The Drug Quality & Security Act Summary:
November 2013

The Drug Quality and Security Act (H.R. 3204) creates a uniform, national standard for tracing pharmaceuticals through the supply chain. The bill ensures the safety of drugs for patients and the immediate preemption provision eliminates the burdensome patchwork of state pedigree laws. Wholesale distributors can start conducting business the same way in all 50 states.

Key Provisions Important to Medical Surgical Distributors:

- National uniform standard with immediate state preemption of pedigree laws.
- Key exemptions for convenience kits, IVs, combination products, etc.
- Affiliate language so that all companies (C Corps, S Corps and LLCs, etc) can conduct intracompany transfers of pharmaceutical product.
- Medical surgical distributors are not mandated to provide all information required to be passed down the supply chain in one document.
- Federal Licensure standards for pharmaceutical distributors.

Key Terms: The terms below are important to understand as different trading partners are required to pass different combinations of the documents depending on upstream and downstream trading partners.

- The transaction information (TI) includes the name of the product, strength and dosage form, National Drug Code (NDC), the container size, the number of containers, the lot number, the transaction date, the shipment date, and the name and address of the businesses from which and to which ownership is being transferred.
- A transaction history (TH) is a paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.
- A transaction statement (TS) is a paper or electronic attestation by the business transferring ownership of the product that it has complied with the Act.

Key Dates:

- Prior to January 1, 2015: The federal Prescription Drug Marketing Act of 1987 (PDMA) requirements remain in place during the interim period between enactment and the start of Phase I requirements.
- January 1, 2015: Phase I begins requiring manufacturers, wholesalers and repackagers to comply with applicable traceability requirements and engage with only "authorized trading partners"
- July 1, 2015: Dispensers must comply with applicable traceability requirements.
- 4 Years After Enactment: Manufacturers must have all product serialized.
- 5 Years After Enactment: Repackagers must have all product serialized.
- 6 Years After Enactment: Wholesalers must only engage in transactions with serialized product.
- 7 Years After Enactment: Dispensers must only engage in transactions with serialized product.
- 10 Years After Enactment: Trading partners must be compliant with Phase II. Phase II is self effectuating (does not require final FDA regulations) and requires an interoperable electronic system that traces serialized product at the unit level through the supply chain.

Key Exemptions: The following products are not subject to the tracing requirements in the bill.

- Medical convenience kits and combination products not approved as drugs or biologics.
- Sterile water and products intended for irrigation.
- Intravenous products.
- Blood and blood components intended for transfusion.
- Radioactive drugs and radioactive biologics.
- Medical gas.
- Compounded drugs.
- Dispensing drugs pursuant to a prescription.

Wholesaler Licensure Provisions: The legislation establishes uniform national licensing standards for pharmaceutical wholesale distributors in seven broad categories:

1. Storage and handling of prescription drugs, including facility requirements.
2. Establishment and maintenance of records of the distribution of such drugs.
3. The furnishing of a bond or other equivalent means of security of either $100,000 or $25,000 if the annual gross receipts of previous tax year is $10,000,000 or less. Requires states to waive bond if evidence provided that it is possessed in another state.
4. Mandatory background checks and fingerprinting.
5. Establishment and implementation of qualifications of key personnel.
6. Mandatory physical inspection.
7. Prohibition of certain persons from receiving or maintaining licensure (persons convicted of a felony or has a history of violating these requirements will be denied a wholesaler license)

States will continue to license wholesale distributors, but they will be required to do so utilizing the federal standards established. Additionally, in the absence of a state licensing program that satisfies the federal requirements, a federal licensing program will be established to license pharmaceutical wholesale distributors in those states. The FDA is required to issue regulations to further clarify the licensure standards two years after enactment.

The Drug Quality and Security Act also preempts state laws, regulations, and requirements regarding wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards established by the bill. In other words, states cannot alter the standards established in the bill, but they may continue to regulate wholesale distributors in areas that are not covered by and not directly related to the licensing standards in the bill. Preemption for licensure does not take effect until after FDA issues final regulations.

Phase I Tracing Requirements Starting January 1, 2015

Manufacturer: Provides transaction information, transaction history and transaction statement to initial purchaser in a single document – paper or electronic.

- *4 yrs. after enactment manufacturer is required to provide info only*

Direct Purchaser: Wholesale Distributor that purchases direct from manufacturer, the exclusive distributor of the manufacturer, or a repackager who purchased direct from the manufacturer

Wholesaler Described Above Provides the Following:
1) Transaction statement - that states product was purchased directly
2) Transaction history
3) Transaction Information
**Does not have to include lot number, initial transaction date, or the initial shipment date from manufacturer*
**If selling to end-user items must be in a single*

Dispenser must receive it in single document (electronic or paper)

Another Wholesaler Distributor can receive these items in any format (combination of self-generated paper, electronic data, or manufacturer-provided information on product package)

Non Direct Purchasing Wholesaler Must Provide the Following to Next Purchaser
1) **Transaction statement**
2) **Transaction history** (shall begin with the wholesale distributor that purchased "direct" and shall inform the purchaser that it initially received a "direct purchase statement", and shall identify the "direct purchaser"
3) **Transaction information**

*May provide items in either:
A) a single document or through any combination of self-generated paper, or
B) electronic data, or manufacturer-provided information on the product package
Required information must be shared in compliance with guidance document to exchange information developed by HHS Secretary