ASC X12®

The Accredited Standards Committee

Session 5: Unique Device Identifier
ASC X12

Margaret Weiker, ASC X12N Chair

LEGAL DISCLAIMER

This presentation is for informational purposes only.

- The content should not be construed as legal advice.
- If you have questions regarding specific information shared during this presentation, please send them to info@x12.org
- Visit www.x12.org for additional details about ASC X12

UNIQUE DEVICE IDENTIFIER COMPONENTS

The UDI is a code on each device label, package, and/or device itself that is comprised of two parts.

- The first part is the device identifier (DI). The DI is static and identifies the version or model of the device, and will be included in the GUDID.
- The second part is the production identifier (PI). The PI is dynamic and distinguishes the device by listing one or more of the following - the lot or batch number, serial number, manufacturing date, and expiration date.

LEGISLATIVE/REGULATORY HISTORY

In 2007, Congress passed legislation that directed the FDA to issue regulations establishing a UDI system for medical devices

- To provide early detection of defective devices
- To facilitate device recalls to enhance patient safety and reduce medical errors

LEGISLATIVE/REGULATORY HISTORY

In 2013, the FDA issued regulations establishing the UDI system. The purpose of the regulation was to initiate improvements in post market surveillance. It required:

- Publication and storage of UDI in a single FDA database accessible to the public.
- Labeler/device manufacturer to submit data on the device to the Global UDI Database (GUDID)

FDA'S SENTINEL PROGRAM

The FDA developed the Sentinel Initiative to comply with the FDA Amendments Act of 2007, which required the FDA to collaborate with public, academic, and private entities to develop methods for obtaining access to disparate healthcare data sources and analyze healthcare safety data. In 2012, Congress directed the FDA to expand Sentinel to include devices.

FDA'S SENTINEL PROGRAM

Sentinel is built upon a secure network portal that enables the FDA to issue requests to participating health plans and aggregate the data – primarily from claims – that are returned.

- By working with participating payers, Sentinel was used to successfully investigate safety concerns with drugs.

CHANGE REQUEST 1308 - ORIGINAL

- Description:

We recommend the inclusion of the UDI specifically for implanted medical devices as a condition of reimbursement for procedures involving these products. This change would also result in changes to Health Insurance Portability and Accountability Act (HIPAA) regulations to allow the transmission of this data from the provider to the health plan. At this stage, we envision that the UDI will serve as an additional identifier related to the primary procedure and not for prior authorization or differential payments based on the specific device used. Requiring the documentation of UDIs of implanted devices in claims transactions as a condition of reimbursement will help assure the collection of a critical mass of data, instead of sporadic and intermittent capture of these identifiers among providers. The focus on implanted medical devices is appropriate since it is a clearly defined set of products, they are not visible to the human eye once implanted, and they have been associated with significant adverse events and costs. We still must determine whether this criterion should require the capture of all implanted device identifiers used in a procedure, or only the UDIs for certain implanted products, particularly with procedures involving multiple implants. Lastly, we will identify whether there are non-implanted devices whose UDI is appropriate for including in claims transaction. To obtain these additional details on UDI use in the claims process, we will conduct outreach to relevant stakeholders, including health plans, health systems and clinician organizations. Based on input from these groups, we will provide an update to ASC X12 as the change request process progresses. In the interim, should you have any questions or if we can be of assistance to help realize this important advance in evaluating the safety and quality of medical devices to improve patient care, please contact Josh Rising, director of medical devices, at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

CHANGE REQUEST 1308

- Received WEDI Foundation White Paper – Facilitating the Capture and Transmission of UDI
- Received letters supporting and not supporting the inclusion of the UDI in claims
- Change Request assigned to Billing and Encounter Information Work Group as primary; Services Review Information Work Group and PACDR SAC as secondary
- Began Business Requirements Gathering at June Meeting

STRENGTHS IN UTILIZING CLAIMS TO REPORT UDI

- A transmission process currently exists for providers to send data to payers, payers to store data in claims database, and payers to send data to the FDA Sentinel system
- There is a process to aggregate data across very large numbers of patients
- There is a successful history in using claims data for post market surveillance of pharmaceuticals

