

Uniform Federal Pharmaceutical Pedigree

HDMA's Position:

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:

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:

HDMA strongly supported the "Safeguarding America's Pharmaceuticals Act of 2008" (H.R. 5839) introduced in the 110th Congress by Congressmen Buyer (R-IN) and Matheson (D-UT) and believes:

- An interim approach to uniform federal pedigree will provide a distribution history statement on all wholesale transactions and enable dispensers to know the origin of their products.
- Requiring documentation of all wholesale transactions as proposed in H.R.5839 will significantly enhance patient safety and supply chain security beyond the current requirements of PDMA.
- To further protect patients and enhance supply chain efficiency, the healthcare supply chain must move toward an electronic system that enables tracking of the wholesale distribution of each prescription drug package at the item level, beginning with the manufacturer, through distribution and final sale to a pharmacy or other authorized dispenser. Current and emerging technologies offer the most promise in further enhancing patient safety and supply chain security.

About HDMA:

HDMA is the national association representing primary healthcare distributors, the vital link in the healthcare system. Each business day, HDMA member companies ensure that more than nine million prescription medicines and healthcare products are delivered safely and efficiently to 164,000 pharmacies, hospitals, nursing homes, clinics and others nationwide. HDMA and its members work daily to provide value and contain costs, saving the nation's healthcare system an estimated \$32 billion per year. For more information, visit www.HealthcareDistribution.org.