HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

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Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 2015 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW.
Washington, DC 20201

Re: Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria: Interoperability Updates and Regulatory Improvements

The Healthcare Supply Chain Association (HSCA) appreciates this opportunity to respond to the proposed 2015 Electronic Health Record (EHR) certification criteria.[1]

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 health care provider alliances.

Frequent Updates to Certification Criteria is Appropriate

HSCA supports the more frequent review of health information technology certification launched by this proposed rule. In addition to the policy objectives identified by the ONC,[2] this approach will allow user input on technology enhancements, functionality and interoperability that might otherwise be overlooked. Some input will speak to enterprise-wide architectures, protocols and functions that will be important as the use of electronic health records matures. Given that the 2015 Edition EHR certification criteria as proposed will be voluntary for both providers and technology developers, we believe a more frequent approach is important to give visibility to these areas of need. This will serve as an important driver to ensure the development and timely availability of "best in breed products."[3]

HSCA supports the proposed requirement that EHR technology be able to capture and display the Unique Device Identifier (UDI) associated with patient care. The UDI belongs in the patient's

[1] See 79 F.R. 10880 *et seq*. (February 26, 2014) ("*Notice*").
[2] *Ibid*. at 10882.
[3] *Id*. at 10883.

electronic health record to ensure that this important identifier is recorded in a place accessible by both patient and provider.[4]

In these comments we identify an area of interoperability between enterprise-wide technology systems that we believe should be addressed to ensure: 1) the UDI is reliably and accurately captured in the EHR as a routine protocol in the clinical setting; and 2) effective recalls occur not only for those devices already used (so that patients can be identified and notified), but also for those devices ordered, shipped, delivered and distributed into provider networks and clinical settings (so that these devices can be identified before use).

The UDI certification criterion should ensure a seamless, electronic communication between the procurement and material management information systems and the EHR system. For example, it is anticipated that a device will be scanned in the clinical setting as a means of capturing the UDI in the EHR. In a modern healthcare system, the device UDI will have been previously captured by the provider's material management information system at the point of procurement or receipt. The creation of an unambiguous device UDI, its capture through AIDC technology, and its publication in an accessible data base are all supported by existing GS1 standards.

We recommend leveraging the GS1 US standards.[5] We believe that GS1 US standards are already positioned to support the implementation of the UDI system by healthcare enterprises. These standards will also serve as a means of ensuring that the UDI is electronically captured and reported in the EHR. By ensuring interoperability between the enterprise-wide material management information systems and EHR technology, uninterrupted and fully automated recording of the device, from procurement, delivery and distribution, to facility inventory and clinical use is possible.[6] With the UDI recorded in the EHR, the device used in the clinical setting can be identified with a specific patient. It can also be associated with its procurement and the supply chain of similar devices.

The UDI Belongs In The Patient Electronic Health Record

HSCA supports a new 2015 certification criterion that requires EHR technology to be able to record and display UDIs in connection with patients' implantable devices.[7] We agree that the

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[4] *Id*. at 10894.

[5] See *Healthcare Supply Chain Association Comments FDA-2011-N-0090* (November 6, 2012).

[6] This scenario of managing a device from procurement to clinical setting has been documented in by Becton, Dickenson and Company (BD), Mercy and its supply chain company, Resource Optimization & Innovation (ROi). See *Perfect Order and Beyond* (Black, Zimmerman: 2011) ("*Perfect Order*"). A copy of *Perfect Order* may be found at this http address: http://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=542&PortalId=0&TabId=785.

[7] See generally *Notice* 10894 – 10896. For a description of the specific proposal, see Notice at 10895: "We propose to adopt a 2015 Edition certification criterion focused on EHR technology's ability to record UDI information about

UDI final rule will enable identification of devices that are in the supply chain and are ultimately used in the clinical setting. Once captured, the UDI will allow access to the data published in the Global Unique Device Identifier Database (GUDID), so that additional device information may also be recorded in the EHR.[8]

With the UDI serving as the key identifier, the EHR will serve as an important pivot point, enabling: 1) a look back – to identify the patient whose care is associated with a specific device (or patients whose care are associated with a specific type of device), and 2) a look forward – to identify similar devices in the supply chain for recall or other inventory management.

