AHRMM Learning UDI Community

Comments to the Food and Drug Administration’s Communications

About the Safety of Medical Devices, FDA -2020-N-0096

**INTRODUCTION:**

The following comments to the Food and Drug Administration’s Communications About the Safety of Medical Devices, “FDA -2020-N-0096”, are being made by the Association for Health Care Resource & Materials Management (AHRMM), Learning UDI Community (LUC). The AHRMM LUC is a collaboration of stakeholders from across the health care field including providers (physicians, clinicians and supply chain professionals), manufacturers, distributors, software application providers, standards organizations, the FDA, and other interested participants. Its purpose is to expand adoption and utilization of the Unique Device Identifier (UDI). It accomplishes this through the creation of multi-disciplinary workgroups that identify barriers and develop consensus-based leading practices to overcome those barriers.

Related to Medical Device Safety Communications, the UDI Impact on Recall Management Process Workgroup was established to evaluate the clinical, supply chain and patient safety impacts, and benefits of using the UDIs to enhance the recall process. The mission of the workgroup is to: 1) define the value to multiple stakeholders (manufacturers, providers, patients, etc.) of using/incorporating the UDI in the recall process; 2) collect information on the current level of UDI usage in the recall management process, and 3) make recommendations to all stakeholder groups on costs and benefits from increasing usage of UDIs to enhance patient safety. To date, 71 individuals representing the above-mentioned stakeholders have participated in this effort.

The LUC Recall Workgroup developed five taskforces (Health Care Providers, Manufacturers, Distributors, IT/Technology and Regulatory/Glossary) to study the current recall process and develop a list of opportunities for enhanced practices. The taskforces analyzed six specific recalls to understand the differences in recall information content and process as data moves from manufacturer to FDA, providers, supply chain and consumers. Specifically, the task forces compared the data elements contained in typical recall notices, how that compared to data available in the FDA databases and the impact that information had on health care provider and distributor response to recalls. Additionally, the IT taskforce compared the data elements contained in the notices to the data elements in FDA recall submission requirements as well as specific templates available to manufacturers for submitting specific recall data elements electronically [[1]](#footnote-1). To gain additional insight, surveys of stakeholder groups were conducted in conjunction with the Association of Healthcare Value Analysis Professionals (AHVAP), AdvaMed, and the Health Industry Distributors Association (HIDA).

**SUGGESTIONS AND COMMENTS:**

1. Include both the UDI-DI and UDI-PI in all communications regarding device safety including adverse event reporting, recalls and field correction notices. Include the UDI-DI and UDI-PI in consumer and health care provider communications.
2. Use the UDI-DI as the “link” between all FDA databases. Leverage the information in GUDID to auto-populate various FDA forms.
3. Consider using the IT structure and workflow developed by the UDI program as a model that could be replicated for the Recall process. The UDI System was set up with manufacturer submission of structured data stored in a publicly available database with multiple methods of access (downloads, APIs, etc.) by various stakeholders. In the case of recalls, manufacturers need to submit standardized recall information in a structured, electronic format based upon the specification of required and optional data elements. Like the GUDID, the manufacturer’s recall information should immediately be available to stakeholders in a standardized digital electronic format so they can integrate it with internal procurement, inventory management, distribution and EHR systems. This allows relevant stakeholders to quickly locate and remove recalled products as well as providing notification and instructions to clinicians and patients depending on the circumstances.
4. Ensure FDA has appropriate funding to support enhancements to GUDID and enforce current UDI and GUDID requirements as well as funding to create and support the infrastructure necessary to support a structured, electronic information recall submission capture process that results in better access to standardized recall data and a searchable database available to manufacturers, distributors, health care providers and other stakeholders. Funding is also needed to eliminate redundant databases and ensure the timely updating and synchronization of all remaining databases.
5. Encourage the participation of FDA recall staff in public-private partnerships and hold public meetings on a periodic basis to ensure that changes/improvements to the recall process are meeting health care system requirements.

**SUPPORTING INFORMATION:**

**The following comments summarize the current recall processes developed by the AHRMM LUC Recall Workgroup and documented by survey results.**

1. Manufacturer contacts the FDA regarding a potential recall

* 70% indicated they had a dedicated FDA contact
* Utilize the 806 form and discussions to determine what information needs to be submitted. Information requested varies by FDA region.

