

Healthcare Supply Chain Association (HSCA) Position:

As healthcare shifts from volume- to value-based federal payment systems, and as negotiations move from price-driven to quality and performance measurements, evolutionary technological changes in the supply chain will help provide meaningful data that can lead to more patient-centered care. Advances in health information technology (HIT) and increasing adoption of global standards have helped connect the supply chain so that healthcare providers, suppliers and manufacturers can more efficiently collaborate and effectively treat patients. HSCA is working to bring about a world in which electronic health records (EHR) connect the supply chain using unique device identifiers (UDI), Track & Trace serialization, and related standards and protocols.

Track-and-Trace Implementation Critical to Modernizing Supply Chain Logistics

- ✓ Effective implementation of the so-called “track-and-trace” provisions of the Drug Quality and Safety Act (DQSA) will help all appropriate aspects of the healthcare supply chain and enhance patient care.
- ✓ DQSA will allow for the detection of illegitimate drugs (counterfeit, stolen, up-labeled, diverted, etc.) in the legitimate supply chain as early as possible, while also helping to identify those who participated in the introduction of the illegitimate product and to prosecute criminals efficiently by automatically generating solid evidence.

Unique Device Identifiers (UDI) Should Be Included in Interoperable Electronic Health Records (EHR)

- ✓ Achieving the full benefits of the FDA’s unique device identification (UDI) system should include UDI in interoperable electronic health records (EHR) that can integrate all sources of supply chain data.
- ✓ Including UDIs in EHRs would not only help improve patient safety and quality of care, including critical recalls, but would also unlock additional supply chain efficiencies and improve order accuracy. According to the FDA, incorporation of UDI in automated systems is estimated to generate an additional \$16 billion in savings **annually**.
- ✓ UDI will improve order accuracy through improved catalog-, inventory- and electronic-order management; efficient product movement; and more efficient access to billing and claims information.

Supply Chain Should Leverage GS1 US Standards, Including GLNs and GTINs in implementing UDI

- ✓ HSCA recommends leveraging GS1 US standards, including Global Location Numbers (GLNs) for identifying locations within the supply chain; Global Trade Item Numbers (GTINs), which identify each product item; and automatic identification and data capture (AIDC) technology, enabling GTINs for each product to be scanned into information systems such as EHRs.

HIT Interoperability Necessary for Comprehensive Care

- ✓ Many HIT systems are “locked” within their data silos, hindering their ability to connect and exchange information with other EHR systems or mechanisms critical for patient care.
- ✓ One way to ensure data interoperability is to deploy common data architecture that requires open-source standards, such as application programming interfaces (API) that enable secure and innovative applications to provide the interoperability necessary to quickly, easily and affordably integrate data with other systems.