The Proposed Criterion Should Apply To All Devices

We believe this proposal represents a much-needed step forward. Capturing a unique identifier for all devices used in the clinical setting and pertinent to the patient's ongoing care is critical.[9] The importance of this step recommends that the ONC's proposal not be limited to implantable, life-saving, or life sustaining devices. We maintain that the criterion should apply to all device UDIs. Because the ONC's proposal would be voluntary in the 2015 Edition and because the underlying standards, technology and architecture for electronically capturing the UDI will be the same regardless of device class, this would not create any additional burden on technology developers or users.

The UDI rule anticipates that all covered Class I, II, and III devices will have UDIs, be identifiable in the GUDID, and be appropriately labeled. Standards and technology in use today make the UDI system feasible to: 1) assign each device a unique number, 2) require that number to be human readable and capable of being scanned into information systems, and 3) use that number to find additional device information in an accessible, trustworthy database.[10]

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implantable devices. More specifically, EHR technology would have to enable a user to electronically record the UDI of an implantable device and other relevant information (such as a procedure note or additional information about the device) as part of a patient's ''implantable device list.'' EHR technology would also be required to allow a user to electronically access and view a patient's list of UDIs and other relevant information associated with a patient's implantable devices. In addition, the EHR technology would need to be able to parse the UDI in order to extract and allow a user to view the ''device identifier'' and ''production identifier'' portions of the UDI.".

[8] The ONC seeks comment on the EHR technology capabilities to be included in the 2017 Edition rulemaking. Specifically, the ONC suggests a minimum set of data elements for each UDI in a patient's list of implantable devices. See *Notice* at 10895.

[9] See *Notice* at 10894: "This proposed certification criterion represents a first step towards enabling EHR technology to facility the widespread capture and use of UDI data".

[10] For a vision of a healthcare system aligned around a common set of global standards enabling device and drug information to be scanned into the patients record in the clinical setting, see *Strength in Unity: The Promise of Global Standards in Healthcare* (McKinsey & Company: October 2012) ("*McKinsey Report on Global Standards*"). For a general summary of the McKinsey Report on Global Standards, go to this http link: http://www.gs1.org/healthcare/mckinsey.

This proposal is not only doable with existing standards and technology, but it is also timely, given the UDI implementation deadline of September 2015 for implantable, life-saving, and life sustaining devices. It would set the stage for EHR technology to capture similar data for Class II and Class I devices, which we expect will be available from some manufacturers before the additional deadlines.[11]

Integration Of Information Systems Is Necessary To Fully Utilize The UDI

We agree that EHR technology will play an important role in the adoption and utilization of UDIs.[12] EHR technology should be leveraged with standards and technologies already employed in the supply chain and material management, such as automated identification and data capture (AIDC) technology.

EHR technology is a part of a landscape of information systems that support the clinical and administrative workflows at provider facilities and healthcare systems. As an example of the use of AIDC technology, when scanning the device labels as a means to capture the UDI, the EHR will be the recipient of device data already recorded in material management information systems. In *Perfect Order*, the UDI recorded in the EHR will have been captured at the point of procurement and used to track the procurement through delivery and receipt, distribution within a hospital system, and storage as a staging area for in-patient use.[13]

The GS1 standards regime uses unique Global Location Numbers (GLNs) for identifying locations in the supply chain (from manufacturer locations to provider "ship to" and "bill to" locations). The standards also use unique Global Trade Item Numbers (GTINs) to identify each product item (i.e., device), as well as unique item numbers to identify packaging hierarchies where more than one "each" is packaged together. GS1 standards also support AIDC technology, enabling

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[11] See *Unique Device Identifier Study: Adoption and Use Trends for Medical Devices* (Booz, Allen, Hamilton: May 2013) ("*Booz Allen UDI Study*") at 13: Ninety-five percent (95%) of manufacturers surveyed indicated and intent to adopt UDI for identifying medical devices in the supply chain. Of these, 34% were already in the adoption process and 7% indicated that adoption was complete. For a general summary of the *Booz Allen UDI Study*, go to this http link: http://www.boozallen.com/insights/insight-detail/unique-device-identifier-study-adoption-and-use-trends-for-medical-devices.

