LEARNING UDI COMMUNITY

AHRMM
Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain
A personal membership group of the American Hospital Association

Catalog Number Work Group Report

LEARNING UDI COMMUNITY

WWW.AHRMM.ORG / LUC

CATALOG NUMBER WORK GROUP REPORT

CHARTER:

The mission of the Catalog Number workgroup was to provide a data consumer's perspective of the business case for entering the Catalog Number in Global Unique Device Identification Database (GUDID) Device Identifier records. In order for the information in the GUDID to be valuable, most stakeholders will need to match existing data sets from their item master to the GUDID. Manufacturer catalog number is the key data point that has been used historically for identifying product information.

BACKGROUND:

The FDA GUDID compliance currently does not include Catalog Number as a required field when submitting unique device identifiers (UDI) for Device Identifier (DI) records. If UDI DI is to replace Catalog Numbers in the healthcare industry, there will be a period of time when both must be available to assist with a cross-walk between the two data points.

The version or model number is a required field in the GUDID, however, the manufacturer/supplier do not always use version or model numbers, in which case the catalog number may be entered into these fields.

Below is the definition of the model/version number per the FDA. For all the GUDID data element definitions, please refer to: GUDID Data Elements Reference Table - March 27, 2017 (http://bit.ly/2xZXti0)

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger	Publicly Released?
Version or Model	The version or model found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.	Enter the Version or Model. Version/Model can be any distinguishing string of letters and/or numbers. Catalog Number can be entered if device does not currently have a Version or Model. If the device does not have a version, model or catalog number, enter a concept that can be used to identify all devices that have specifications, performance, size, and composition within limits set by the labeler.	None	Required	Type: Alphanum. Length: 80	NA	Yes	Yes

© AHRMM 2017. Association for Healthcare Resource & Materials Management

CATALOG NUMBER WORK GROUP REPORT

Below is the definition of the catalog number per the FDA.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger	Publicly Released?
Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Enter the Catalog or Reference Number. Catalog Number is critical for UDI adoption in electronic health records. Please provide catalog number as part of your device record. Catalog/Reference number can also serve as Version/Model if it represents the devices that have specifications, performance, size, and composition within limits set by the labeler.	Add Delete Edit	Optional	Type: Alphanum. Length: 80	NA	No	Yes

AFFECTED STAKEHOLDERS:

Manufacturers, distributors, providers, clinicians, solution companies, GPOs, etc. will be using GUDID.

Perspective of *Data Consumers* of GUDID Data:

- Catalog Number is most commonly used identifier of product in healthcare industry today.
- Matching GUDID data to existing databases requires a cross-walk between Device Identifiers and Catalog Numbers.
- Version or Model Number is not a reliable substitute for Catalog Number as a Version or Model Number can cover several different products (i.e. different sizes).
- Some ERP systems, or versions being used by providers, do not have a field for the DI.

Perspective of *Data Providers* of GUDID Data:

- Data Providers populated their Catalog Number in the version/model number GUDID field per the FDA Data Entry Notes provided in the FDA GUDID Data Elements Reference Table: http://bit.ly/1JmCVhI.

© AHRMM 2017. Association for Healthcare Resource & Materials Management

- Some suppliers do not have a Model Number and populated their Catalog Number in the Version/ Model Number field (required) and left the Catalog Number field (optional) blank due to concerns about populating the same information in both fields in regards to data quality.
- Labelling of the product has been the focus for many suppliers.
- Concerns about Catalog Number include regulatory pre-market approval, need for a stable numbering system, which the model number provides.

DELIVERABLES:

Business Case

This work group has concluded that maintaining a cross walk between Device Identifiers and Manufacturer Catalog Number (defined as Catalog Number maintained in a provider item master for purposes of ordering that product) is necessary to support the adoption of UDI across the healthcare ecosystem.

Processes that use Catalog Number include: procurement, inventory management, recall management, spend analyses, item master management, linkage to clinical systems, and linkage to charge master systems.

To introduce the UDI DI as an alternative identifier, and in the future the primary identifier of product, will require several years of transition as processes, systems, and resources are updated to accommodate UDI.

A source of truth for the industry will need to contain both UDI DI and Catalog Number to support this transition, therefore the GUDID Catalog Number field should be populated by the manufacturers. Benefits and Issues are outlined below:

Benefits

- Catalog Number is currently the most commonly used product identifier in healthcare, requiring Catalog Number will support adoption within the *data consumer* groups.
- A source of truth for a cross-walk between the UDI DI and Catalog Number will support adoption as product labelled with UDI enters the supply chain and systems need to be able to connect using Catalog Number and DI.

Issues

- *Data Providers* who only have a Catalog Number would have to populate both Catalog Number and Version or Model Number fields with the same information. Based on GUDID data analysis, this would require approximately 545,000 existing DI records to be potentially updated and resources may be limited.
- Determining the most effective method for communicating this change to all Data Providers.
- Based on GUDID Data from September 2017, the catalog number field is null for 45% of records.

© AHRMM 2017. Association for Healthcare Resource & Materials Management

CATALOG NUMBER WORK GROUP REPORT

Next Steps

- Work with other data quality groups to address the issue and develop an overall update process, for all LUC data quality initiatives, related to the entering new/correcting existing information in the GUDID.
- Request that manufacturers and suppliers enter their Catalog Numbers in the Catalog Number field for all new records moving forward.
- For each scenario for *data providers* (DP) develop "data entry notes" to ensure consistency in entry of the version or model number and catalog number fields.

© AHRMM 2017. Association for Healthcare Resource & Materials Management