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Office of the Commissioner
Federal Research Center
10903 New Hampshire Ave
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RE: Docket No. FDA-2019-N-5799 "Modernizing FDA's Data Strategy"

Dear Dr. Abernethy and Mr. Desai,

Symmetric Health Solutions has made it our mission to build upon the Unique Device Identification (UDI) System created and implemented by the US Food and Drug Administration (FDA). We have successfully linked the device identifiers of the UDI (UDI-DIs) found in the AccessGUDID to over 70 other publicly available data sources resulting in improvements to the quality and transparency of information available to healthcare supply chain and clinical decision makers. We currently serve over 200 hospitals and continue to grow because we have overcome a significant challenge to provider UDI adoption, applying artificial intelligence techniques to match the data in existing inventory and clinical systems to UDIs on the labels of devices. The linkages we have created are realizing the objectives of the 2013 FDA UDI regulation -- improving patient outcomes, reducing medical errors, evaluating product performance, and increasing data transparency. Our customers and their medical device suppliers are benefiting significantly from the UDI system. But data challenges remain that impact patients served not only by our health systems but by any of the thousands of vendors and hospitals that are now or are planning to implement UDI as a key device identifier.

We believe that strengthening the quality and use of UDI should be a top FDA data modernization priority. We are commenting in this open forum to offer our perspective not only as a data solution provider, but as an advocate for healthcare systems that rely on government source data to improve patient and device safety. We are actively involved in multi-stakeholder workgroups focused on overcoming obstacles to UDI adoption, including the American Hospital Association's Association for Healthcare Resources and Materials Management (AHRMM) Learning UDI Community, and welcome opportunities to continue our involvement in public-private collaboration to address the issues raised below.

We have chosen to answer only a subset of the questions posed in the Federal Register notice, those that we believe are most relevant to the UDI's role in medical device data modernization.

Symmetric Health Solutions - Federal Register Responses

1a. Standards and policy, including: How can FDA best use policy and common data standards to help ensure the effective and efficient use of data assets?

Discussion Points:

- The UDI System was part of regulatory harmonization efforts of the International Medical Device Regulatory Forum (IMDRF)[1] establishing guiding principles aimed at implementing a globally unique device identifier linked to publicly available jurisdiction-specific repositories that collectively will be used to access globally standard device data.
- Significant resources have been invested by FDA, device manufacturers, standards development organizations, Office of National Coordinator for Health IT, National Library of Medicine, electronic health Record vendors, ancillary system developers, registries and data analytics groups resulting in:
    - The successful application of UDI on device labels and submission of over 2.5 million records to the Global UDI Database (GUDID)
    - Over 200 EHR vendors certified to record UDI for implants per 2015 ONC Certification requirements[2]
    - Representation of UDI in key HL7 messages such as HL7 FHIR[3] to support UDI in US Core Data for Interoperability that is defined in both ONC[4] and CMS[5] interoperability regulations; and
    - Support of UDI-DI in claims by ANSI X12 and multiple healthcare and payer organizations.
- Gaps remain in FDA's UDI system implementation that require policy changes to improve the value of the UDI system for all stakeholders.
    - Hospital systems in the US are scanning millions of UDIs to improve inventory management and to document implant and other therapeutic device use, but ONC does not require the UDI to be scanned by all health IT systems and FDA does not require manufacturers to consistently and accurately report the UDI-DI and UDI-PI in recall notices. Therefore, health systems capturing UDI are not realizing the value of UDI to more efficiently manage recalls, defeating one of the main objectives of the UDI regulation.[6]

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[1] IMDRF UDI Final Guidance. http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf

[2] 2015 ONC Health IT Certification Edition. https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base

[3] HL7 FHIR Device Resource Release 4, https://www.hl7.org/fhir/device.html

[4] ONC Cures Act Final Rule, https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf

[5] CMS Interoperability and Patient Access Final Rule. https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf

[6] Office of Inspector General Report. Shortcomings of device claims data complicate and potentially increase Medicare costs for recalled and permanently failed devices. https://oig.hhs.gov/oas/reports/region1/11500504.pdf

- Manufacturers, hospitals and patients are not able to use AccessGUDID as intended in the UDI regulation, as a master data source for monitoring evaluation and performance of a device through distribution and use by using a common identifier to register and list, report adverse events, manage recalls and monitor devices in post-approval studies.
- The world is reviewing, analyzing, and making impactful decisions based on FDA data but there are no policies in place for reporting and obtaining feedback on quality improvement of AccessGUDID and other FDA data sources.
- Current FDA device tracking regulations and guidance do not align with ONC requirements for creating an implantable device list based upon UDI and data in AccessGUDID. FDA device tracking is limited in the scope of devices covered by the tracking policy and does not support implant tracking based upon use of UDI.

