

Drug Pedigree Requirements

Now, All Drugs Across America Require Pedigrees

Federal PDMA Pedigree required in every state

December 2006 Pedigree Deadline

- All drugs distributed in the U.S. require transaction record-keeping

Injunction Does Not Delay Pedigree

- The vast majority of pedigree requirements remain in effect, even with the federal court injunction

35+ States require more stringent pedigrees

- Pedigree requirements in the majority of states exceed the federal PDMA

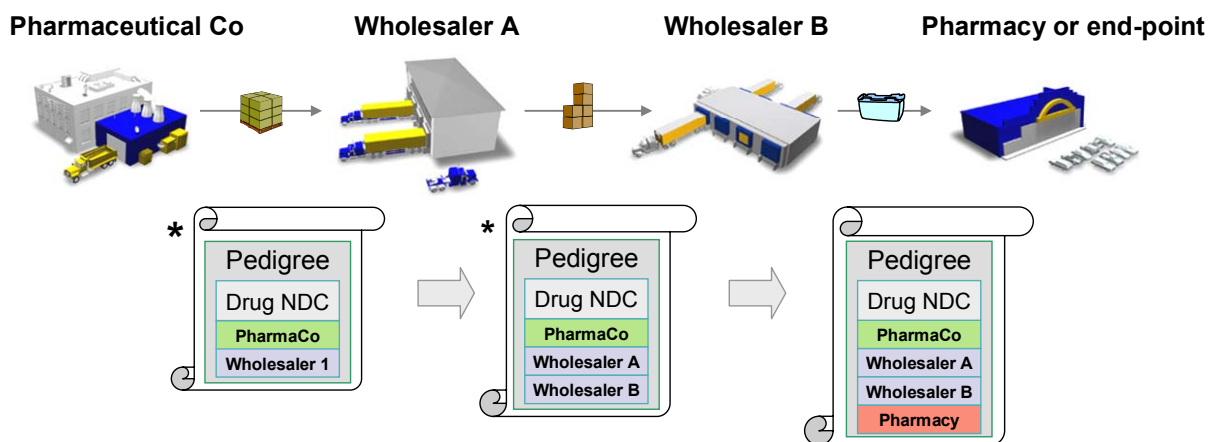
To protect the millions of pharmaceutical drugs distributed daily from counterfeiting, diversion and other product integrity threats, federal law requires drug pedigrees in every state today. In addition, a majority of states have more stringent pedigree requirements than the federal law. Make sure you're prepared.

The federal Prescription Drug Marketing Act (PDMA) *pedigree is not delayed by the court injunction.*

Since December 2006, all drugs distributed by wholesalers, distributors or repackagers require pedigrees, unless the seller has been designated by the manufacturer as an Authorized Distributor of Record for that drug.

These pedigree requirements also cover prescription drugs included with medical surgical convenience kits and medical devices, as well as repackaged drugs.

Compliant Pedigrees Ensure Transaction Security



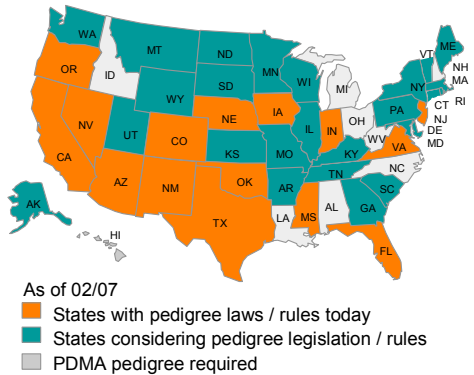
Over 200 million drug products are protected with electronic pedigrees already. The pedigree reflects the chain of custody back to the manufacturer or Authorized Distributor of Record. * Federal PDMA exempts an Authorized Distributor (ADR) of Record from pedigree. Most states don't exempt ADRs.

