Ensuring a Safe and Efficient Supply Chain for Prescription Medical-Surgical Products

Issue Background:
Congress passed the Prescription Drug Marketing Act (PDMA) in 1987, creating a chain of custody tracking requirement for distributors of prescription drugs and products (Section 503.50(a)(6)). These tracking requirements, known as product ‘pedigrees’ are intended to ensure the safety and integrity of the pharmaceutical supply chain, a multi-step distribution process that ensures providers and patients receive the wide-range of life-saving medical-surgical products they require. Enforcement of these requirements rests with the U.S. Food and Drug Administration (FDA). After numerous delays, critical, related regulations went into effect in December 2006. Under PDMA pedigrees may be paper or electronically based.

The FDA regulations were challenged by a group of independent pharmaceutical Distributors in court in late 2006 – early 2007. PDMA is currently on hold under court injunction.

Today, 29 states have passed pedigree laws, many of which are similar to the PDMA, creating a patchwork of competing and overlapping legislation and regulation.

The Impact:
Under current law, ‘authorized distributors of record’ (ADRs) are not required to pass pedigree information to licensed distributors below them in the supply chain. ADR status is determined by drug/product manufacturers, who may designate as many ADRs for their products as they wish. The PDMA regulations do not outline specific criteria for granting ADR status. As such, ADR status may be based on factors other than a concern for supply chain integrity/safety. A distributor can be an ADR for certain product lines in a manufacturer’s portfolio, but not others. The current system has created a situation, a ‘Catch-22’, where many small licensed distributors are required to pass drug pedigrees containing information to which they may not have guaranteed access.

Inconsistencies within the regulations have created a landscape where few prescription products may actually be distributed with chain of custody documentation. This runs counter to the original mandate of the PDMA.

Complying with a quickly expanding list of 29 unique state requirements is costly, onerous, and inefficient, especially for small businesses that distribute prescription products in order to serve their unique customers’ needs. Ensuring the integrity of the pharmaceutical supply chain is too important to be left to a patchwork of new state regulations.

More importantly, without a legislative fix, pedigree requirements will fail to ensure patient safety. Licensed distributors that have not been granted ADR status may no longer be able to serve their unique customers’ needs. These customers are often individual or small physician offices, community hospitals, and small clinics or specialty hospitals. Small, licensed distributors fill a vital role by providing flexible order sizes of healthcare products to small provider sites on a ‘need to have basis.’

What We Hope to Accomplish:
HIDA member distributors are committed to ensuring the safety and integrity of the prescription products supply chain. In order to do so, Distributors must be able to reasonably comply with Federal pedigree laws and regulations. HIDA seeks legislation that allows non-ADR, licensed distributors, to provide pedigree information back to the last ADR in the supply chain who purchased the product directly from the manufacturer (information that is easily accessed and available) —this will eliminate the aforementioned ‘Catch-22.’

Such legislation will achieve the goal of supply chain safety and ensures that smaller provider sites will receive the critical medical products they need to serve their patients. Immediate action is critical due to increasing activity in the states and the temporary nature of the aforementioned injunction.