Recommendations:

- Consider FDA policy updates from the perspective of a Master Data Management strategy, focusing on clearly and accurately defining and enforcing the population of data fields associated with product, establishment and administrative identification -- e.g. NDC, UDI-DI, DUNs, FEI Number, Approval and Clearance Identifiers, etc. -- across all medical products.
- Specific to devices, change all references to UDI in FDA submission and reporting requirements from optional to required, if available, to show strong policy commitment to the success of the UDI System.
- Use UDI-DI to auto-populate device identification in internal FDA systems such as product data in recalls, adverse events, and other manufacturer submissions to FDA CDRH.
- Ensure sufficient FDA resources to support coordination of policy and technical changes so that the UDI portion of ONC/CMS interoperability requirements will be successful and meet the data capture requirements of those using device data -- e.g. healthcare systems and front-line workers.
- Ensure that FDA policies augment and do not pose barriers to ONC and CMS policies that incentivize and reward UDI scanning and use of AccessGUDID.
    - Strengthen reporting and enforcement of data quality issues with UDI scanning and with data quality and completeness of fields in AccessGUDID.
    - Create automated processes for handling data issues received from the public.
    - Require UDI-DI capture in projects funded by FDA.
- Update device tracking guidance to align FDA tracking of implants with ONC policies for implant tracking including any potential updates to ONC policies to require recording of UDI for implant by all health IT systems.

1c. Standards and policy, including: As we move into increased sharing and integrated data sets, how might FDA manage data in a way that avoids unnecessary duplication?

Discussion Points:

- UDI-DI (device identifier of UDI) was established to link device data across the device ecosystem – approval, commercial distribution, recalls, adverse events, patient health records, device maintenance, registries, fraud and abuse, and claims – but is inconsistently captured, stored and transmitted in FDA systems making it difficult for those relying on this data to consistently count on FDA as the authoritative source for device identification data.
- Today, product codes continue to be used to link all FDA data sources (e.g. registration listings, approvals, clearances, recalls, adverse events, AccessGUDID, etc.). This poses a significant challenge in the ability to evaluate the performance of one model/version of a device compared to similar devices in a product code area. For example, product code "JXG" or "Shunt, Central Nervous System and Components" had an insignificant amount of recall and adverse event data when viewed in the aggregate, but using the UDI to target adverse event data with Strata implantable pressure valves could have prevented the over 1.9k adverse events needed to detect a safety signal that resulted in a worldwide recall of this product in 2017.[7] This example has particular significance because a family member of one of our employees recently had emergency surgery to remove this device in June 2020, after five years of repeated neurological problems and three years after the device had been recalled. It wasn't until our employee looked up the implant that the family was informed of its worldwide recall -- more than 300k devices, three years earlier, in 2017. The prominent Maryland hospital and physicians that treated the patient were unaware of the recall and associated adverse events.
- GMDN is linked to each UDI-DI stored in AccessGUDID. The GMDN provides a more detailed level of specificity to product code and has the advantage of being an International nomenclature for categorizing devices. GMDN has not been incorporated into any FDA database except GUDID and there do not appear to be any publicly supported efforts to implement GMDN as part of real-world evidence initiatives.
    - Consider how much time, money, and frustration could be saved in the FDA and the industry if a specific classification like GMDN tied to a UDI-DI was used starting with approval or clearance all the way through to reimbursement. As an example, if the mappings between UDI-DI and GMDN were implemented into the 510(k) pathway, there are matching tools available that would allow FDA and manufacturers to streamline the selection of product codes and predicate medical devices for the 510(k) clearances.

[7] https://open.fda.gov/

- GUDID was expected to be a master data source for FDA product identification aimed at reducing manufacturer burden of duplicate data submission in multiple regulatory databases including Registration and Listing, Adverse Events, and Recalls. Today, each of these systems continues to require separate and duplicate submission of the same basic information that could be obtained by relying on UDI and GUDID -- brand, model, lot, serial number, etc.
- DUNs number and FEI numbers were also expected to be master data identifiers for manufacturer information, but issues remain with consistency and usability of these identifiers especially as a resource for linking across FDA (CDER, CDRH, ORA, CBER etc.) data sets.
- OpenFDA was expected to provide online open access to merged FDA data for reuse by vendors, but OpenFDA is not a reliable source for healthcare and the results from OpenFDA queries is often inconsistent with data obtained by querying each of the underlying OpenFDA data sources.

Recommendations:

- Revisit FDA's GUDID as a master data source for key device identification attributes housed in FDA databases. Manufacturers and health systems have established product master data systems based on UDI. FDA could collaborate with a consortia of industry and health system stakeholders to better understand leading master data management efforts that were initiated because of UDI and apply them to FDA data modernization strategies. FDA could also support ongoing data user engagement to encourage reporting and correction of data errors from using FDA data sources (submitters) and data users (public and healthcare systems).
- Revisit previous attempts to use DUNs number and FEI numbers and other key FDA identifiers as standard identifiers to improve overall FDA data consistency and application.
- Enhance and sufficiently resource OpenFDA with feedback loops to better link FDA data sources that impact Real World Data capture (e.g. PMA, 510(k), GUDID, Recalls, Adverse Events), using master data for establishment and product (FEI# and DUNS# and UDI-DI). Our company has attempted to send data errors and resolutions free of charge for several FDA databases, including a line level report showing 87% of AccessGUDID records have an error in a regulated field. AHRMM Learning UDI Community sent a report showing 15% of the FDA identified implantable devices were incorrect. The same report included an easy to implement solution that would increase the list's accuracy to 97% and a process to get it to 100% from feedback. We have had no response back from FDA but continue to be willing to provide open feedback on data errors.
- Streamline and digitize recall data to improve its quality and consistency and reduce confusion resulting from multiple and delayed recall postings to support improved manufacturer and healthcare recall management processes.

