THE DRUG SUPPLY CHAIN SECURITY ACT

Section 1: Short Title: "The Drug Supply Chain Security Act"

Section 2: Pharmaceutical Distribution Supply Chain

Section 581: This section adds a new section to the Federal Food, Drug, and Cosmetic Act (FFDCA). This section sets forth definitions for the Drug Supply Chain Security Act (Act).

Section 582: This new section in the FFDCA sets forth product tracing requirements for "downstream" pharmaceutical supply chain members: drug manufacturers, repackagers, wholesale distributors, and dispensers. These entities will be required to pass certain information and representations about pharmaceutical transactions when there is a change of ownership. Entities in the supply chain may only accept product if this information is provided. These entities will also be required to engage in verification and notification activities in circumstances pertaining to suspect and illegitimate product. Once product is serialized, manufacturers, repackagers, and wholesale distributors are required to respond to requests to verify product at the unit level in circumstances pertaining to suspect and illegitimate product and must also verify product at the unit level for saleable returns. Third party logistics providers that warehouse or provide other logistics services, but do not take ownership of the product, will be required to accept information from the owner of the product before taking possession, and alert the owner in the case of a suspect or illegitimate product.

Entities will also be required to promptly respond to requests for information from the Secretary, or another State or Federal official, in the event of a recall or investigation of suspect or illegitimate product, and to keep records of investigations of suspect and illegitimate product. However, instead of imposing one-size-fits-all requirements, requirements are tailored to the supply chain members to reflect the different and unique roles that each sector plays in the pharmaceutical distribution supply chain. To further strengthen pharmaceutical supply chain security, not later than 1 year after the date of enactment of this Act, the trading partners of drug manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers must be properly registered or licensed.

The timeline for serializing product and accepting and transferring only serialized product is phased in: manufacturers in 4 years after the date of enactment of this Act; repackagers in 5 years; wholesale distributors and third-party logistics providers in 6 years; and dispensers in 7 years. This section also sets forth how grandfathered product will be addressed, both with respect to serialization and tracing requirements.

Section 3: Enhanced Drug Distribution Security

Section 582: This section further amends Section 582, as added by this Act, to require interoperable, electronic unit level product tracing 10 years after the date of enactment of this Act. The unit-level product tracing requirements are tied to guidance issued by the Secretary on unit level product tracing and standards for interoperable data exchange, which are informed by public meetings and pilot projects. Specific procedures for the issuance and revision of such guidance are set forth in this section.

The Secretary is required to contract with a private, independent consulting firm to conduct an assessment of the feasibility of unit level product tracing requirements on dispensers with 25 or fewer full-time employees. The Secretary, taking into consideration this assessment, shall provide for alternative methods of compliance, including establishing a process by which a dispenser may obtain a waiver from any of the requirements if the Secretary determines that such requirements would result in undue economic hardship. The Secretary is also required to establish one or more pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. The transaction history requirements sunset 10 years after the date of enactment of the Act, when the interoperable, electronic unit level product tracing requirements begin.

Section 4: National Licensure Standards for Wholesale Distributors

503(e)/Section 583: This section amends Section 503(e) of the FFDCA to increase the minimum wholesale distributor licensure standards under current law by regulation. Beginning 1 year after the date of enactment of the Act, any person who owns or operates an establishment that engages in wholesale distribution shall report to the Secretary, on an annual basis, regarding each State by which the person is licensed and the name and address of each facility at which the person conducts business. Not later than 1 year after the date of enactment of this Act, the Secretary shall establish a database that identifies each wholesale distributor by name, contact information, and the State where the wholesale distributor is licensed and make this database available on the Internet Website of the Food and Drug Administration. If a State chooses not to license a wholesale distributor to the standards set forth in the newly added Section 583 of the FFDCA, the Secretary shall license qualified wholesale distributors in that State and collect reasonable fees to cover the costs of this licensing program. This section also makes clear that a third-party logistics provider is not required to obtain a license as a wholesale distributor. The amendments made in Section 4 go into effect 1 year after the date of enactment of the Act.

Section 5: National Licensure Standards for Third-Party Logistics Providers

Section 584: This section sets forth new minimum third-party logistics provider licensure standards in the FFDCA. Beginning 1 year after the date of enactment of the Act, a facility of a third-party logistics provider shall report to the Secretary, on an annual basis, regarding the State by which the facility is licensed and the name and address of the facility. If a State chooses not to establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider and collect reasonable fees to cover the costs of administering a federal licensing program for entities in such States. The Secretary is required to issue regulations regarding the minimum licensure standards, including establishing a process by which a third-party accreditation program approved by the Secretary, shall upon request by a third-party logistics provider, issue a license to a third-party logistics provider that meets the minimum requirements set forth in this Act. If the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements, the Secretary shall issue a license to a third-party logistics provider consistent with this section.

Section 585: Uniform National Policy: This section makes explicit that, beginning on the date of enactment of this Act, the product tracing requirements set forth in this Act preempt State product tracing requirements, including paper or electronic pedigree systems. This section also makes clear that, beginning on the date of enactment of this Act, no State may establish or continue any standards, requirements, or regulations with respect to wholesale distributor or third-party logistics provider licensure requirements less stringent than the standards and requirements set forth in Sections 503(e) and 584. This section makes clear that pre-emption of product tracing shall not be construed to pre-empt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in this Act.

Section 6: Penalties: This section amends Section 301(t) of the FFDCA to add failure to comply with the requirements under Sections 582 and 584 as prohibited acts. It also amends Section 502 to make a product misbranded if it fails to bear a product identifier as required under section 582.

Section 7: Conforming Amendments: This section makes a conforming amendment to 303(b)(1)(D) to update the cross cite in current law to wholesale distributor licensure requirements in Section 503(e).

Section 8: Savings Clause: This section makes clear that except as provided in the amendments made to wholesale distributor licensure requirements in Section 4(a) and the penalties in Section 6(a), nothing in this Act (including the amendments made by this Act) shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act under any provision of such Act or the Public Health Service Act.