Pedigree Requirements

Everyone has some level of pedigree requirement. Even Authorized Distributors of Record must provide pedigrees in certain states. Since pedigree requirements vary among federal and state regulations, key core pedigree capabilities include:

- ✓ **3 year pedigree record-keeping.** All wholesalers must retain pedigrees they receive and/or provide for three years. This includes both Authorized Distributors of Record (ADR) and non-ADR wholesalers.
- ✓ **Pedigrees for all drugs.** Most wholesalers must provide a pedigree for all drugs they distribute. Pedigrees must be provided to all wholesale customers including wholesalers, distributors, pharmacies, physicians, dentists and veterinarians. Pedigrees are not needed when dispensing drugs to patients and consumers.
- ✓ **Transaction details.** Each PDMA pedigree must contain all transactions back to the manufacturer or last Authorized Distributor of Record, including the names and addresses of all parties to the transactions, and the transaction dates.
- ✓ **Transaction history.** While the federal PDMA requirement to record transactions back to manufacturer is stayed by the injunction, many wholesalers are doing it now because it's a requirement of a number of states including Arizona, California, Colorado, Florida, Indiana, Nebraska, Nevada, New Jersey and Texas. By following this approach, these wholesaler ensure their inventory is acceptable everywhere.
- ✓ **Transaction types.** All transactions including sales, distributions, drop shipments and returns require pedigree.

The State of Pedigree



A majority of states have or are considering pedigree legislation.

- 15 states have pedigree laws or rules today
- More than 20 states have proposed legislation or rules
- The PDMA pedigree is the minimum bar in states that don't have specific pedigree requirements

State pedigree regulations are diverse and may vary regarding:

- Authentication and certification requirements
- Repackaging, medical device, and med/surge convenience kits with drugs
- Lot number, expiration date, NDC, wholesaler license, transaction identifier
- Returns, even if pedigree was not required on forward sale
- Some states have normal chain of distribution requirements, others don't

Universal Pedigree Approach Reduces Risk, Cost

With the variations across the states, many wholesalers and distributors find it's easier and more reliable to have a single, consistent process. So they manage a complete pedigree for every drug. This way, they're confident their inventory is acceptable in any state. By providing pedigree, they're demonstrating that they're a trusted source of drugs. This secures existing relationships and opens doors for new trade opportunities. The universal pedigree approach accommodates all drugs you receive, which could come from or pass through any state.

Electronic pedigree saves you time and money because it automates record-keeping, streamlines the authentication process, and is far more secure and trusted than paper pedigrees. The **EPCglobal Drug Pedigree Standard** enables compliance with all federal and state pedigree requirements and ensures interoperability. Leveraging the standard eases your task of compliance.



Pedigree Compliance – Drug Supply Chain Security – Maximum Business Value

When considering an electronic pedigree solution, you want a vendor whose software is current and compliant with all the regulations, and nimble to address your unique business operations. At SupplyScape, we track the changing regulations to ensure E-Pedigree enables our customers to address the requirements both in record-keeping and in process.

SupplyScape's customers have come to rely on the leading-edge functionality, customer-focused design, and built-in operational flexibility of our pharmaceutical security solutions. Regardless whether your challenge is protecting product integrity, improving compliance, or extracting maximum value from your supply chain investments, SupplyScape offers the solution for you, delivered quickly and at the lowest total cost of ownership.

No organization combines SupplyScape's market leadership in developing innovative supply chain security solutions with our expertise in pharmaceutical business operations, supply chain management and pedigree regulations.

Next Steps

Call to arrange a Pedigree Assessment. SupplyScape experts will work with you to jointly:

- Develop a Rapid Compliance Action Plan
- Uncover the potential new business value from your regulatory compliance investments in pedigree

For More Information

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- EPCglobal Drug Pedigree Standard: Peeking Behind the Curtain
- Understanding Pedigree Requirements for pharmaceutical and biotech, 3PLs, wholesalers, pharmacies and end-points