GS1 US COMMENT

to the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the National Coordinator for Health Information Technology (ONC)

regarding

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

Docket No. RIN 0992-AB92

GS1 US appreciates the opportunity to provide this comment to the Office of the National Coordinator for Health Information Technology (ONC) regarding the Voluntary 2015 Edition of the Electronic Health Record (EHR) Certification Criteria.

This GS1 US submission is split into two parts: comments to the proposed requirements for the 2017 Edition, and comments to the proposed requirements for the 2015 Edition:

- For the comments to the proposed requirements for the 2017 Edition, GS1 US commented in narrative form as these requirements did not have a corresponding table in the comment submission template. These comments address proposed requirements related to Unique Device Identification (UDI) found on pp. 59 – 60 in the Word version of the notice.

- For the comments to the proposed requirements for the 2015 Edition, GS1 US had four comments that were applicable to numerous individual requirements. In order to support the ONC review process, those comments are presented together in the Executive Summary, and then individually in the table for each of the requirements to which they apply.

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WHO IS GS1 US?

GS1 US is a not-for-profit member organization established over 35 years ago by the grocery industry to administer and manage Universal Product Codes, also known as U.P.C.'s. The U.P.C. remains one of the most successful standards in history – with billions of barcodes scanned daily worldwide. This method of identifying products and capturing product data has evolved into what is now known as the GS1 System, the world's most widely used supply chain standards, which include:

- globally-unique numbering formats (identification numbers) for **identifying** supply chain objects;
- barcodes and radio frequency identification (RFID) for **capturing** identification numbers; and
- data synchronization and electronic information exchange for **sharing** data.

GS1 US brings industry communities together to solve supply chain problems through the adoption and implementation of GS1 Standards. More than 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration and for maximizing the cost-effectiveness, speed, visibility, security and sustainability of their business processes using GS1 Standards. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). Some of the world's largest corporations participate in our boards and work groups, motivated by the knowledge that GS1 Standards help their companies reduce costs and increase both the visibility and security of their supply chains.

GS1 US is not:

- a software provider
- a hardware provider
- a commercial solutions provider
- a technology company
- a government agency

GS1 US is a local member organization of GS1®, a global information standards organization that has been recognized as a voluntary, consensus standards body pursuant to OMB Circular A-119. GS1 has been accredited by the Food and Drug Administration (FDA) as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System, and GS1 US serves as the first point of contact for the FDA. In addition, GS1 US works with and actively supports numerous federal government entities, including:

Department of Agriculture (USDA)
Department of Commerce (DOC)
Department of Defense (DOD)
Department of Homeland Security (DHS)
Department of Justice (DOJ)
Department of State
Department of the Treasury (DOT)
Department of Veteran Affairs (VA)
Commodity Futures Trading Commission (CFTC)
Consumer Product Safety Commission (CPSC)
Customs & Border Protection (CPB)
Environmental Protection Agency (EPA)
Federal Communications Commission (FCC)
Federal Deposit Insurance Corporation (FDIC)
Federal Trade Commission (FTC)
Food and Drug Administration (FDA)
National Aeronautics & Space Administration (NASA)
Securities & Exchange Commission (SEC)
United States Postal Service (USPS)
National Institute of Standards & Technology (NIST)
United States Congress
United States Trade Representative (USTR)

OVERVIEW OF THE UDI RULE & GS1 STANDARDS

GS1 US offers the following background information on the UDI Rule and the associated GS1 Standards. GS1 has been accredited by the FDA as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System, and GS1 US serves as the first point of contact for the FDA. (The information provided in this chapter is from the GS1 US UDI Implementation Guide *Using the GS1 System for U.S. FDA Unique Device Identification (UDI) Requirements*©, which was reviewed by the FDA prior to publication.)

The UDI Rule establishes a unique device identification system for medical devices. Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device. UDIs will be presented on device labels in both a human-readable format and a machine-readable format that can be read by automatic identification data capture (AIDC) technology (e.g., a barcode). In addition, re-usable devices that need to be "reprocessed" before reuse will also be directly marked with a UDI. The UDI will provide a standardized way to identify medical devices across all information sources and systems, including electronic health records and devices registries. In addition, device labelers will submit device information to a new FDA database called the Global Unique Device Identification Database (GUDID). The GUDID will provide critical information about medical devices, and the UDI will provide the key for obtaining device information from the GUDID. (Additional information is available in the GUDID Draft Guidance for Industry prepared by the FDA.)

UDI SEGMENTS

A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the labeler (e.g., manufacturer) of the device using the format specified and agreed upon during the FDA UDI Issuing Agency accreditation process. A UDI includes two segments: a "device identifier" and a "production identifier":

- **Device Identifier (DI):** a mandatory[1], fixed portion of a UDI that identifies the labeler and the specific version or model of a device
- **Production Identifier (PI):** a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: (i) the lot or batch number within which a device was manufactured; (ii) the serial number of a specific device; (iii) the expiration date of a specific device; (iv) the date a specific device was manufactured; and (v) for a Human Cellular/Tissue-based Product (HCT/P) regulated as a device, the distinct identification code

According to the Rule, a *device identifier* is always present in a UDI. However, a *production identifier* is only required if it appears on the device label. Nonetheless, most devices include at least one piece of production information on the label, and therefore most UDIs would include a *production identifier*. Therefore, UDIs can be comprised of either ***DI only***, or ***DI and PI***.

Because GS1 is an FDA-accredited Issuing Agency for UDI, the GS1 Global Trade Item Number® (GTIN®) can be considered a UDI device identifier, and production identifiers are represented by GS1 Application Identifiers (AIs).

1 U.S. Food & Drug Administration, Unique Device Identification System – Final Rule, p. 115. http://federalregister.gov/a/2013-23059

UDI SEGMENT WITH CORRESPONDING GS1 STANDARD(S)	
Device Identifier (DI)	GS1 Global Trade Item Number (GTIN)
Production Identifier (PI)	GS1 Application Identifiers (AIs):
Batch/lot number	AI (10)
Production/manufacturing date	AI (11)
Expiration date	AI (17)
Serial number	AI (21)

Table A: UDI Components with Corresponding GS1 Standards

UDI LABELING

The Rule requires that UDIs be presented on device labels in both human-readable format and AIDC format (e.g., a barcode)[2]. GS1 Standards provide for several different barcodes that can be used as the UDI AIDC format. Barcodes are utilized for a variety of applications, and the GS1 System supports seven different barcodes in order to enable users to select the barcode that best fits their application. Pursuant to the *GS1 General Specifications*, some barcodes are only approved for retail applications, some barcodes are only approved for non-retail applications, and some are approved for both. In addition, some GS1 BarCodes are able to carry production information (encoded with GS1 AIs) and others are not. Therefore, the GS1 BarCode options for UDI vary depending on (1) whether the barcode will be read in a retail environment, and (2) whether the barcode will need to encode "DI only" or "DI and PI." The table below identifies the GS1 BarCode options for each combination.

BARCODE ENVIRONMENT	UDI SEGMENTS TO BE ENCODED	GS1 BARCODE OPTIONS
RETAIL	**DI only**	**EAN/UPC** **GS1 DataBar®**
RETAIL	**DI and PI**	**EAN/UPC** ***+ one of the following:*** **GS1 DataMatrix** **GS1 DataBar** **GS1-128**
NON-RETAIL *	**DI only ***	**GS1-128** **GS1 DataMatrix** **GS1 DataBar** **ITF-14**
NON-RETAIL	**DI and PI**	**GS1 DataMatrix** **GS1-128** **GS1 DataBar**

Table B: GS1 BarCode Options Based on Barcode Application Environment & UDI Information to be Encoded

* The barcode options shown above for "Non-Retail – encoding DI only" are the most prevalent. However, it should be noted that EAN/UPC could also be used in this group according to the standard.

