Pharmaceutical Distribution Security Alliance (PDSA)

Our Mission

The Pharmaceutical Distribution Security Alliance's (PDSA) mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

About Us

The Pharmaceutical Distribution Security Alliance is a multi-stakeholder and interdisciplinary initiative. Membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. More than 20 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support to the group.

Membership

For more information about the PDSA or this document, please contact:

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Pharmaceutical Distribution Security Alliance

The Pharmaceutical Traceability Enhancement Code (RxTEC) Act of 2012:

An Electronic Traceability System to Help Enhance Patient Safety and Distribution Chain Security

Increases Patient Access to Safe Medicines:

- Provides new tools to trace a potentially suspect finished pharmaceutical product for humans with more precision.
- Helps target regulatory actions and recalls.
- Establishes the foundation of an electronic traceability system that is currently achievable from a technological, financial, and implementation perspective and that will not further exacerbate supply issues.
- Includes new authorities and penalties to address counterfeit products, cargo theft, illegal online drug sellers, and new rules regarding e-labeling.

Replaces the Patchwork of Inconsistent and Inefficient State Laws:

- State pedigree laws could have a nation-wide impact on health care costs as participants in the pharmaceutical distribution chain continue to make substantial investments and adjust operations in order to comply with often burdensome timelines and requirements.
- Stakeholders could also incur further costs when dealing with the patchwork of requirements as other states implement inconsistent or different distribution chain security measures.
- A federal system is needed so industry participants and regulators may harmonize operations on a global basis, yielding significant costs savings and investment efficiencies while enhancing safety and security worldwide. Levels the playing field nationwide and improves patient safety without introducing excessive burden or anti-competitive pressure on any one portion of the distribution chain.
- Creates a collaborative public-private solution that can be consistently applied and leveraged across all states to ensure that pharmaceutical product flowing from every state is subject to enhanced security standards.

Lowers Costs and Regulatory Burdens for All Sectors when Compared to Compliance with California's Pedigree Law:

- Pharmacies anticipate lower costs to comply with a nation-wide RxTEC model than to comply with CA or other similar pedigree or track & trace type systems.
- Large and small wholesale distributors estimate facing 5 - 10 times higher costs respectively to comply with CA than under the RxTEC model.
- Brand and generic manufacturers estimate 2 -5 times higher costs to comply with CA than under the RxTEC model.
- The systems and infrastructure that sector stakeholders will need to build in order to manage and maintain the data required under a pedigree system like the CA law is estimated to cost sector stakeholders more than $100 million each, which would significantly increase if stakeholders had to comply with a patchwork of state and international requirements.

Improves Security of the Drug Distribution System:

- Enhances consumer confidence by helping to ensure that only licensed "good actors" can distribute finished prescription pharmaceutical products throughout the distribution chain.

Aids State and Federal Agencies in Tracing the Distribution History of Suspect Products:

- Establishes new processes and an electronic traceability system that regulators can leverage to hold distribution chain members accountable for helping ensure that legitimate product reaches the patient.
- Provides new authority to regulators to facilitate the identification of a suspect product.
- Provides regulators with timely and accurate information in the event of a recall.

Increases Efficiency throughout the Pharmaceutical Distribution System:

- When fully implemented, improves efficiency and effectiveness of drug recalls and returns.
- Enables healthcare providers to leverage technology for record keeping purposes.

Establishes Foundational Technology for Future Enhancements:

- Provides critical building blocks that can be expanded as public health threats, interoperability standards, and technologies evolve.
- Establishes connectivity and infrastructure throughout the distribution chain that will enable a variety of other capabilities and efficiencies.

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Key Features

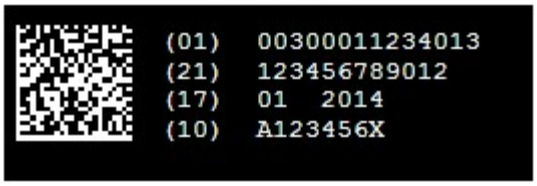
Provides Immediate Measures to Help Increase Pharmaceutical Distribution Chain Security:

- **Modernizes and Strengthens State and Federal Authorities:**
  - Federal preemption of state pedigree/track & trace/traceability laws.
  - Adoption of interim federal requirements for wholesale distribution during RxTEC system development.
  - New authorities and penalties to address counterfeit products, cargo theft and illegal online drug sellers, and new rules regarding e-labeling.
  - Strengthens Federal standards for wholesale distributors with state enforcement authorities.
  - Establishes Federal licensing requirements for third-party logistics providers (3PL) with state registration.
  - Streamlines requirements for manufacturers who also operate as wholesale distributors.

