

# UNIFORM FEDERAL PEDIGREE

## HDMA's Position

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HDMA supports enacting a uniform federal pedigree requirement as a necessary step to further enhance the security of the nation's prescription medicine supply chain. A practical and comprehensive approach at the federal level will increase safety, facilitate efficient interstate commerce and minimize the inconsistencies among competing state requirements. National uniformity will enable manufacturers, distributors and pharmacies to:

- Help combat threats to the safety of the supply chain;
- Utilize the most effective technologies to help stop counterfeiting and diversion of prescription medicines; and
- Facilitate efficient interstate commerce.

## Issue

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The "Prescription Drug Marketing Act (PDMA) of 1987" established minimum federal pedigree requirements to trace the ownership of pharmaceuticals through the supply chain. The purpose of PDMA was to further secure the nation's medicine supply from counterfeit and diverted prescription medicines.

However, state regulatory authorities have wide latitude to expand both licensure and pedigree requirements as long as they meet the current minimum federal thresholds. In recent years, more than half of the states have imposed new and inconsistent pedigree requirements for manufacturers, distributors and pharmacies or other authorized dispensers. The resulting patchwork of state-level requirements creates confusion and duplicates resources, particularly for national and regional companies. Moreover, since PDMA was enacted more than 20 years ago, the pharmaceutical industry has significantly evolved in the manufacture, distribution and dispensing of prescription medicines. This has added considerable complexity to regulatory compliance while meeting today's healthcare needs.

## Additional Information

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HDMA believes in the following principles for federal pedigree legislation:

- A uniform, national requirement that incorporates a primary distribution (or direct-purchase pedigree) model until such time as a standard and technology solutions are reasonably available to facilitate the implementation of cost-effective electronics by manufacturers, wholesalers and dispensers (pharmacies, physicians, hospitals, clinical and other provider settings where drugs are dispensed to patients).
- Serialization of prescription drugs at the unit, case and pallet levels, along with a standardized data exchange system.
- Heightened wholesaler licensure requirements.
- Penalties for pharmaceutical related crimes such as cargo theft, illegal importation, fraud and abuse.

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The Healthcare Distribution Management Association (HDMA) is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that nearly nine million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated \$42 billion each year to our nation's healthcare system. For more information, visit [www.HealthcareDistribution.org](http://www.HealthcareDistribution.org).