[2] U.S. Food & Drug Administration, Unique Device Identification System – Final Rule, p. 122. http://federalregister.gov/a/2013-23059

DIRECT MARKING

The rule requires that the UDI also be directly marked on the medical device itself for re-usable devices that need to be "reprocessed" before reuse. Direct marking supports accurate identification even when a device is no longer accompanied by its label or package. Within the GS1 System, direct marking is referred to as Direct Part Marking (DPM). DPM is the process of marking a GS1 symbol directly onto an item (as opposed to using a label or another indirect marking process). There are a variety of methods for applying DPM, including both intrusive methods (e.g., dot peen; etching; direct laser marking; etc.) and non-intrusive methods (e.g., cast/forge/mold; laser bonding; stencil; etc.) GS1 Standards define key aspects of DPM including substrate requirements, symbol dimensions, symbol quality, and symbol placement.

GUDID

Whenever a device must bear a UDI, the rule requires the labeler of that device to submit information concerning the device to the FDA to facilitate the rapid identification of the device and the labeler, and to provide links to other FDA data. The Global Unique Device Identification Database (GUDID) will serve as a reference catalogue for every device with an identifier. No identifying patient information will be stored in this device information center.

The FDA has published a GUDID Draft Guidance for Industry that indicates that there will be two options/methods for Publishing/Reporting UDI and associated data to the FDA's GUDID:

- Structured input via the GUDID Web Interface
- HL7 Structured Product Labeling (SPL) submitted via the FDA Electronic Submissions Gateway (ESG)

In addition, the draft guidance also provides labelers with the option to designate third-party submitters for GUDID submissions. Third-party submitters are companies/individuals authorized to submit GUDID information on behalf of the labeler using one of the two options/methods specified above (e.g., GDSN-certified Data Pools such as 1WorldSync, FSEnet, GHX Health ConneXion, etc.). [3]

[3] The GS1 Global Data Synchronization Network™ (GDSN®) provides an efficient and effective approach to (1) storing GTINs 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 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. Healthcare supply chain trading partners use the GDSN to synchronize product information.

COMMENTS REGARDING PROPOSED UDI REQUIREMENTS FOR THE 2017 EDITION

This chapter presents GS1 US comments regarding the proposed requirements for the 2017 Edition related to UDI (pp. 59 – 60). These comments are presented in narrative form because these requirements did not have a corresponding table in the comment submission template.

RECORD A MINIMUM SET OF DATA ELEMENTS

The first proposed requirement in this section was to:

- *Record a minimum set of data elements for each UDI in a patient's implantable device list, including:*
  - *Labeler Name (Manufacturer);*
  - *Brand Name;*
  - *Version or Model;*
  - *Global Medical Device Nomenclature Name;*
  - *Single Use indicator;*
  - *Labeled as containing natural rubber latex or dry natural rubber; and*
  - *MRI Safety Status.*

As a preliminary matter, GS1 US strongly supports the proposed requirement to record UDIs (i.e., the identifier) in EHRs to promote patient safety. Beyond the identifier, GS1 US also understands the importance of this proposed minimum set of UDI data elements to be available for clinical decision making when viewing or reporting from EHRs. UDI data should be stored in provider systems such as Enterprise Resource Planning (ERP) Systems, Materials Management Information System (MMIS), clinical systems and other databases. Such systems will be the provider's system of record for UDI data -- and will serve as the authoritative source that other provider systems and applications (like EHRs) can query or link to for UDI data. Therefore, GS1 US recommends that EHR requirements focus on the importance of recording the identifier (i.e., the UDI = DI+PI) in EHRs, and that future requirements could be developed around the ability to use the identifier as the link to UDI data in a system of record.

Replicating data across a variety of systems increases data quality issues. GS1 US notes that the word "record" does not prescribe the source of the data or how it will be entered into the EHR (i.e., manual data entry; pulling data from an authoritative data source, FDA Global UDI Database or GUDID, data warehouse or data pool; etc.) and suggests allowing providers to use the best source based on their system requirements. It is important to remember that manual data entry is a time-consuming and error-prone approach to data capture. GS1 US recommends avoiding requirements that would result in manual data entry *when that data is available in another authoritative database*. As noted above, replicating data across a variety of systems increases data quality issues among those systems -- introducing manual data entry into the mix increases the risk exponentially. It is unclear whether the intention of the proposed requirement is for the FDA GUDID to be the data source for these EHR data elements. If so, please note our comments in the next section below regarding the use of the FDA GUDID as a data source for EHR fields.

ACCEPT ELECTRONIC UDI DATA VIA AUTOMATIC IDENTIFICATION & DATA CAPTURE

GS1 US agrees with the second proposed EHR capability to accept *electronic UDI data via automatic identification and data capture (AIDC) or other assistive technologies used in healthcare systems (e.g., barcode scanners and RFID)*. However, GS1 US recommends that the wording of this requirement be modified to better align with the terminology of the U.S. FDA UDI Rule. In the U.S. FDA UDI Rule, § 801.3 *Definitions* provides the following definition for the term "Automatic identification and data capture (AIDC)":

> Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process. [4]

GS1 US notes that this definition speaks only to identifiers in the AIDC, not to "UDI data" as worded in the proposed EHR requirement. For further clarification, we note the following definition of the term "Unique device identifier (UDI)" *(included in the AIDC definition)* from the same section of the rule:

> Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:
>
> (1) A device identifier--a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
>
> (2) A production identifier--a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
>
> (i) The lot or batch within which a device was manufactured;
>
> (ii) The serial number of a specific device;
>
> (iii) The expiration date of a specific device;
>
> (iv) The date a specific device was manufactured;
>
> (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter. [5]

Although common usage may describe lot/batch, serial number, expiration date, etc. as "UDI data," the above definition from the rule indicates that those elements are considered identifiers (more specifically, *production identifiers*) within the context of the U.S. FDA UDI Rule. This is an important distinction because there are proposed EHR requirements regarding the UDI identifier (i.e., UDI=DI+PI) and proposed EHR requirements regarding "UDI data." GS1 US recommends aligning the wording of EHR UDI requirements with the wording used the U.S. FDA UDI Rule to clarify these terms and reinforce their meaning in the context of UDI. Specifically, GS1 US recommends that the proposed EHR requirement be revised as follows:

> Accept UDIs (device identifiers and production identifiers) via automatic identification and data capture (AIDC) or other assistive technologies used in healthcare systems (e.g., barcode scanners and RFID).

[4] U.S. Food & Drug Administration, Unique Device Identification System – Final Rule, p. 113. http://federalregister.gov/a/2013-23059
[5] U.S. Food & Drug Administration, Unique Device Identification System – Final Rule, p. 115. http://federalregister.gov/a/2013-23059

INCORPORATE GUDID DEVICE IDENTIFICATION ATTRIBUTES

The third proposed requirement in this section was to:

- *Use the device identifier portion of the UDI to obtain and incorporate GUDID device identification attributes in the patient's implantable device list.*

There are three primary issues surrounding the use of the FDA GUDID as a data source for EHR fields.

The first issue with using the UDI device identifier-DI or GTIN as the primary key to use the FDA GUDID as a data source for EHR fields is there are clinically-relevant data elements (also known as attributes) which are editable in the FDA GUDID (e.g., Labeled as containing natural rubber latex or dry natural rubber; MRI Safety Status, etc.). The FDA GUDID includes system rules that govern the editability of each attribute. Some attributes are not editable (i.e., if there is a change to the attribute, a new Device Identifier (DI) must be assigned and registered). Other attributes are editable (i.e., the attributes may be updated within the existing DI record). (See the FDA GUDID Draft Guidance for Industry for more information.)

Because EHRs are historical records, it is important that they reflect information as it was known at the time of treatment. This is especially important with clinically-relevant fields. If the FDA GUDID was the data source for these editable clinically-relevant fields, and if a clinically-relevant attribute was edited in the FDA GUDID, the EHR would not properly reflect the information as it was known at the time of treatment or reflective of the product in hand based on the date of manufacture. In order to use the FDA GUDID as the data source, it would be necessary to either (i) record only non-editable FDA GUDID attributes in EHR fields, or (ii) modify the GUDID rules so that clinically-relevant fields are not editable.

The second issue with using the FDA GUDID as a data source for EHR fields relates to state Departments of Health privacy regulations. The GS1 Healthcare US provider community has indicated that there are state regulations that govern how certain information is recorded in patient records in order to protect a patient's privacy, and that these regulations do often cover data like product description and brand name. The FDA GUDID has its own data standards for how these attributes are defined that are not aligned with such privacy regulations. Therefore, EHR fields could not use the FDA GUDID as the data source unless those attributes are aligned with privacy regulations.

