“Building Patient Safety”

Patient Safety

Healthcare Supply Chain Efficiency

Automatic Data Capture (Bar Codes, Data Matrix, RFID)
e-Commerce (EDI / XML Transactions)
Electronic Record Management (e-Records, e-Prescriptions)
Assets & Equipment Tracking

Traceability (e-Pedigree, Recalls)

Standardized Product Definition (GDSN®)
Standardized Location Identification (GLN)
Standardized Product Identification (GTIN®)

Standardization ➔ Interoperability
Tracking/Documenting Serialized Products & Achieving 2015 Compliance

Ronald Bone, SVP Distribution Support
McKesson Pharmaceutical Solutions
Supply Chain Integrity Is Critical

- International legislative and regulatory agencies have concerns about the Pharmaceutical Supply Chain’s ability to effectively protect products
  - Expiration Date Handling
  - Cold Chain Management
  - Returns Processing
  - Recall Management
  - Tainted Products (Counterfeit and Mislabeled)
- A single weak link in the supply chain means we ALL fail
- We need to be knowledgeable about the products we buy
- We need to have our electronic systems capture and validate the information, and provide actionable information to the staff
- As wholesalers, our greatest priority is the security of the supply chain
United States Federal ePedigree

- U.S. Congressmen Buyer & Matheson introduced “Safeguarding America’s Pharmaceuticals Act,” to provide a uniform federal pedigree standard

- Key Provisions of the Bill:
  - Standard supply chain definitions across all states
  - Standard pedigree requirements
  - Standardized drug identifiers
  - High-risk drugs criteria
  - Report evaluating the feasibility and operational efficiencies of adopting security technologies
  - Preempts state laws on serialization and pedigree

- Outcome of this legislation is uncertain due to complexity of the bill and the timing; likely to be considered in 2009 or beyond
State of California ePedigree

Implementation Dates

- From January 1, 2009, to December 31, 2016, inclusive, manufacturers, wholesalers, re-packagers and pharmacies shall initiate steps to accept and pass electronic pedigrees for all dangerous drugs, subject to the requirements.

- All Manufacturers (branded and generic) must serialize 50% of their dangerous drugs by 2015, and the balance by 2016.

- After July 1, 2016, wholesalers and re-packagers may not sell, trade, transfer or receive a dangerous drug without receiving and providing a pedigree.

- After July 1, 2017, retailers may not sell, trade or transfer a dangerous drug at wholesale without providing a pedigree and may not receive a dangerous drug without a pedigree.
Progress on Serialization / Pedigree

- GS1 and EPCglobal developing the standard for serialization and pedigree

- FDA Amendments Act requires FDA to publish a serialization standard by March, 2010

- A small number of manufacturers in the US have moved forward with Serialization / Pedigree projects
Building Patient Safety

SCANNING

eCOMMERCE

ePRESCRIPTION

eRECORDS

ASSET TRACKING

TRACEABILITY

STANDARD DATA FORMAT

UNIQUE LOCATION ID

UNIQUE PRODUCT ID
The Wholesaler’s Role

- Gather the required data on the inbound shipment from the manufacturer
  - The critical new data element that we have not had before is a unique serial number at the lowest unit of sale.

- Verifying the electronic information received from the manufacturer against the physical product.
  - A new process of quarantining mismatching product is yet to be developed.
  - What are the ramifications to availability of drugs if 100% accuracy is not achieved?

- Picking units of products for the providers and retailers by serial number and commission a tote which connects the serialized units inside the tote with a serial number on the tote to enable quick check at the pharmacy.
  - What are the ramifications at the pharmacy site if this process has errors that need to be resolved before the product can be dispensed?