[12] See *Notice* at 10894. The ONC notes that automated identification and data capture (AIDC) technology will streamline the capture and exchange of UDIs and associated device data in clinical and administrative workflows.

[13] See *Perfect Order* at page 3. See also page 2, where the Perfect Order collaboration success is explained: "Patients and clinicians at Mercy are benefiting from the same technology, data standards and processes utilized by other industries worldwide. Mercy utilizes bedside scanning to ensure the right patient has received the right product at the right time. When a nurse scans the product barcode at a patient's bedside, that DB product has already been scanned and tracked at multiple points from the BD factory all the way to the patient. Scanning also helps to manage specific lot numbers and expiration dating, and improve product tracking during product recalls, when the product has been logged into the patient's electronic health record.".

GTINs for each product to be scanned into information systems, such as provider material management information systems (and the EHR).[14]

We urge the ONC to ensure that the certification criterion include the ability of EHR technology to capture data from and exchange data with other technology systems in use at provider facilities. Specific to device data, provider material management information systems are an important part of tracking devices in clinical and administrative workflows, from procurement to the clinical setting.

GS1 Standards Support The Capture And Use Of UDIs

The ONC states that "additional standards and technical specifications will be required to support the full range of capabilities contemplated" by its proposal and that it expects EHR technology to "be able to automate these processes once appropriate standards and technology specifications are developed".

HSCA appreciates the proposal's "first-step" approach as the ONC anticipates additional standards and technology development before the full vision of device data exchange and capture can occur.[15] However, relevant technology and the underlying standards are well-developed in many sectors, such as retail and food services. They are also under adoption and implementation in the healthcare sector by leading providers and suppliers.

The ONC proposes that EHR technology record UDI information about implantable devices and be able to "parse the UDI" so that the user can view the device identifier and the production identifier.[16] Specifically, the ONC proposes that the user be able to 1) electronically record the UDI as part of the patient's implantable device list, 2) electronically access and view a patient's list of UDIs, and 3) use the device identifier to "manually retrieve associated data elements from an authoritative source based on the GUDID" and "manually use the production identifier

[14] See *Perfect Order* for a collaboration between Becton, Dickerson and Company (BD), Mercy, and Mercy's supply chain company, Resource Optimization & Innovation, LLC (ROi) using GS1 standards from point of manufacture to point of use.

[15] See *Notice* at 10895.

[16] See *Notice* at 10895: "We propose to adopt a 2015 Edition certification criterion focused on EHR technology's ability to record UDI information about implantable devices. More specifically, EHR technology would have to enable a user to electronically record the UDI of an implantable device and other relevant information (such as a procedure note or additional information about the device) as part of a patient's "implantable device list." EHR technology would also be required to allow a user to electronically access and view a patient's list of UDIs and other relevant information associated with a patient's implantable devices. In addition, the EHR technology would need to be able to parse the UDI in order to extract and allow a user to view the "device identifier" and "production identifier" portions of the UDI. The purpose of this requirement is to ensure that a user will be able to use the device identifier to manually retrieve associated data elements from an authoritative source based on the GUDID, once available and, similarly, to ensure that a user will be able to manually use the production identifier in the event of a device recall. We expect that EHR technology would be able to automate these processes once appropriate standards and technical specifications are developed.".

in the event of a device recall". The ONC also anticipates that these functionalities will be automated at some point in the future.