Although this discussion present two specific challenges related to using the FDA GUDID as a data source, GS1 US suggests that the best approach is to:

- Record the UDI in the EHR using the DI to provide the link to other authoritative data sources based on the system requirements and to support traceability
- Define the list of required UDI data elements, but do not specify the source for that information (to enable providers to use the best source for that information based on their requirements)
- Record UDI data elements that cannot be edited without issuing a new UDI to minimize data quality issues.

The third issue with using the FDA GUDID as a data source for EHR fields is hospital supply management practices developed over the years to overcome the lack of unique device identifiers. For example, nomenclatures and standardized classification systems like the United Nations Standard Products and Services Codes® (UNSPSC®) and the Universal Medical Device Nomenclature System™ (UMDNS) are well-entrenched. Nomenclature elements within the GUDID may conflict with these and other standards used in healthcare systems today, which complicates the

integration of UDI in provider systems and processes. GS1 US recommends that the ONC be aware of these challenges and work with industry to develop strategies for addressing them. For example, the GDSN includes an attribute for UNSPSC which could be leveraged as a cross-walk for nomenclature elements within the GUDID.

MAKING UDI AND UDI DATA AVAILABLE TO OTHER SYSTEMS

Three proposed requirements in this section were to:

- *Use the device identifier or production identifier portion of the UDI to generate lists of patients with a particular implantable device.*
- *Make a UDI and its associated identification attributes accessible to the EHR technology for reporting purposes (e.g., adverse event reporting, registry population, recalls).*
- *Exchange a UDI and UDI data with procedure reporting systems (including adverse event incident reporting systems and medical specialty reporting systems) and other systems that associate a patient with a device.*

The main thrust of these proposed requirements is that EHR technology needs to make UDI (DI + PI) and UDI-related information for individual patients interoperable with and available to other systems. [Note: Using the GS1 System for UDI, the device identifier (DI) is represented by GTIN, and production identifiers are represented by GS1 Application Identifiers (AIs). See the chapter of this document entitled *Overview of the UDI Rule & GS1 Standards* and the section in the next chapter entitled *Recording & Presenting UDIs* for more information.] Although the optimal approach is generally to use relational databases (i.e., record only the identifier and use it to get the associated information from an authoritative data source), the use of the EHR as a historical record also indicates the need to store certain pieces of data in the EHR to ensure that the data accurately reflects information as it was known at the time of treatment. Nonetheless, not all UDI data needs to be stored in the EHR. Determining which UDI data are needed for reporting purposes, as well as the best source for that data is likely a task that may be best left to the provider community who administer those reporting systems. Therefore, GS1 US recommends that these requirements be worded in terms of the ability of the EHR to (i) tie into master data systems, and (ii) communicate UDI and UDI-related data to reporting systems to support traceability for recalls and transparency for patients concerned when a recall is issued.

EXPAND THESE AND OTHER CAPABILITIES TO ADDITIONAL TYPES OF DEVICES USED BY PATIENTS

The final proposed requirement is to *"Expand these and other capabilities to additional types of devices used by patients"*. GS1 US agrees with this suggestion for adoption in subsequent rulemaking.

COMMENTS REGARDING PROPOSED REQUIREMENTS FOR THE 2015 EDITION

This chapter presents GS1 US comments regarding the proposed requirements for the 2015 Edition. GS1 US had four comments that were applicable to numerous individual requirements. In order to support the ONC review process, those comments are presented together in the Executive Summary below, and are copied into the table for each of the requirements to which they applied in the comment template following.

EXECUTIVE SUMMARY

Medications & Medication Lists

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

2D Barcodes

GS1 US recommends that ONC pursue a "technology-neutral" (but adopted by the associated standards organization) approach regarding EHR's ability to consume AIDC carriers and avoid requirements to use specific types of AIDC for certain functions, much like the FDA did with UDI. A technology-neutral approach enables industry to better respond to progress, technological advancements, and implementation considerations. For this reason, GS1 US believes that requiring EHRs to "consume 2D barcodes" is sufficient however consider a technology-neutral approach to be consistent with the UDI Rule. This approach enables the ONC to ensure that EHRs have flexible AIDC capabilities, and that choices regarding which data carrier is best for various function are left to progress naturally in the marketplace. (GS1 has endorsed the use of GS1 DataMatrix in healthcare.) As a general matter, GS1 US notes that 2D barcodes cannot be read by the same scanners used for linear barcodes. Linear barcodes use laser scanners, and 2D barcodes require camera-based scanners. (Camera-based scanners needed for 2D barcodes can also read linear barcodes.) For additional information about 2D barcodes, see the GS1 DataMatrix guide.

Access & View of "Other Relevant" UDI Data

As a preliminary matter, GS1 US strongly supports the proposed requirement to record UDIs (i.e., the identifier) in EHRs to promote patient safety. Beyond the identifier, GS1 US also understands the importance of this proposed minimum set of UDI data elements to be available for clinical decision making when viewing or reporting from EHRs. UDI data should be stored in provider systems such as Enterprise Resource Planning (ERP) Systems, Materials Management Information System (MMIS), clinical systems and other databases. Such systems will be the provider's system of record for UDI data -- and will serve as the authoritative source that other provider systems and applications (like EHRs) can query or link to for UDI data. Therefore, GS1 US recommends that EHR requirements focus on the importance of recording the identifier (i.e., the UDI = DI+PI) in EHRs, and that future requirements could be developed around the ability to use the identifier as the link to UDI data in a system of record.

Recording & Presenting UDIs

The 2015 Edition includes the requirement for EHRs to have the ability to parse the UDI, which is vitally important as it supports searchable database fields and visually meaningful field presentations in EHR screens. In conjunction with that, GS1 US recommends that the requirements to "electronically record the UDI" be further defined. Under the current language, it would be likely that EHRs would simply contain a field named "UDI" and that scanning a barcode would simply populate that field with the raw barcode data, which is unsearchable and not visually meaningful.

Consider the following barcodes encoding a hypothetical UDI based on the GS1 System including a GTIN (as the device identifier), and three production identifiers: Expiration Date, Batch/Lot, and Serial Number.

Figure 1: GS1-128
encoding GTIN with Expiration Date, Batch/Lot & Serial Number

Figure 2: GS1 DataMatrix
encoding GTIN with Expiration Date, Batch/Lot & Serial Number

The barcodes above would communicate the following raw data:

0120887511007346171503311 0A1B2C3D4E521123456789

The numbers shown in **aqua** are the GS1 Application Identifiers that indicate the type of data contained in the following segment of the barcode, and the numbers shown in **navy** are the actual values for the data elements, i.e.:

GS1 Application Identifier	Data Element	Value
01	GTIN	20887511007346
17	Expiration Date	150331
10	Batch/Lot Number	A1B2C3D4E5
21	Serial Number	123456789

Table C: UDI Segments in a GS1 Barcode String

Under the current wording (i.e., "electronically record the UDI"), scanning a medical device barcode encoding the hypothetical UDI from above would create the following entry:

UDI: 0120887511007346171503311 0A1B2C3D4E521123456789

As you can see, this data is not meaningful upon visual inspection. There would be no way for a reader to discern what the DI is (so they can look it up in the GUDID) or even what the expiration date is. Moreover, this field does not provide searchable information. To avoid this, GS1 US recommends that the requirement to "electronically record the UDI" be modified to require that the UDI be recorded in the EHR database in its complete and parsed state, and presented on EHR screens in its complete and parsed state using visually meaningful fields. (This would require 7 fields: a field for the UDI in its raw state, a field for the Device Identifier, and a field for each of the 5 possible pieces of production information.)

For example, the hypothetical UDI from above should be recorded and presented as follows:

UDI: 01208875110073461715033110A1B2C3D4E521123456789
Device Identifier: 20887511007346
Batch/Lot Number: A1B2C3D4E5
Expiration Date: 2015-03-31
Production Date: [1]
Serial Number: 123456789
ICCBBA: [2]

This approach leverages the requirement to parse the UDI to ensure that UDI information is searchable and understandable to readers.