- Set up data quality reporting and correction processes for public facing data (e.g. UDI barcode scanning issues, AccessGUDID attributes used in ONC EHR Certification Criteria, missing or inaccurate data in Registration & Listing, Recalls, Adverse Events etc).

3a. Data strategies and data sharing, including: How can FDA's data strategy facilitate broader goals of integration and interoperability of health care data and scientific data/virtual patient data generated using scientific models?

Discussion Points:

- As mentioned in 1a. ONC and CMS as well as HL7, X12, GMDN, SNOMED and other standards development organizations have included UDI in certain Health IT requirements, including as part of US Core Data for Interoperability, with the goal of establishing UDI as the means to adequately identify a device through distribution and use. However, there are still questions about whether UDI is required to be captured and how the data requirements in ONC and CMS requirements align with FDA requirements.
- The community of stakeholders that are working to promote UDI adoption (including the 600 member AHRMM Learning UDI Community) has identified barriers to adoption. Among these are specific actions FDA could take to facilitate integration and interoperability of regulatory data with healthcare data. Two major gaps that have been identified are the quality of data in AccessGUDID and in the recall information posted by FDA. A major quality issue for GUDID is missing records for products that are in commercial distribution. A major quality issue impacting recalls is the lack of a common set of data fields that are common across the lifecycle of a recall, from initial manufacturer submission to FDA to processing within FDA, and offering access and download in a timely manner to device consumers in order to reduce risk of recall exposure.
- The device ecosystem is depending on FDA data to support interoperability requirements related to UDI capture in health records.
- Patients would benefit from FDA going beyond support of UDI for implants by developing a data strategy that uses the UDI system to support other use cases including but not limited to:
    - Ongoing commitment to the rollout of UDI for all classes of products including the capture of Class I products in September 2020. The recent disruption to the COVID-19 healthcare supply chain was made worse by UDI not being consistently available on Class I products. Had the UDI for Class I products been required and enforced prior to the pandemic, millions of dollars and thousands of hours could have been saved by hospitals curtailing counterfeit purchases of

needed supplies,[8] a foundational reason the UDI legislation was passed. That is, scanning UDI and using the data in AccessGUDID as a means to automatically authenticate a device.

- Transmission of UDI as part of mobile device interoperability requirements to support consistent use of the same identifier for both networked and non-networked devices.
- Inclusion of UDI in medical device maintenance systems to support preventive maintenance, use of UDI in electronic IFUs etc.

Recommendations:

- Set up FDA enforcement process for manufacturers that have not met minimal UDI requirements (e.g. enforce missing UDI-DI records for implants that are in commercial distribution).
- Avoid any further exceptions, extensions or modifications of enforcement recognizing that to be of benefit, a UDI system must apply to all regulated medical devices.
- Set up collaboration between FDA, ONC, manufacturers and healthcare providers and vendors to define common data fields to be submitted and made accessible for FDA patient safety purposes and to strengthen the capture of UDI at point of use.
- Renew the commitment of using the GUDID as an authoritative source for internal FDA data use.
- Define data strategies that include ongoing evolution of the UDI system to include use cases beyond traditional implant use case.

3d. Data strategies and data sharing, including: For stakeholders, including regulated industry that submit data to FDA, how can FDA enhance the efficiency of the preparation and submission of data to FDA?

Discussion Points:

- Today, FDA initial submission requirements appear to be designed to meet the specific regulatory purpose of the particular data source and not to support a total product lifecycle that include reuse of product data as the device moves through various stages.
- There is inconsistency between FDA, ONC, and CMS regarding the use of standard product categorizations that creates significant burden for health systems and payers that rely on these groupings for documentation, billing and research purposes. As an example, a particular device is mandated to receive a product code from FDA, HCPCS codes from CMS, and document GMDN/SNOMED terms to meet ONC EHR certification

[8] https://www.washingtonpost.com/business/2020/03/26/gouged-prices-middlemen-medical-supply-chaos-why-governors-are-so-upset-with-trump/

requirements. The lack of a consistent standard for this key product characteristic requires resources for mapping and maintenance.

Recommendations:

- FDA can enhance the efficiency and accuracy of submissions by gaining a better understanding of the product data lifecycle, not only to meet regulatory requirements but also to meet the needs of health systems and others that use data for public health purposes. Enhance the submission of data to FDA with the recognition that the data is used not only internally but as input for evaluating products, recording product use, monitoring product performance and using data from performance to modify device design or remove a product market.
- Actively bridge the gap between manufacturers trying to submit accurate regulatory data (e.g. approval, recall and adverse event) with providers that need the information to be correct for supply chain and clinical purposes.
- Coordinate with CMS, ONC, and other bodies on data strategies and policies that will reduce reliance on multiple code sets used for the same purpose -- device categorization.