We believe the GS1 standards for trade items and data synchronization represent technology essential to the vision of the ONC. We anticipate a significant amount of GUDID data will be populated by GS1-accredited Data Pools. These Data Pools also enable product manufacturers to share product attributes, including a device identifier and product identifiers, through the Global Data Synchronization Network (GDSN).[17] The Global Trade Item Number (GTIN)[18] for each unique product is published in the GDSN, and will serve as the device identifier in the GUDID. The GTIN will also serve as the core data element for the barcode on the product's label.[19] Other attributes that will serve as GUDID product identifiers will also be published in the GDSN. These and other attributes required by the UDI rule will be electronically uploaded to the GUDID from the GDSN.[20]

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[17] See *Implementation Guideline: Using the GS1 System for FDA UDI Requirements* (GS1 Healthcare US: April 2, 2014) ("*GS1 Implementation Guideline*") at 10: "The Global Data Synchronization Network (GDSN) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with supply chain partners. The GDSN is a network of interoperable data pools connected by the GS1 Global Registry®. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.".

[18] See *GS1 Implementation Guideline* at page 9: "The Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN uniquely identifies a product at each packaging level (e.g., a box of 15 Brand X tissues; a carton of six boxes of Brand X tissues; etc.). GTINs can be encoded into barcodes and used in supply chain transactions (e.g., purchase order; invoice; etc.) to promote accurate product identification. (Detailed information about encoding barcodes is provided in Section 4 of this guideline.) As an FDA Accredited Issuing Agency, GS1 has been given permission to designate the GTIN as equivalent to the Device Identifier (DI) portion of the FDA UDI.".

[19] See *GS1 Implementation Guide* at 9: "Manufacturers mark all of their products with the applicable GTIN so that they can be properly identified as they move through the supply chain. In order to do this, manufacturers encode the GTIN into GS1 data carriers [i.e., barcodes and/or Radio Frequency Identification (RFID) tags], and then affix a data carrier to each product. GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture (e.g., the black bars and spaces on the barcode). In addition to the symbolic representation, most GS1 data carriers include a *plain text version of the GTIN* as well to facilitate manual data entry when necessary [e.g., the numbers below the black bars of the barcode, known in the GS1 System as the Human Readable Interpretation (HRI)]. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 BarCodes) and two RFID tags [i.e., GS1 Electronic Product Code / Radio Frequency Identification Tags (EPC/RFID Tags)]. While the FDA does not specify a specific data carrier standard, use of a GS1 Data Carrier to specify the UDI will help meet the FDA requirement to provide the UDI in a machine-readable format.".

[20] The *GS1 Implementation Guide* provides an overview of how the GS1 system will serve as a means for manufacturers (labelers) to meet the requirements of the UDI rule.

The Perfect Order report shows how the use of the GTIN as the key device identifier in the supply chain allows for "end-to-end" integration. With technologies and systems that can communicate using a common standard, a device is visible from the factory to the bedside or operating room.

With global standards for locations (GLNs), trade items (GTINs) and global synchronization (GDSN), the GS1 standards create the platform to 1) identify, 2) capture, and 3) share device data.[21]

GS1 data carriers enable capture of product data.[22] Barcodes (GS1 data carriers) hold data to uniquely identify the product at every level of packaging. This ensures access to product information and visibility of product movement through the supply chain and clinical setting. At the item level, the barcode carries the GTIN for that item. A barcode will also carry unique data at the packaging levels.[23]

GS1 standards also enable data sharing.[24] The Global Data Synchronization Network (GDSN) enables the sharing of GTINs and other product attributes, including product descriptions, product classification, and GLN of brand owner.[25]

As part of the procurement process, the hospital will use a "ship to" GLN where it will receive the device order. GTINs and SSCCs are used at the point of receipt to validate delivery accuracy.[26] GTINs and GLNs unique to the hospital will be used to put the device order into inventory. This information is stored in the hospital's MMIS. As part of the inventory process, GTINs with extended data are used to rotate and replenish inventory, for quality control processes, and to help search for products (devices) and place them in various departments throughout the hospital system.[27] (GTINs are used to order and track devices for use in labs, pharmacies, storage locations, and in-patient care.)