Note 1: Not all of the PI fields will be populated for every device because not all PI is required/used for each device.

Note2: ICCBBA is a UDI PI, and therefore is included as a recommended field above. However, it is not a GS1 Standard. (It is a standard administered by ICCBBA for human tissue/cell products.

The table below presents GS1 specifications for each UDI segment when expressed with GS1 Standards.

UDI IDENTIFIERS	GS1 STANDARD	GS1 ENCODING SPECIFICATIONS
DEVICE IDENTIFIER	GTIN	fixed-length field of 14 numeric characters
BATCH/LOT NUMBER	AI (10)	variable-length field of up to 20 alphanumeric characters
MANUFACTURING / PRODUCTION DATE	AI (11)	fixed-length field of six numeric characters as **YYMMDD** where: **YY** = the tens and units of the year (e.g., 2014 = 14). **MM** = the number of the month (e.g., March = 03). **DD** = the number of the day of the relevant month (e.g., second day = 02)
EXPIRATION DATE	AI (17)	fixed-length field of six numeric characters as **YYMMDD** where: **YY** = the tens and units of the year (e.g., 2014 = 14). **MM** = the number of the month (e.g., March = 03). **DD** = the number of the day of the relevant month (e.g., second day = 02)
SERIAL NUMBER	AI (21)	variable-length field of up to 20 alphanumeric characters

Table D: UDI Segments when represented by GS1 Standards

ONC COMMENT SUBMISSION TEMPLATE

A. PROPOSED FOR 2015 EDITION CERTIFICATION CRITERIA

§ 170.315(a)(1) Computerized physician order entry - medications

MU Objective

Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

2015 Edition EHR Certification Criterion

(1) Computerized provider order entry – medications. Enable a user to electronically record, change, and access medication orders.

Preamble FR Citation: 79 FR 10886	**Specific questions in preamble?** *No*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(2) Computerized physician order entry - laboratory

MU Objective

Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

2015 Edition EHR Certification Criterion

(2) Computerized provider order entry – laboratory. (i) Enable a user to electronically record, change, and access laboratory orders.
(ii) Ambulatory setting only. Enable a user to electronically create laboratory orders for electronic transmission:
(A) With all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8); and
(B) In accordance with the standard specified at § 170.205(l)(1) and, at a minimum the version of the standard at § 170.207(c)(2).

Preamble FR Citation: 79 FR 10887	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(3) (Computerized physician order entry – radiology/imaging)

MU Objective

Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

2015 Edition EHR Certification Criterion

(3) Computerized provider order entry – radiology/imaging. Enable a user to electronically record, change, and access radiology and imaging orders.

Preamble FR Citation: 79 FR 10887	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(4) (Drug-drug, drug-allergy interaction checks)

MU Objective

Implement drug-drug and drug-allergy interaction checks.

2015 Edition EHR Certification Criterion

(4) Drug-drug, drug-allergy interaction checks. (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

Preamble FR Citation: 79 FR 10887	**Specific questions in preamble?** *Yes*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(5) (Demographics)

MU Objective

Record the following demographics: preferred language; sex; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.

2015 Edition EHR Certification Criterion

(5) Demographics. (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.

(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.

(ii) Inpatient setting only. Enable a user to electronically record, change, and access the preliminary cause of death and date of death in the event of a mortality.

Preamble FR Citation: 79 FR 10888	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(a)(6) (Vital signs, body mass index, and growth charts)

MU Objective

Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.

2015 Edition EHR Certification Criterion

(6) Vital signs, body mass index, and growth charts**.** (i) Vital signs**.** Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.

(ii) Calculate body mass index**.** Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) Optional—Plot and display growth charts**.** Plot and electronically display, upon request, growth charts for patients.

Preamble FR Citation: 79 FR 10889	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(a)(7) (Problem list)

MU Objective

Maintain an up-to-date problem list of current and active diagnoses.

2015 Edition EHR Certification Criterion

(7) Problem list. Enable a user to electronically record, change, and access a patient's active problem list:

(i) Ambulatory setting**.** Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(8) (Medication list)

MU Objective
Maintain active medication list.

2015 Edition EHR Certification Criterion

(8) Medication list. Enable a user to electronically record, change, and access a patient's active medication list as well as medication history:
(i) Ambulatory setting. Over multiple encounters; or
(ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(9) (Medication allergy list)

MU Objective

Maintain active medication allergy list.

2015 Edition EHR Certification Criterion

(9) Medication allergy list. Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history:
(i) Ambulatory setting. Over multiple encounters; or
(ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(10) (Clinical decision support)

MU Objective
Use clinical decision support to improve performance on high-priority health conditions.

2015 Edition EHR Certification Criteria

(10) Clinical decision support. (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

(A) Problem list;
(B) Medication list;
(C) Medication allergy list;
(D) At least one demographic specified in paragraph (a)(5)(i) of this section;
(E) Laboratory tests; and
(F) Vital signs.

(ii) Linked referential clinical decision support. (A) EHR technology must be able to:
(1) Electronically identify for a user diagnostic and therapeutic reference information; or
(2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (3).

(B) For paragraph (a)(10)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.

(iii) Clinical decision support configuration. (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) EHR technology must enable interventions to be electronically triggered:
(1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.
(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section.
(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4)(i)(A)(1) of this section.

(iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:
(A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:
(1) Bibliographic citation of the intervention (clinical research/guideline);
(2) Developer of the intervention (translation from clinical research/guideline);
(3) Funding source of the intervention development technical implementation; and
(4) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d).

(vii) Decision support – service. Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at § 170.204(e).

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *Yes*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(11) (Electronic notes)

MU Objective

Record electronic notes in patient records.

2015 Edition EHR Certification Criterion

(11) Electronic notes. Enable a user to electronically:
(i) Record, change, and access electronic notes; and
(ii) Search within and across electronic notes stored within EHR technology.

Preamble FR Citation: 79 FR 10891	**Specific questions in preamble?** *Yes*

Public Comment Field: No comment.

§ 170.315(a)(12) (Drug formulary checks)

MU Objective

Implement drug formulary checks.

2015 Edition EHR Certification Criterion

(12) Drug-formulary checks. EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

Preamble FR Citation: 79 FR 10892	**Specific questions in preamble?** *Yes*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(13) (Smoking status)

MU Objective

Record smoking status for patients 13 years old or older.

2015 Edition EHR Certification Criteria

(13) Smoking status. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

Preamble FR Citation: 79 FR 10892	**Specific questions in preamble?** *No*

Public Comment Field: No comment.

§ 170.315(a)(14) (Image results)

MU Objective

Imaging results and information are accessible through Certified EHR Technology.

2015 Edition EHR Certification Criterion

(14) Image results Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *No*

Public Comment Field: No comment.

§ 170.315(a)(15) (Family health history)

MU Objective

Record patient family health history as structured data.

2015 Edition EHR Certification Criterion

(15) Family health history**.** Enable a user to electronically record, change, and access a patient's family health history according to the standard and implementation specification specified at § 170.205(m)(1).

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *No*

Public Comment Field:
No comment.

§ 170.315(a)(16) (Patient list creation)

MU Objective

Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

2015 Edition EHR Certification Criterion

(16) Patient list creation**.** Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

(i) Problems;
(ii) Medications;
(iii) Medication allergies;
(iv) At least one demographic specified in paragraph (a)(5)(i) of this section;
(v) Laboratory tests and values/results; and
(vi) Ambulatory setting only**.** Patient communication preferences.

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *Yes*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(17) (Patient-specific education resources)

MU Objective

Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

2015 Edition EHR Certification Criterion

(17) Patient-specific education resources. EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests:

(i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3); and

(ii) By any means other than using the standard specified in § 170.204(b).

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *Yes*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(18) (Inpatient setting only – electronic medication administration record)

MU Objective

Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

2015 Edition EHR Certification Criterion

(18) Inpatient setting only—electronic medication administration record. (i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):

(A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.

(B) Right medication. The medication to be administered matches the medication ordered for the patient.

(C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) Right route. The route of medication delivery matches the route specified in the medication order.

(E) Right time. The time that the medication was ordered to be administered compared to the current time.