Development of RxTEC System to Improve Product Visibility throughout the Supply Chain:

- **FDA Promulgates Final Regulations (18 months after enactment)**
- **Manufacturers Apply RxTEC to Individual Units and Homogenous Cases (3 Years after Regulations) :**
  - The RxTEC is a data carrier that includes the Global Trade Item Number (GTIN) – the product identifier, a serial number, expiration date and lot number, applied using globally harmonized standard such as GS1, as shown below. All data will be in both human and machine readable formats.

GTIN ---->
Serial Number ---->
Expiration Date ---->
Lot ---->



  - Have systems and processes to utilize RxTEC to support lot level tracing upon change of ownership and for recalled product, and verification of individual saleable units as determined necessary by the Secretary to investigate a suspect product.
  - Maintain manufacturer's own records that associate serial numbers to product and lots.

- **Repackagers (4 years after regulations):** subject to the same requirements as manufacturers

- **Wholesale Distributors (5 years after regulations):**
  - Receive products encoded with RxTEC from manufacturers.
  - Have systems and processes to utilize RxTEC data to support lot level tracing upon change of ownership, lot level recall of a product, and lot level verification of a suspect product as determined necessary by the Secretary to investigate a suspect product.
  - Provide information from RxTEC to business partners.
  - May store RxTEC data for business partners and provide access to such information in lieu of data transmission.

- **Dispensers (6 years after regulations):**
  - Receive products encoded with RxTEC from licensed wholesale distributors or acquire product from manufacturers or 3PLs licensed pursuant to federal standards.
  - Receive RxTEC data from the wholesale distributor selling the drug product to the dispenser, or allow the wholesale distributor to maintain and store such RxTEC data.
  - Use RxTEC data maintained by the dispenser or by the wholesale distributor to respond to a request from the Secretary in the event of a recall, or as determined necessary to investigate a suspect product.
  - Have systems and processes to utilize RxTEC data to support lot level tracing upon change of ownership, lot level recall of a product, and lot level verification of a suspect product as determined necessary by the Secretary to investigate a suspect product.

- **Fully Operational (6 years after regulations):**
  - RxTEC system fully effective and all products in inventory RxTEC encoded and traceable at the lot level upon change of ownership lot level recall of a product, and lot level verification of a suspect product.

Establishes a Public-Private Community to Make Recommendations on Pharmaceutical Distribution Chain Security:

- **Pharmaceutical Distribution Chain Community Provides Stakeholder Input:**
  - Comprised of 21 total members -- 3 members appointed by the Secretary, and 18 members appointed by the Comptroller General after an open membership solicitation and nomination process. Appointed members shall represent a balance among various sectors in the pharmaceutical distribution chain, with business size, type, and interests taken into consideration.
  - Creates a mechanism to provide regular consultation and advice to the Federal Government from all sectors in the finished pharmaceutical product distribution chain on safety and security issues including RxTEC implementation, best practices, pilot projects, and other insights.

New Federal Authorities to Request RxTEC Data:

- May request RxTEC data from manufacturers to protect public health in certain circumstances (e.g., recalls and investigations of suspect product) prescribed by statute (3 years after regulations).
- May request RxTEC data from all stakeholders to protect public health in certain circumstances (e.g., recalls and investigations of suspect product) prescribed by statute (6 years after regulations).

Assessment and Additional Authorities:

- Stakeholders, the Community, and FDA assess success, gaps and potential enhancements.
- FDA evaluates the RxTEC system's impact on health care delivery system and patient access to medicines, scalability of RxTEC, the capabilities of different sectors to employ RxTEC technology, costs and benefits of RxTEC, and the impact additional electronic traceability or similar requirements would have on each pharmaceutical distribution chain sector and the public health (6.5 years after regulations).
- FDA reports to Congress on the findings of their evaluation. FDA's report may consider whether additional electronic traceability requirements are needed to protect public health, taking into consideration objective security or patient safety factors, and including consideration of the impact that such additional requirements would have on patient safety, the drug supply, cost and regulatory burdens, and timely access to medicine (6 months after FDA evaluation).