July 22, 2020

Amy Abernethy, PhD, MD, Principal Deputy Commissioner, FDA

Vid Desai, Chief Technology Officer, FDA

Office of the Commissioner

Federal Research Center

10903 New Hampshire Avenue

Silver Springs, MD 20993

RE: Docket Number: FDA-2019-N-5799 “Modernizing FDA’s Data Strategy”

Dear Dr. Abernethy and Mr. Desai:

The American Hospital Association’s professional membership group, Association for Health Care Resource & Materials Management (AHRMM), sponsors the Learning Unique Device Identifier (UDI) Community (LUC). The LUC is comprised of physicians, clinicians, hospital supply chain professionals, manufacturers, distributors, software application providers, health care consultants and representatives from Group Purchasing Organizations (GPOs), GS1, HIBCC, HIDA and the FDA. The mission of the LUC is to enhance patient safety and improve supply chain efficiency by developing recommended practices that speed the adoption and maximize the utilization of the UDI.

To date, there have been 13 LUC workgroups involving over 600 individuals that have addressed a wide range of issues from making the business case for UDI to incorporating the UDI throughout the recall process. The following comments and recommendations are the results of the learnings and experiences of these multi-disciplinary workgroups.

**RECOMMENDATIONS:**

1. **Leverage the UDI as the link between various FDA databases. Change all references to the UDI in FDA submissions and reporting requirements from optional to required. Add the UDI-DI and UDI-PI as consistently required in Adverse Events and Recalls when the UDI is on the label of the device.**
* The UDI was designed to be the unique identifier that would allow medical devices to be tracked from manufacture through the supply chain and point of use, and into the patient record. It was designed to facilitate connecting patient level data to specific medical devices to enable the collection of real-world evidence.
* There has been a significant investment implementing FDA, ONC and CMS requirements related to the UDI but the UDI’s potential has not been achieved due to the lack of structured data that would support interoperability and connect the information from various FDA data bases with information from health care systems.
1. **Reduce redundancy and enhance data quality by using the GUDID as the master data source for product data to auto-populate adverse event, recall and other manufacturer submissions to FDA CDRH.**
* Using AccessGUDID to auto populate other FDA submissions would reduce the burden on manufactures while simultaneously encouraging them to fully populate the GUDID with timely, accurate information.
1. **Set up and appropriately staff a data quality assurance process that includes enforcement of minimum UDI requirements by manufacturers as well as collaborative**
**efforts with data users to encourage reporting and correction of data errors.**
* A significant barrier to broader adoption of the UDI is related to missing and inaccurate data in the GUDID.
1. **Create a streamlined and digitized process for reporting adverse events and recalls. Ensure common data fields (which require the UDI-DI and UDI-PI) with common definitions are used consistently by manufacturers. Make manufacturer’s electronic submissions immediately available to health care providers and other stakeholders involved in adverse event and recall processes. Simplify the electronic reporting process by enabling a scan of the barcode containing the UDI to auto populate fields and ensuring there is one data dictionary across the FDA.**
* The current manual, paper-based recall process is inefficient and ineffective with the potential to compromise patient safety. The following are all the different FDA data sources for recall and adverse event data. The same query posed to each source yields different results. Additionally, the process is totally different for medical devices, biologicals and drugs.

Recall data sources:

* Medical Device Recall (Yearly Lists).
* Medical Device Recall (Database).
* OpenFDA.
* Compliance Dashboard.
* Enforcement Reports.
* Recalls, Market Withdrawals and Safety Alerts.
* Additional Information about Recalls.
* Archive for Recalls, Market Withdrawals & Safety Alerts.
* FDA.gov Archive.

Adverse Events Data Sources

* [MAUDE](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)
* [MedSun](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchreport.cfm)
* There is no consistency between manufacturers regarding which information is included in a recall notice. The time lag between a manufacturer issuing a recall notice to its customers and the time FDA classifies the recall can be months.

Thank you for the opportunity to comment and for carefully considering the implementation of these recommendations. Please contact me at mschiller@aha.org if you have any questions.

Sincerely,



Michael Schiller

Senior Director, AHRMM