(ii) Right documentation. Electronically record the time and date in accordance with the standard specified in §170.210(g), and user identification when a medication is administered.

Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *No*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(a)(19) (Inpatient setting only – advance directives)

MU Objective

Record whether a patient 65 years old or older has an advance directive.

2015 Edition EHR Certification Criteria

(19) Inpatient setting only—advance directives**.** Enable a user to electronically record whether a patient has an advance directive.

Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(20) (Implantable Device list)

MU Objective

N/A

2015 Edition EHR Certification Criteria

(20) Implantable device list**.** (i) Enable a user to electronically access and view a list of Unique Device Identifiers and other relevant information associated with a patient's Implantable Device(s).

(ii) Enable a user to electronically record in a patient's Implantable Device list the following information at the time the Device is implanted or removed:

(A) The Unique Device Identifier associated with the Implantable Device; and

(B) Other relevant information about the Implantable Device or procedure.

(iii) For each Unique Device Identifier in a patient's Implantable Device list, allow a user to separately access and view electronically the Device Identifier and Production Identifier portions of the Unique Device Identifier.

Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *Yes*

Public Comment Field:

Recording & Presenting UDIs: This section includes the requirement for EHRs to have the ability to parse the UDI, which is vitally important as it supports searchable database fields and visually meaningful field presentations in EHR screens. In conjunction with that, GS1 US recommends that the requirements to "electronically record the UDI" be further defined. Under the current language, it would be likely that EHRs would simply contain a field named "UDI" and that scanning a barcode would simply populate that field with the raw barcode data, which is unsearchable and not visually meaningful. Consider the following barcodes encoding a hypothetical UDI based on the GS1 System including a GTIN (as the device identifier), and three production identifiers: Expiration Date, Batch/Lot, and Serial Number.

GS1-128 barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

§ 170.315(a)(20) (Implantable Device list)

(01) 20887511007346
(17) 150331
(10) A1B2C3D4E5
(21) 123456789

GS1 DataMatrix barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

The barcodes above would communicate the following raw data:

01208875110073461715033110A1B2C3D4E521123456789

The numbers shown in **aqua** are the GS1 Application Identifiers that indicate the type of data contained in the following segment of the barcode, and the numbers shown in **navy** are the actual values for the data elements, i.e.:

GS1 Application Identifier	Data Element	Value
01	GTIN	**20887511007346**
17	Expiration Date	**150331**
10	Batch/Lot Number	**A1B2C3D4E5**
21	Serial Number	**123456789**

Under the current wording (i.e., "electronically record the UDI"), scanning a medical device barcode encoding the hypothetical UDI from above would create the following entry:

UDI: 01208875110073461715033110A1B2C3D4E521123456789

As you can see, this data is not meaningful upon visual inspection. There would be no way for a reader to discern what the DI is (so they can look it up in the GUDID) or even what the expiration date is. Moreover, this field does not provide searchable information. To avoid this, GS1 US recommends that the requirement to "electronically record the UDI" be modified to require that the UDI be recorded in the EHR database in its complete and parsed state, and presented on EHR screens in its complete and parsed state using visually meaningful fields. (This would require 7 fields: a field for the UDI in its raw state, a field for the Device Identifier, and a field for each of the 5 possible pieces of production information.) For example, the hypothetical UDI from above should be recorded and presented as follows:

UDI: 01208875110073461715033110A1B2C3D4E521123456789
Device Identifier: 20887511007346
Batch/Lot Number: A1B2C3D4E5
Expiration Date: 2015-03-31
Production Date: [1]
Serial Number: 123456789
ICCBBA: [2]

§ 170.315(a)(20) (Implantable Device list)

This approach leverages the requirement to parse the UDI to ensure that UDI information is searchable and understandable to readers.

Note 1: Not all of the PI fields will be populated for every device because not all PI is required/used for each device.

Note2: ICCBBA is a UDI PI, and therefore is included as a recommended field above. However, it is not a GS1 Standard. (It is a standard administered by ICCBBA for human tissue/cell products.

Access & View of "Other Relevant" UDI Data: As a preliminary matter, GS1 US strongly supports the proposed requirement to record UDIs (i.e., the identifier) in EHRs to promote patient safety. Beyond the identifier, GS1 US also understands the importance of this proposed minimum set of UDI data elements to be available for clinical decision making when viewing or reporting from EHRs. UDI data should be stored in provider systems such as Enterprise Resource Planning (ERP) Systems, Materials Management Information System (MMIS), clinical systems and other databases. Such systems will be the provider's system of record for UDI data -- and will serve as the authoritative source that other provider systems and applications (like EHRs) can query or link to for UDI data. Therefore, GS1 US recommends that EHR requirements focus on the importance of recording the identifier (i.e., the UDI = DI+PI) in EHRs, and that future requirements could be developed around the ability to use the identifier as the link to UDI data in a system of record.

§ 170.315(b)(1) (Transitions of care)

MU Objective

The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

2015 Edition EHR Certification Criteria

(1) Transitions of care. (i) Send and receive via edge protocol. EHR technology must be able to electronically:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) and that leads to such summaries being processed by a service that has implemented the standard specified in §170.202(a); and

(B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) from a service that has implemented the standard specified in §170.202(a).

(ii) Receiving accuracy. EHR technology must meet or exceed the standard specified at §170.212(a)

(iii) Display.

(A) EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: §170.205(a)(1) through (4).

(B) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at §170.205(a)(3).

(iv) Create. (A) Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(4) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(1) Encounter diagnoses. The standard specified in §170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(3);

(2) Immunizations. The standard specified in §170.207(e)(2);

(3) Cognitive status;

(4) Functional status;

(5) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;

(6) Inpatient setting only. Discharge instructions; and

(7) Unique Device Identifier(s) for a patient's implantable device(s).

(B) Patient matching data quality. EHR technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

(1) Data. first name, last name, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, current address, historical address, phone number, and sex.

(2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.

(3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.

(4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(5) Constraint. Represent current and historical address information, including the street address, city, state, zip code, according to the United States Postal Service format;

(6) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.

(7) Constraint. Represent sex according to the HL7 Version 3 ValueSet for Administrative Gender.

Preamble FR Citation: 79 FR 10896	**Specific questions in preamble?** *Yes*

Public Comment Field:

Presenting/Expressing UDIs: This Edition includes the requirement for EHRs to have the ability to parse the UDI, which is vitally important as it supports searchable database fields and visually meaningful field presentations in EHR screens. In conjunction with that, GS1 US recommends that the requirements to "electronically record the UDI" be further defined. Under the current language, it would be likely that EHRs would simply contain a field named "UDI" and that scanning a barcode would simply populate that field with the raw barcode data, which is unsearchable and not visually meaningful. Consider the following barcodes encoding a

§ 170.315(b)(1) (Transitions of care)

hypothetical UDI based on the GS1 System including a GTIN (as the device identifier), and three production identifiers: Expiration Date, Batch/Lot, and Serial Number.

GS1-128 barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

(01) 20887511007346
(17) 150331
(10) A1B2C3D4E5
(21) 123456789

GS1 DataMatrix barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

The barcodes above would communicate the following raw data:

0120887511007346171503311 0A1B2C3D4E521123456789

The numbers shown in **aqua** are the GS1 Application Identifiers that indicate the type of data contained in the following segment of the barcode, and the numbers shown in **navy** are the actual values for the data elements, i.e.:

GS1 Application Identifier	Data Element	Value
01	GTIN	**20887511007346**
17	Expiration Date	**150331**
10	Batch/Lot Number	**A1B2C3D4E5**
21	Serial Number	**123456789**

Under the current wording (i.e., "electronically record the UDI"), scanning a medical device barcode encoding the hypothetical UDI from above would create the following entry:

UDI: 0120887511007346171503311 0A1B2C3D4E521123456789

As you can see, this data is not meaningful upon visual inspection. There would be no way for a reader to discern what the DI is (so they can look it up in the GUDID) or even what the expiration date is. Moreover, this field does not provide searchable information. To avoid this, GS1 US recommends that the requirement to "electronically record the UDI" be modified to require that the UDI be recorded in the EHR database in its complete and parsed state, and presented on EHR screens in its complete and parsed state using visually meaningful fields. (This would require 7 fields: a field for the UDI in its raw state, a field for the Device Identifier, and a field for each of the 5 possible pieces of production information.)

