McKESSON

Empowering Healthcare

McKesson's Vision for Traceability Using GS1 Standards

March, 2012

McKesson's Principles for Traceability

- Improve patient safety
- Promote efficient interstate commerce by preempting varying state pedigree laws
- Employ the most effective technologies to reduce counterfeiting and diversion of prescription medicine;
- Enable each participant in the supply chain access to electronic inventory data at the unit level.
- Enable efficient nationwide inventory management and rapid response in times of emergency.

McKesson's Traceability Framework

- Electronic system that enables the tracing of each prescription medicine package at the unit level.
  - All members of the supply chain must participate in a closed system.
  - Serialization of prescription medicine at the unit, case and pallet levels
  - A robust and standardized data exchange system
- The goal is to protect the supply chain against counterfeit, adulterated or other substandard product by facilitating improved ability to identify non-legitimate products.

McKesson embraces GS1 as the path to achieve traceability

- GS1 has the US National Drug Code (NDC) embedded in the GTIN.
- GS1 standard supports the use of the FDA SNI (Serial Number Identifier).
- In the pharmaceutical space GS1 has a long history of working with all segments of the supply chain.
- GS1 US has a very active traceability user group working on pilots

The benefit of using GS1 standards

- Every member of the supply chain will have visibility of expiry dates of all products which should significantly lower returns
- GS1 has the US National Drug Code embedded in the GTIN.
- GS1 standard supports the use of the FDA SNI (Serial Number Identification) guidance
- For pharmaceuticals products GS1 has a long history

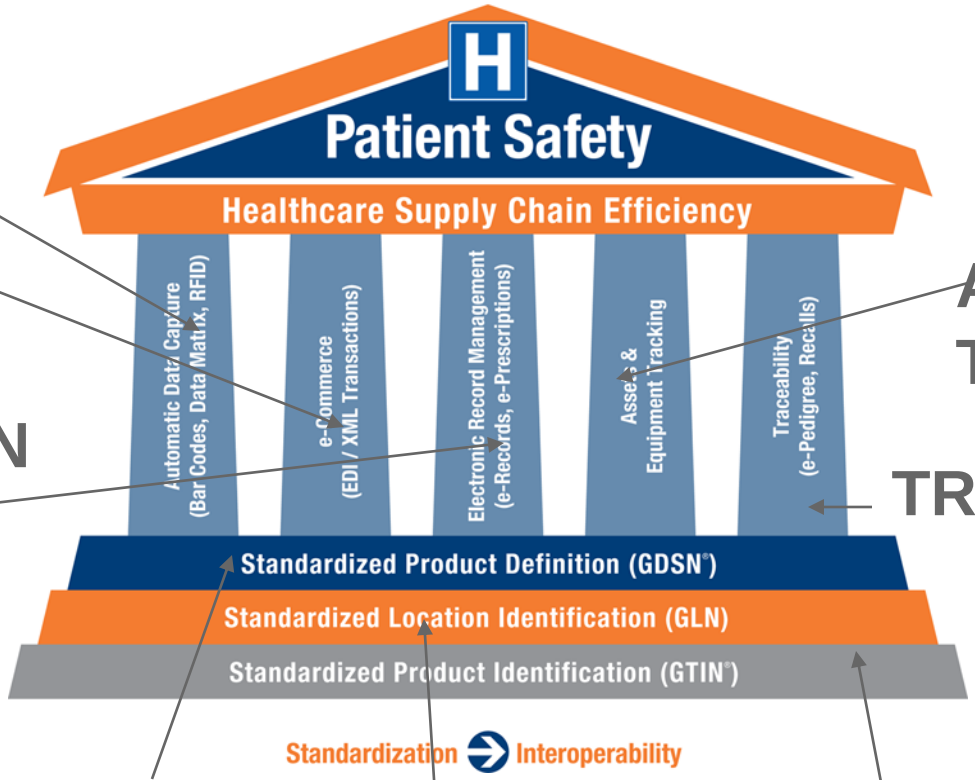
Building Patient Safety

SCANNING

eCOMMERCE

ePRESCRIPTION

eRECORDS



ASSET TRACKING

TRACEABILITY

STANDARD DATA FORMAT

UNIQUE LOCATION ID

UNIQUE PRODUCT ID

State of California ePedigree has provided a model

- Phase-In approach with staggered implementation dates across the supply chain
  - January 1, 2015 Manufacturers (generic and branded) must serialize and pedigree 50% of their drugs
  - January 1, 2016 Manufacturers (generic and branded) must serialize and pedigree the final 50% of their drugs
  - July 1, 2016 Wholesalers may not acquire, sell, trade or transfer pharmaceutical drugs without a pedigree
  - July 1, 2017 Pharmacies may not acquire, sell, trade or transfer pharmaceutical drugs without a pedigree

- Industry grappling with two significant challenged that are essential for unit level tracing if 2D barcodes are the carrier of choice:
  - Inference (allowing the reading of a case serial number and infer the contents of the case)
  - Aggregation of unit to case (data association of serialized items to the case serialized number)

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