HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

April 21, 2014

United States Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Re: Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format – Request for Comment
Docket No. FDA-2014-N-020

The Healthcare Supply Chain Association (HSCA) appreciates this opportunity to comment on the Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format. HSCA is a broad-based trade association that represents 14 group purchasing organizations (GPOs), including for-profit and not-for-profit corporations, purchasing groups, associations, multi-hospital systems and healthcare provider alliances.

GPOs help healthcare providers — such as hospitals, nursing homes and home health agencies — realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, wholesalers/distributors, and other vendors. GPOs do not purchase or take ownership of products; rather, they develop and negotiate competitive contract pricing.

It is a wholesaler/distributor that maintains the pedigree of a product, takes ownership of medical products such as pharmaceuticals, and then sells the drugs to the GPO members at the GPO-negotiated price. GPOs are frequent supply data partners with wholesalers/distributors, providing appropriate supply inquiries on behalf of their provider members and clients. These inquiries are critical to the smooth functioning of the healthcare supply chain and require an efficient and effective electronic exchange of information.

As a result, HSCA would like to make several general comments regarding this important matter:

HSCA and its members have aligned with the position of GS1 US concerning the development of supply chain standards. We support the comments of GS1 US to the FDA regarding the interoperability of the healthcare supply chain. Specifically, we agree that interoperability depends on the extent to which systems are aligned in connection with standards and systems. For example, systems supporting some supply chain and pharmacy practices utilize National Drug Codes (NDCs) to identify drugs. Conversely, point-of-sale systems use UPC barcodes, which encode Global Trade Item Numbers® (GTIN®). However, because GS1 Standards enable members of the pharmaceutical

supply chain to integrate NDCs into their GTINs, those systems increase the degree of trackability and traceability.

In addition, Electronic Data Interchange (EDI) enables the computer-to-computer exchange of business transactions between companies using a standard format. GPOs - and many others in the healthcare supply chain - utilize X12 EDI because it is interoperable with other systems that supply chain stakeholders utilize, adding to overall efficiency. The primary challenge to any collaborative supply chain solution is ensuring that the data can be shared and understood. One major inhibitor of interoperability is the paper format. Paper formats present the largest challenges, as they are not machine-ready, not searchable and not interoperable with other systems. We strongly maintain that paper systems need to be replaced with innovative electronic systems and tools that allow for usable, interoperable, seamless exchange of secure data from disparate sources and that data identifiers need to be standardized.

We believe that the FDA should coordinate its work with the Office of the National Coordinator for Health IT (ONC) as it continues its work in developing stage 3 meaningful use objectives under the HITECH Electronic Health Record (EHR) incentive program. In fact, recently, the ONC's HIT Policy Committee has recommended that EHRs include a new field to capture the unique identifiers of implanted devices. This field would be considered a voluntary objective under stage 3 of meaningful use. The UDI system developed by the Food and Drug Administration (FDA) will provide each medical device with a code corresponding to its make and model in order to unambiguously identify devices used in patient care. Similar to UDI in EHRs, achieving the full benefits of a standardized individual identifier system for pharmaceutical products, however, requires its inclusion within interoperable EHRs that integrates adverse event reports and materials management systems.[1]

In general, HSCA is very supportive of this effort and believe that the FDA should similarly work to ensure that the Drug Supply Chain Security Act (DSCSA) requirements allow for future coordination and innovation necessary to achieve interoperable EHRs.

HSCA maintains that capture of both UDI and appropriate pharmaceutical product information within EHRs would result in several benefits to patient care, including establishing improved recall resolution, enhanced care coordination and a definitive source of information for both patients and providers. Including this information would also create new and important opportunities to perform comparative research and effectiveness.

As a result, we believe that it is appropriate for the FDA to consider in its review of interoperability such issues as the product identifier, data element, format and/or field

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[1] U.S. Food and Drug Administration. Strengthening our National System for Medical Device Post market Surveillance. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/UCM301924.pdf./ Gross TP, Crowley J. Unique Device Identification in the Service of Public Health. N Engl J Med. 2012; 367:1583-1585.

that would be appropriate to include in the development of the DSCSA requirements in relation to the meaningful use of EHRs. Special consideration should be given to guidance documents issued by the FDA first regarding the appropriate attributes for secure tracing at the package level and then later at the serialized product level. Included in this guidance information should be the relationship of DSCSA requirements to 2D barcodes, National Drug Codes, serial number, lot and expiration date.

In summary, we believe that implementation of the DSCSA holds the promise of linking all appropriate aspects of the healthcare supply chain and ultimately positively connecting to patient care. The new law may also positively affect the drug supply by making the process of tracking and tracing of pharmaceuticals more secure and less vulnerable to "gray market" activities. DSCSA will allow for the detection of illegitimate drugs (counterfeit, stolen, up-labeled, diverted, etc.) into 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.

Sincerely,

Curtis Rooney
HSCA President