§ 170.315(b)(1) (Transitions of care)

For example, the hypothetical UDI from above should be recorded and presented as follows:

UDI: **01208875110073461715033110A1B2C3D4E521123456789**
Device Identifier: **20887511007346**
Batch/Lot Number: **A1B2C3D4E5**
Expiration Date: **2015-03-31**
Production Date: [1]
Serial Number: **123456789**
ICCBBA: [2]

This approach leverages the requirement to parse the UDI to ensure that UDI information is searchable and understandable to readers.

Note 1: Not all of the PI fields will be populated for every device because not all PI is required/used for each device.

Note2: ICCBBA is a UDI PI, and therefore is included as a recommended field above. However, it is not a GS1 Standard. (It is a standard administered by ICCBBA for human tissue/cell products.

§ 170.315(b)(2) (Clinical information reconciliation and incorporation)

MU Objective

The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

2015 Edition EHR Certification Criteria

(2) Clinical information reconciliation and incorporation. (i) Correct patient. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(4), EHR technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(ii) Reconciliation. Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(A) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;

(B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;

(C) Enable a user to review and validate the accuracy of a final set of data; and

(D) Upon a user's confirmation, automatically update the list, and electronically incorporate the following data expressed according to the specified standard(s):

(1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(2);

(2) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);

(3) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(2).

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *Yes*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(b)(3) (Electronic prescribing)

MU Objective

Generate and transmit permissible prescriptions electronically (eRx).

2015 Edition EHR Certification Criterion

(3) Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

(i) The standard specified in § 170.205(b)(2); and

(ii) At a minimum, the version of the standard specified in § 170.207(d)(2).

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

§ 170.315(b)(4) (Incorporate laboratory tests and values/results)

MU Objective

Incorporate clinical laboratory test results into Certified EHR Technology as structured data.

2015 Edition EHR Certification Criteria

(4) Incorporate laboratory tests and values/results. (i) Receive results. (A) Ambulatory setting only. (1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

(2) Electronically display the tests and values/results received in human readable format.

(B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Electronically display the test report information:

(A) Specified in 42 CFR 493.1291 (a)(1) through (a)(3) and (c)(1) through (c)(7);

(B) Related to reference values as specified in 42 CFR 493.1291(d);

(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and

(D) For corrected reports as specified in 42 CFR 493.1291(k)(2).

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(b)(5) (Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers)

MU Objective

Provide structured electronic laboratory results to eligible professionals.

2015 Edition EHR Certification Criteria

(5) Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers. EHR technology must be able to electronically create laboratory test reports for electronic transmission:

(i) That includes the information:
(A) For a test report as specified in 42 CFR 493.1291 (a)(1) through (a)(3) and (c)(1) through (c)(7);
(B) Related to reference values as specified in 42 CFR 493.1291(d);
(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and
(D) For corrected reports as specified in 42 CFR 493.1291(k)(2); and
(ii) In accordance with the standard specified in § 170.205(j)(2) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(b)(6) (Data portability)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(6) Data portability. Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(4) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);
(ii) Immunizations. The standard specified in § 170.207(e)(2);
(iii) Cognitive status;
(iv) Functional status;
(v) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;
(vi) Inpatient setting only. Discharge instructions; and
(vii) Unique Device Identifier(s) for a patient's Implantable Device(s).

Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*

Public Comment Field:

Presenting/Expressing UDIs: This Edition includes the requirement for EHRs to have the ability to parse the UDI, which is vitally important as it supports searchable database fields and visually meaningful field presentations in EHR screens. In conjunction with that, GS1 US recommends that the requirements to "electronically record the UDI" be further defined. Under the current language, it would be likely that EHRs would simply contain a field named "UDI" and that scanning a barcode would simply populate that field with the raw barcode data, which is unsearchable and not visually meaningful. Consider the following barcodes encoding a hypothetical UDI based on the GS1 System including a GTIN (as the device identifier), and three production identifiers: Expiration Date, Batch/Lot, and Serial Number.

§ 170.315(b)(6) (Data portability)

GS1-128 barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

(01) 20887511007346
(17) 150331
(10) A1B2C3D4E5
(21) 123456789

GS1 DataMatrix barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

The barcodes above would communicate the following raw data:

0120887511007346171503311 0A1B2C3D4E5211 23456789

The numbers shown in **aqua** are the GS1 Application Identifiers that indicate the type of data contained in the following segment of the barcode, and the numbers shown in **navy** are the actual values for the data elements, i.e.:

GS1 Application Identifier	Data Element	Value
01	GTIN	**20887511007346**
17	Expiration Date	**150331**
10	Batch/Lot Number	**A1B2C3D4E5**
21	Serial Number	**123456789**

Under the current wording (i.e., "electronically record the UDI"), scanning a medical device barcode encoding the hypothetical UDI from above would create the following entry:

UDI: 0120887511007346171503311 0A1B2C3D4E5211 23456789

As you can see, this data is not meaningful upon visual inspection. There would be no way for a reader to discern what the DI is (so they can look it up in the GUDID) or even what the expiration date is. Moreover, this field does not provide searchable information. To avoid this, GS1 US recommends that the requirement to "electronically record the UDI" be modified to require that the UDI be recorded in the EHR database in its complete and parsed state, and presented on EHR screens in its complete and parsed state using visually meaningful fields. (This would require 7 fields: a field for the UDI in its raw state, a field for the Device Identifier, and a field for each of the 5 possible pieces of production information.)

§ 170.315(b)(6) (Data portability)

For example, the hypothetical UDI from above should be recorded and presented as follows:

UDI: 01208875110073461715033110A1B2C3D4E521123456789
Device Identifier: 20887511007346
Batch/Lot Number: A1B2C3D4E5
Expiration Date: 2015-03-31
Production Date: [1]
Serial Number: 123456789
ICCBBA: [2]

This approach leverages the requirement to parse the UDI to ensure that UDI information is searchable and understandable to readers.

Note 1: Not all of the PI fields will be populated for every device because not all PI is required/used for each device.

Note2: ICCBBA is a UDI PI, and therefore is included as a recommended field above. However, it is not a GS1 Standard. (It is a standard administered by ICCBBA for human tissue/cell products.

Clinical Quality Measures – Electronically Processing eMeasures

Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*

Public Comment Field:
No comment.

Clinical Quality Measures – Functions and Standards for CQM Certification

Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*

Public Comment Field:
No comment.

§ 170.315(c)(1) (Clinical quality measures – capture and export)

MU Objective
N/A

2015 Edition EHR Certification Criterion

(1) Clinical quality measures—capture and export. (i) Capture. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

(ii) Export. EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*

Public Comment Field:
No comment.

§ 170.315(c)(1) (Clinical quality measures – capture and export)
§ 170.315(c)(2) (Clinical quality measures – import and calculate)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(2) Clinical quality measures—import and calculate. (i) Import. EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i).

(ii) Calculate. EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(c)(3) (Clinical quality measures – electronic submission)

MU Objective

N/A

2015 Edition EHR Certification Criteria

(3) Clinical quality measures—electronic submission. Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the standards specified at § 170.205(h) and (k); and
(ii) That can be electronically accepted by CMS.

Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(c)(4) (Clinical quality measures – patient population filtering)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(4) Clinical quality measures – patient population filtering. EHR technology must be able to record structured data for the purposes of being able to filter CQM results to create different patient population grouping by one or a combination of the following patient characteristics:

(i) Practice site and address;
(ii) Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/PIN combination;
(iii) Diagnosis;
(iv) Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles; and
(v) Demographics including age, sex, preferred language, education level, and socioeconomic status.

Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(c)(4) (Clinical quality measures – patient population filtering)

§ 170.315(d)(1) (Authentication, access control, and authorization)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(1) Authentication, access control, and authorization. (i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

Preamble FR Citation: 79 FR 10904	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(d)(2) (Auditable events and tamper-resistance)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(2) Auditable events and tamper-resistance. (i) Record actions. EHR technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1); and

(B) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).