A GLN may be used to identify the patient room or operating room. The individual item GTIN (with extended data on product packaging) is scanned at the point of care. At this point the GTIN and associated data will be captured in the patient's EHR, ensuring a seamless, "end-to-end" visibility of the device.[28]

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[21] For a brief visualization of this concept, see *Improving Patient Safety and Supply Chain Efficiency with GS1 Standards in Healthcare* (GS1 US: 2012) ("*Identify, Capture, Share*"). The PDF may be found at this http address:
[22] See *Identify, Capture, Share* at pages 12, 13.
[23] *Id*. at pages 14, 15.
[24] *Id*. at pages 16, 17.
[25] GS1-certified Data Pools and Group Purchasing Organizations (GPOs) play an important role in establishing attributes to be published to the GDSN.
[26] See *Identify, Capture, Share* at pages 28, 29.
[27] *Id*. at pages 30, 31.
[28] *Id*. at pages 32, 33.

At the factory: Medical devices are enumerated with GTINs and the GTIN is printed in a GS1-128 barcode at the shippable packaging level. Additional GTINs and production data are applied in barcodes at other levels of packaging, depending on the product. The GTINs are scanned at multiple points in its internal supply chain. This information is stored in a material management information system.

At the distribution center: Distribution centers use the SSCC, GTINs and production data when receiving products from manufacturing plants to verify receipt and track inventory.

At hospital receiving: The GTINs are entered into the hospital's item master, and used to track and order products. The GTIN can be pre-loaded into the provider's item master, simplifying the process of validating receipt of product delivery. (This also ensures that orders are more accurate.) Once GTINs are stored in the provider's information systems, they become the primary reference number for transacting. The GTIN serves as a common identifier, enabling the tracing of supplies from the point of replenishment to the point of use.

At the hospital store room: GTINs are used to order and track medical devices for use in labs, pharmacy, storage locations and in-patient care areas. The GTIN product shipped from the Store Room may be in multiple units of measure including the "Case," "Pack" or "Each" level. GTINs can also be scanned to help search for products in the hospital's MMIS. Software may be used to "scan-out" products to various departments throughout the facility.

In the patient room: Caregivers scan patient wrist bands to identify the patient and the location where care is taking place. Since the GTIN is globally unique, it can be used to perfect internal and external transactions. A simple scan of the product barcode will identify the product in each system, allowing for flawless product identification. (Barcode scanning leads to more efficient data and better replenishment processes. This information is used in the patient EHR and can aid in comparative effectiveness research and for improved product recall management.)

In the operating room: Tracking products in the operating room is similar to the process used in patient rooms. As surgeries are performed, products used during the procedure are documented on the patient chart in the EHR. GTIN data can then be tracked from end-to-end, all the way from the point of order to the near exact time the product was applied to a specific patient. Transactions entered in the patient EHR can also be seamlessly used for patient billing. In time, industry-supported recall notifications for specific GTINs could trigger automatic reports alerting administrators of affected patients.

Conclusion

HSCA supports the concept that the UDI be captured in the EHR. We believe the criterion for the 2015 Edition should apply to all devices to better ensure technologies and protocols are in

place as all classes of devices come into compliance with the UDI rule ahead of the rule's phase-in for Class II and Class I devices.

We recommend an alignment of EHR technologies with those standards and technologies that currently support supply chain management. In particular, we believe the GS1 standards for locations, trade items and data synchronization can be extended to the concept of capturing the UDI in the EHR. This represents an important step forward for the healthcare sector for creating the visibility of devices in the supply chain, from production, procurement and use that is used extensively in other sectors today.

Respectfully Submitted:

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