler or representative.</p>  |
| NM    | <p>Requirements TBD by Board of Pharmacy.</p>  |
| NJ    | <p>Pedigree identifying all sales.<br/> Recognizes authorized distributors of record.<br/> Criminal liability for noncompliance.<br/> Increased requirements for wholesaler permits.</p>   |
| OK    | <p>Requirements TBD by Board of Pharmacy.<br/> Wholesalers must provide bond and fingerprints of a representative.</p>   |
| TX    | <p>e-Pedigree that records each wholesale distribution.<br/> Each recipient must provide certification that they have authenticated the pedigree</p>   |
| VA    | <p>Paper/e-Pedigree of each distribution.<br/> Requirements will be limited to specific drugs (high-risk/vulnerable to counterfeit)</p>  |