(ii) Default setting. EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraph (d)(2)(i)(B).

(iii) Prevent disabling. EHR technology must prevent all users from being able to disable the capabilities specified in paragraphs (d)(2)(i)(A) and (B) of this section through the EHR technology.

(iv) Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the EHR technology.

(v) Detection. EHR technology must be able to detect whether the audit log has been altered.

Preamble FR Citation: 79 FR 10904	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(d)(3) (Audit report(s))

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(3) Audit report(s) Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at § 170.210(e).

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(d)(4) (Amendments)	
MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2015 Edition EHR Certification Criterion (4) Amendments. Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section. (i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location. (ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(d)(5) (Automatic Log-Off)	
MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2015 Edition EHR Certification Criterion (5) Automatic log-off. Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(d)(6) (Emergency access)	
MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2015 Edition EHR Certification Criterion (6) Emergency access. Permit an identified set of users to access electronic health information during an emergency.	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(d)(7) (End-User Device Encryption)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(7) End-user device encryption**.** Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).

(B**)** Default setting**.** EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(d)(8) (Integrity)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(8) Integrity**.** (i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(d)(9) (Accounting of Disclosures)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(9) Accounting of disclosures**.** Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(e)(1) (View, download, and transmit to third party)

MU Objective

EPs

Provide patients, and their authorized representatives, the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

EHs and CAHs

Provide patients, and their authorized representative, the ability to view online, download, and transmit information about a hospital admission.

2015 Edition EHR Certification Criterion

(1) View, download, and transmit to 3rd party. (i) Patients (and their authorized representatives) must be able to use EHR technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) View. Patients (and their authorized representatives) must be able to use EHR technology to electronically view in accordance with the standard adopted at § 170.204(a)(2), at a minimum, the following data:

(1) The Common MU Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(2) Ambulatory setting only. Provider's name and office contact information.

(3) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(B) Download.

(1) Patients (and their authorized representatives) must be able to use EHR technology to electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats.

(2) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1) and (2) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

(ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1) and (3) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

(3) Inpatient setting only. Patients (and their authorized representatives) must be able to electronically download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).

(C) Transmit to third party. Patients (and their authorized representatives) must be able to:

(1) Enter a 3rd party destination of their choice to electronically transmit:

(i) The ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) of this section in accordance with the standard specified in § 170.202(a).

(ii) Inpatient setting only. Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).

(2) Accomplish a transmission of their ambulatory summary or inpatient summary through a method that conforms to the standard specified at §170.202(e) and that leads to such summary being processed by a service that has implemented the standard specified in §170.202(a).

(ii) Activity history log. (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

(1) The action(s) (i.e., view, download, transmission) that occurred;

(2) The date and time each action occurred in accordance with the standard specified at § 170.210(g);

(3) The user who took the action; and

(4) The addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed).

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at §170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

§ 170.315(e)(1) (View, download, and transmit to third party)

Preamble FR Citation: 79 FR 10906 | **Specific questions in preamble?** *Yes*

Public Comment Field:

Presenting/Expressing UDIs: This Edition includes the requirement for EHRs to have the ability to parse the UDI, which is vitally important as it supports searchable database fields and visually meaningful field presentations in EHR screens. In conjunction with that, GS1 US recommends that the requirements to "electronically record the UDI" be further defined. Under the current language, it would be likely that EHRs would simply contain a field named "UDI" and that scanning a barcode would simply populate that field with the raw barcode data, which is unsearchable and not visually meaningful. Consider the following barcodes encoding a hypothetical UDI based on the GS1 System including a GTIN (as the device identifier), and three production identifiers: Expiration Date, Batch/Lot, and Serial Number.

GS1-128 barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

(01) 20887511007346
(17) 150331
(10) A1B2C3D4E5
(21) 123456789

GS1 DataMatrix barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

The barcodes above would communicate the following raw data:

0120887511007346171503311 0A1B2C3D4E5211 23456789

The numbers shown in **aqua** are the GS1 Application Identifiers that indicate the type of data contained in the following segment of the barcode, and the numbers shown in **navy** are the actual values for the data elements, i.e.:

GS1 Application Identifier	Data Element	Value
01	GTIN	**20887511007346**
17	Expiration Date	**150331**
10	Batch/Lot Number	**A1B2C3D4E5**
21	Serial Number	**123456789**

Under the current wording (i.e., "electronically record the UDI"), scanning a medical device barcode encoding the hypothetical UDI from above would create the following entry:

UDI: 0120887511007346171503311 0A1B2C3D4E5211 23456789

§ 170.315(e)(1) (View, download, and transmit to third party)

As you can see, this data is not meaningful upon visual inspection. There would be no way for a reader to discern what the DI is (so they can look it up in the GUDID) or even what the expiration date is. Moreover, this field does not provide searchable information. To avoid this, GS1 US recommends that the requirement to "electronically record the UDI" be modified to require that the UDI be recorded in the EHR database in its complete and parsed state, and presented on EHR screens in its complete and parsed state using visually meaningful fields. (This would require 7 fields: a field for the UDI in its raw state, a field for the Device Identifier, and a field for each of the 5 possible pieces of production information.) For example, the hypothetical UDI from above should be recorded and presented as follows:

UDI: **01208875110073461715033110A1B2C3D4E521123456789**
Device Identifier: **20887511007346**
Batch/Lot Number: **A1B2C3D4E5**
Expiration Date: **2015-03-31**
Production Date: _____[1]
Serial Number: **123456789**
ICCBBA: _____[2]

This approach leverages the requirement to parse the UDI to ensure that UDI information is searchable and understandable to readers.

Note 1: Not all of the PI fields will be populated for every device because not all PI is required/used for each device.

Note2: ICCBBA is a UDI PI, and therefore is included as a recommended field above. However, it is not a GS1 Standard. (It is a standard administered by ICCBBA for human tissue/cell products.

§ 170.315(e)(2) (Ambulatory setting only – clinical summary)

MU Objective

Provide clinical summaries for patients for each office visit.

2015 Edition EHR Certification Criterion

(2) Ambulatory setting only—clinical summary. (i) Create. Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(4).

(ii) Customization. Enable a user to customize the data included in the clinical summary.

(iii) Minimum data from which to select. EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set);

(B) Medications administered during the visit. At a minimum, the version of the standard specified in § 170.207(d)(2);

(C) Immunizations administered during the visit. At a minimum, the version of the standard specified in § 170.207(e)(2);

(D) Diagnostic tests pending and future scheduled tests. At a minimum, the version of the standard specified in § 170.207(c)(2);

(E) The provider's name and office contact information; date and location of visit; reason for visit; clinical instructions; future appointments; referrals to other providers; and recommended patient decision aids; and

(F) Unique Device Identifier(s) for a patient's Implantable Device(s).

Preamble FR Citation: 79 FR 10907	Specific questions in preamble? ***Yes***

Public Comment Field:

Medications administered during the visit: The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs.

§ 170.315(e)(2) (Ambulatory setting only – clinical summary)

Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)

Presenting/Expressing UDIs: This Edition includes the requirement for EHRs to have the ability to parse the UDI, which is vitally important as it supports searchable database fields and visually meaningful field presentations in EHR screens. In conjunction with that, GS1 US recommends that the requirements to "electronically record the UDI" be further defined. Under the current language, it would be likely that EHRs would simply contain a field named "UDI" and that scanning a barcode would simply populate that field with the raw barcode data, which is unsearchable and not visually meaningful. Consider the following barcodes encoding a hypothetical UDI based on the GS1 System including a GTIN (as the device identifier), and three production identifiers: Expiration Date, Batch/Lot, and Serial Number.