1. Manufacturer submits recall information to FDA

* 60% e-mail to FDA portal or ORA mailbox
* 55% submit data in a combination of PDF and Excel formats while 25% use exclusively PDF format.
* 75% include UDI in the information submitted to FDA.

1. Manufacturer mails recall information in PDF format to health care providers, distributors and 3rd party recall alerting services (customers).

* 40% submit information to FDA and customers simultaneously. An additional 30% submit information to customers within one week of submission to FDA.
* 40% include the UDI in the information submitted to health care providers.

1. FDA processes the recall [[2]](#footnote-2)

* During any of the manual steps, the UDI-DI and UDI-PI information originally submitted by the manufacturer could be removed at the discretion of the FDA staff. For example, 75% of manufacturers indicated they provided the UDI to the FDA but a survey of recalls in the FDA database showed <23% contained the UDI.
* FDA staff at the district office manually enters data from the manufacturer submission into the FDA database.
* FDA internally processes the recall including classifying the recall. This process can take at least 2-3 months and sometimes longer.
* FDA publishes the classified recall in the FDA database(s).
* For Class I Recalls the FDA staff creates a webpage that links to the entry in the FDA recall database and other recall information.

1. Distributors receive paper copies in PDF format of the manufacturer’s recall notice

* Manually retype identifying information (e.g. catalog number, lot, etc.) to determine if they have impacted product on the shelf and to identify health care providers who were shipped impacted product.
* Forward copies of the manufacturers notice to the health care providers who received impacted products.
* Process recall per manufacturer’s instructions.

1. Health care providers receive recall notifications from multiple sources

* 90% manufacturer, 80% 3rd party recall alerting service, 75% distributors, 60% FDA.
* Absent use of a 3rd party alerting service, most must manually retype identifying information to determine if they have impacted products on the shelf or, in the case of implants, if they have been used on a patient.
* Every time another recall notification is received, providers must determine if it is a new recall or a copy of a previous recall notification.
* End users searching the FDA recall database(s) need to understand:
* There are seven-potential portal (URLs) that can be used to access recall information.
* The data available varies based on the portal utilized to access it. For example, the recall data that is within the OpenFDA API is frequently inconsistent and does not contains the exact data content or format as that published on the FDA’s Enforcement reports database.
* The difference between initiated date and posted date.

**PRIMARY PAIN POINTS WITH CURRENT PROCESS:**

Manufacturers:

* Slow FDA response time - delays in recall classification designation and close out process
* Confirming customer receipt of notification and customer response

Distributors:

* No standard format – every manufacturer does it differently
* Need first and last ship date

Health Care Providers:

* No consistent manner for clearly and unambiguously identifying the product with UDI
* No standard format for recall notices
* Information is provided in PDF format and requires significant manual effort to transform it into actionable information.
* Too many notifications, websites and databases for the same recall

**EXAMPLE OF FUTURE STATE PROCESS**

**The following example depicts a future state recall process that would improve timely notification to health care providers to enhance patient safety, increase efficiency and reduce costs. These steps as envisioned will maximize use of GUDID data maintained in accordance with current FDA requirements.**

* The FDA would collaborate with all stakeholders to determine a standard set of required and optional data elements and associated definitions. The UDI -DI and UDI-PI would be included as required data elements.
* Manufactures would submit FDA-required recall information in a structured, electronic format that uses the UDI as the link to access GUDID information to auto-populate applicable data elements. This will greatly improve accuracy and reduce burdens on manufacturers. The submission process would be designed to ensure manufactures could populate data elements that were not contained in the GUDID via electronic methods in an FDA provided application designed to eliminate manual data entry.
* The submitted information would populate a database that could be immediately accessed by all stakeholders (with proper security).
* Information from this database could be downloaded and integrated into health care provider, distributor and other 3rd party information systems to allow for the timely identification and location of medical devices impacted by the recall.

The future report of the AHRMM LUC UDI Impacts on Recall Management will also provide representation of a prototype of how recall information may be facilitated in the future.

1. https://www.fda.gov/files/Electronic-Submission-of-806-Reports-of-Corrections-and-Removals.pdf [↑](#footnote-ref-1)
2. FDA process description is based on input from manufacturers, consultants, and health care providers. It has not been validated by the FDA [↑](#footnote-ref-2)