

Pharmaceutical Supply Chain Security

PROTECTING THE INTEGRITY OF A COMPLEX DELIVERY NETWORK

Primary pharmaceutical distributors are committed to ensuring a secure pathway for all medicines and healthcare products. We offer peace of mind to the millions of patients who depend on these products and help them feel confident that their medicines are safe and secure. In partnership with manufacturers, pharmacies, healthcare practitioners, law enforcement and regulators, distributors continuously monitor, protect and enhance the security of the nation's medicine supply.



As medicines move through the supply chain, distributors have procedures in place to safeguard products from theft and diversion. These include:

- Advanced physical security systems that feature surveillance cameras, alarms and perimeter controls;
- Established practices to safely store and transport medical products;
- Monitoring and reporting suspicious orders to the DEA to help mitigate the diversion of prescription medicines; and,
- Information-sharing programs with local law enforcement and supply chain security coalitions, such as the Pharmaceutical Cargo Security Coalition, to share best practices on securing of the nation's healthcare supplies.

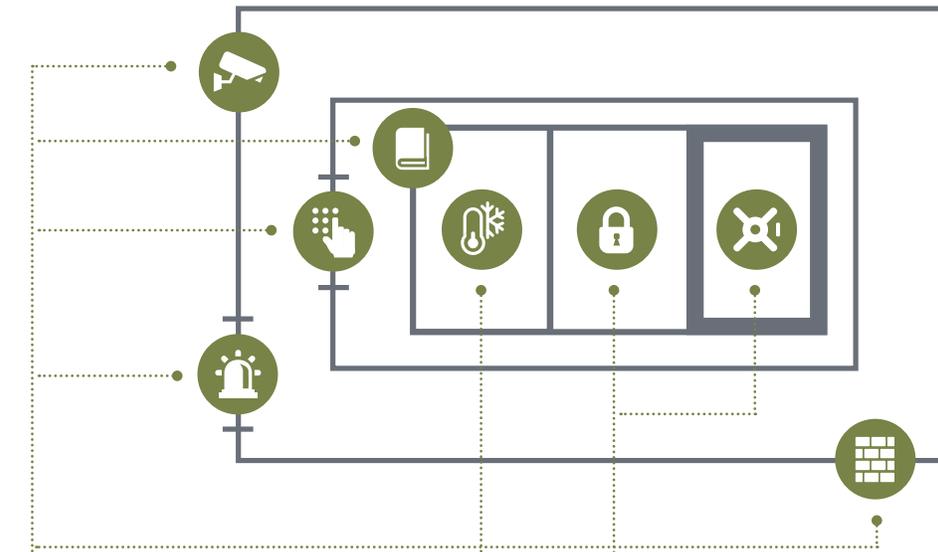
The Healthcare Distribution Alliance (HDA) is committed to partnering with its members, regulators and policymakers to ensure supply chain security by:

- Leading the effort to make the supply chain safer and more efficient by helping to secure a national framework to trace prescription medications in the supply chain through the 2013 enactment (and ongoing implementation) of the Drug Supply Chain Security Act;
- Strongly advocating for the enactment of The Safe Doses Act (PL 112-186), which expanded federal penalties for pharmaceutical cargo thefts; and,
- Supporting tough, rigorous and consistent standards for state licensing of pharmaceutical distributors that help ensure criminals do not infiltrate the supply chain and gain access to prescription medicines.

To help members navigate this complex issue, HDA also developed the "Supply Chain Security Guidelines," "Recommendations for Securing Pharmaceutical Storage Facilities" and "Security Guidelines: Protecting Last-Mile Pharmaceutical Shipments" to provide the steady guidance needed to meet this new challenge and adapt to the requirements of ensuring the safe and efficient distribution of prescription medicines.

A LOOK INSIDE: DISTRIBUTION FACILITIES

Pharmaceutical distribution facilities feature sophisticated security systems and technology to securely store prescription drugs using an integrated, multi-layered security approach. The FDA, DEA and individual states have regulations that outline comprehensive security specifications for the entire warehouse and operations.



Security specifications:

Special alarms and electronic security systems, door locks, perimeter security, limited employee access, employee screening, supervision of visitors and employees, and written policies and procedures for receipt, security, storage, inventory and distribution of pharmaceuticals.



Controlled substances:

Schedule III, IV and V controlled substances are in a secure, locked cage, which must meet security and construction criteria set by DEA, such as alarms, doors and cage size.

Schedule II controlled substances are kept in high-security vaults. The vaults' walls, floors and ceilings are required to be concrete and at least 8" thick and reinforced with steel rods. The DEA must review and approve all designs before construction and inspect and approve them after construction is complete.



Temperature control:

Medicines that require a certain temperature are stored within specialized, temperature-controlled containment devices and refrigerated storage areas.