GS1-128 barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

(01) 20887511007346
(17) 150331
(10) A1B2C3D4E5
(21) 123456789

GS1 DataMatrix barcode encoding GTIN with Expiration Date, Batch/Lot & Serial Number

The barcodes above would communicate the following raw data:

01208875110073461715033110A1B2C3D4E52121234567 89

The numbers shown in **aqua** are the GS1 Application Identifiers that indicate the type of data contained in the following segment of the barcode, and the numbers shown in **navy** are the actual values for the data elements, i.e.:

GS1 Application Identifier	Data Element	Value
01	GTIN	**20887511007346**
17	Expiration Date	**150331**
10	Batch/Lot Number	**A1B2C3D4E5**
21	Serial Number	**123456789**

§ 170.315(e)(2) (Ambulatory setting only – clinical summary)

Under the current wording (i.e., "electronically record the UDI"), scanning a medical device barcode encoding the hypothetical UDI from above would create the following entry:

UDI: 01208875110073461715033110A1B2C3D4E521123456789

As you can see, this data is not meaningful upon visual inspection. There would be no way for a reader to discern what the DI is (so they can look it up in the GUDID) or even what the expiration date is. Moreover, this field does not provide searchable information. To avoid this, GS1 US recommends that the requirement to "electronically record the UDI" be modified to require that the UDI be recorded in the EHR database in its complete and parsed state, and presented on EHR screens in its complete and parsed state using visually meaningful fields. (This would require 7 fields: a field for the UDI in its raw state, a field for the Device Identifier, and a field for each of the 5 possible pieces of production information.) For example, the hypothetical UDI from above should be recorded and presented as follows:

UDI: 01208875110073461715033110A1B2C3D4E521123456789
Device Identifier: 20887511007346
Batch/Lot Number: A1B2C3D4E5
Expiration Date: 2015-03-31
Production Date: [1]
Serial Number: 123456789
ICCBBA: [2]

This approach leverages the requirement to parse the UDI to ensure that UDI information is searchable and understandable to readers.

Note 1: Not all of the PI fields will be populated for every device because not all PI is required/used for each device.

Note2: ICCBBA is a UDI PI, and therefore is included as a recommended field above. However, it is not a GS1 Standard. (It is a standard administered by ICCBBA for human tissue/cell products.

§ 170.315(e)(3) (Ambulatory setting only – secure messaging)

MU Objective

Use secure electronic messaging to communicate with patients on relevant health information.

2015 Edition EHR Certification Criterion

(3) Ambulatory setting only—secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient (or authorized representative) and EHR technology user are authenticated; and
(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

Preamble FR Citation: 79 FR 10908	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(f)(1) (Immunization information)

MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(1) Immunization information. Enable a user to electronically record, change, and access immunization information.

Preamble FR Citation: 79 FR 10908	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(f)(2) (Transmission to immunization registries)

MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(2) Transmission to immunization registries. EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(4); and
(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).

Preamble FR Citation: 79 FR 10908	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance) and § 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)

MU Objective

Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

Revised 2014 Edition EHR Certification Criterion

§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance)

2015 Edition EHR Certification Criterion

§ 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)

(3) Transmission to public health agencies – syndromic surveillance. EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) Ambulatory setting only. (A) The standard specified in § 170.205(d)(2), (d)(5), or (k).
(B) Optional. The standard (and applicable implementation specifications) specified in § 170.205(d)(4).
(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

Preamble FR Citation: 79 FR 10909	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(f)(4) (Inpatient setting only – Transmission of reportable laboratory tests and values/results)

MU Objective

Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(4) Inpatient setting only—transmission of reportable laboratory tests and values/results. EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and
(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(f)(5) (Ambulatory setting only – cancer case information)

MU Objective

Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(5) Ambulatory setting only—cancer case information. Enable a user to electronically record, change, and access cancer case information.

Preamble FR Citation: 79 FR 10910	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(f)(6) (Ambulatory setting only – transmission to cancer registries)

MU Objective

Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(6) Ambulatory setting only—transmission to cancer registries. EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and
(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(g)(1) (Automated numerator recording)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(1) Automated numerator recording. For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(g)(2) (Automated measure calculation)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(2) Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(g)(3) (Safety-Enhanced Design)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(3) Safety-enhanced design User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.315(a)(1) through (4), (8) through (10), and (18) and (b)(2) and (3).

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(g)(4) (Quality Management System)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(4) Quality management system. For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single QMS was used for applicable capabilities, it would only need to be identified once.
(ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.
(iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(g)(5) (Non-percentage-based measures report)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(5) Non-percentage-based measures use report (i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage-based (except for the capabilities specified in § 170.315(a)(12), (b)(1), and (d)) electronically record evidence that a user used or interacted with the capability and the date and time that such use or interaction occurred, in accordance with the standard specified at § 170.210(g).

(ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(5)(i) of this section for the user's identified Medicare or Medicaid EHR reporting period.

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport)

MU Objective

N/A

2015 Edition EHR Certification Criterion

1) Transmit – Applicability Statement for Secure Health Transport. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).

Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(h)(2) (Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(2) Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(b).

Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(h)(3) (Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(3) Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(c).

Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct)	
MU Objective N/A	
2015 Edition EHR Certification Criterion (4) Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).	
Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

B. PROVISIONS OF THE PROPOSED RULE AFFECTING THE ONC HIT CERTIFICATION PROGRAM

Non-MU EHR Technology Certification	
Preamble FR Citation: 79 FR 10918	**Specific questions in preamble?** *Yes*
Public Comment Field: No comment.	

ONC Regulations FAQ 28	
Preamble FR Citation: 79 FR 10920	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

Patient List Creation Certification Criteria	
Preamble FR Citation: 79 FR 10920	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

ISO/IEC 17065 (§ 170.503(b)(1))	
Preamble FR Citation: 79 FR 10920	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

ONC Certification Mark (§ 170.523(k)(1))	
Preamble FR Citation: 79 FR 10921	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

Certification Packages for EHR Modules	
Preamble FR Citation: 79 FR 10921	**Specific questions in preamble?** *Yes*
Public Comment Field: No comment.	

C. OTHER TOPICS FOR CONSIDERATION FOR THE 2017 EDITION CERTIFICATION CRITERIA RULEMAKING

Additional Patient Data Collection	
Preamble FR Citation: 79 FR 10922	**Specific questions in preamble?** *Yes*
Public Comment Field: No comment.	

Medication Allergy Coding	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*
Public Comment Field: The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)	

Certification Policy for EHR Modules and Privacy and Security Certification Criteria	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*
Public Comment Field: No comment.	

Provider Directories	
Preamble FR Citation: 79 FR 10926	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment.	

Oral Liquid Medication Dosing	
Preamble FR Citation: 79 FR 10926	**Specific questions in preamble?** *Yes*
Public Comment Field:	
The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)	

Medication History	
Preamble FR Citation: 79 FR 10927	**Specific questions in preamble?** *Yes*
Public Comment Field:	
The United State Food & Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. It is expected that this effort will ultimately include requirements for standards-based identification of prescription drugs. Therefore, GS1 US recommends that the ONC and the community be aware of these efforts, and the probable need to align current and future EHR requirements that include the identification of medications with any future FDA requirements for standards-based identification of prescription drugs that may result from that effort. (For more information, see: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/)	

Blue Button +	
Preamble FR Citation: 79 FR 10927	**Specific questions in preamble?** *Yes*
Public Comment Field:	
No comment.	

2D Barcoding	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*

Public Comment Field:

GS1 US recommends that ONC pursue a "technology-neutral" (but adopted by the associated standards organization) approach regarding EHR's ability to consume AIDC carriers and avoid requirements to use specific types of AIDC for certain functions, much like the FDA did with UDI. A technology-neutral approach enables industry to better respond to progress, technological advancements, and implementation considerations. For this reason, GS1 US believes that requiring EHRs to "consume 2D barcodes" is sufficient however consider a technology-neutral approach to be consistent with the UDI Rule. This approach enables the ONC to ensure that EHRs have flexible AIDC capabilities, and that choices regarding which data carrier is best for various function are left to progress naturally in the marketplace. (GS1 has endorsed the use of GS1 DataMatrix in healthcare.)

As a general matter, GS1 US notes that 2D barcodes cannot be read by the same scanners used for linear barcodes. Linear barcodes use laser scanners, and 2D barcodes require camera-based scanners. (Camera-based scanners needed for 2D barcodes can also read linear barcodes.) For additional information about 2D barcodes, see the GS1 DataMatrix guide.

Duplicate Patient Records	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

Disaster Preparedness	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

Certification of Other Types of HIT and for Other Health Care Settings	
Preamble FR Citation: 79 FR 10929	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.