BENEFIT OF UTILIZING CLAIMS TO REPORT UDI

- Many of the post market surveillance goals for medical devices would be achieved
- Payers could conduct their own quality analyses on devices and assist with locating patients implanted with recalled devices
- Registries could link with claims to enhance longitudinal analyses of devices
- The FDA's Sentinel system could be utilized to assess device performance as is currently done with drugs
-

BENEFIT OF UTILIZING CLAIMS TO REPORT UDI

- Pilot programs could transmit UDI for interested providers and health plans
- Collaborating providers and payers would decide which implants would involve transmission of the UDI
- All-payer claims databases would be able to incorporate UDI for analysis and evaluation across multiple payer datasets

SOME CONCERNS REGARDING UDI IN CLAIMS

- May affect processing and payment of the claim
- Will require introduction of new billing processes that do not currently exist
- Significant departure from existing claim submission routines
- Will require new billing system look-up and interface
- Associated costs and benefits have not been determined
- Should be vetted through a formal rule-making process
- Competing regulatory priorities

PROPOSED UDI REQUIREMENTS IN CLAIMS

- Situational Element based on trading partner agreement
- Limited to high-risk devices such as hip, knee replacements and cardio stents
- Used for reporting purposes only

OTHER PROPOSED TRANSACTIONS FOR REPORTING UDI

- Claim attachment
- Health Care Services Review – Notification

CHANGE REQUEST 1308

- Reviewed and discussed with multiple stakeholders at the June Standing Meeting
  - Developed a plan for moving forward
    - Establish a specific workspace
    - Hold conference calls to review and discuss
    - Collaborate with other SDOs
  - Revised the change request wording to be generic and only suggest we find a solution to the business need

CHANGE REQUEST 1308- REVISED

- Description and Business Reason:

Failures of medical devices over the past two decades demonstrate the need for more rigorous and timely evaluation of the safety and quality of products once they are on the market and used in large numbers of patients. For example, metal-on-metal hip replacements, which have been implanted in an estimated 500,000 Americans, fail at higher rates than those made of other materials. However, the U.S. Food and Drug Administration (FDA) increased regulation of these devices only years after the identification of problems with these products in Australia and Europe. Similarly, life-threatening failures with implantable cardioverter-defibrillator leads—used in hundreds of thousands of people to detect and correct abnormal heart rhythms—resulted in several recent recalls because of product design defects. Health systems, health plans, clinicians and patients require better postmarket surveillance tools to more quickly identify problems with specific device models. As a result, Congress mandated that the FDA develop a unique device identifier (UDI) system to require manufacturers to place a unique ID number on each medical device or its packaging, corresponding to the product's manufacturer, model and other clinically relevant information. The FDA committed to finalizing regulations establishing this UDI system by the end of June 2013, with manufacturers expected to begin including device identifiers on certain high-risk product labels within a year. UDIs have the potential to facilitate the tracking of medical devices through their distribution and use, benefiting health systems, health plans, patients, clinicians and public health officials by providing for more rapid identification of medical devices associated with adverse events; assisting with prompt and efficient resolution of device recalls; delivering an easily accessible source of definitive device identification; and increasing health savings through a more accurate accounting of the devices used. While the UDI will be the cornerstone for significant improvements in monitoring medical device safety and quality, the full benefits of this system only be achieved when it is in widespread use by healthcare providers and incorporated in electronic health information, and exchanged between entities.

CHANGE REQUEST 1308- REVISED (CONT)

- Description and Business Reason:

EDI transactions currently do not include details on the specific medical devices used by clinicians. As a result, health plans and health systems lack a process to efficiently collect data on the safety and quality of different medical devices. ASC X12 in conjunction with the other SDOs can explore ways to remedy the deficiency. The following are all claim specific examples of how UDI could be exchanged between entities. One way this could be accomplished is UDI capture in claim transactions, which could contribute critical data to improve patient outcomes and enhance the evaluation of medical device safety, quality and performance. Unlike other electronic health information sources, claims transactions can provide longitudinal data on patient outcomes across healthcare institutions and for prolonged follow up times. These capabilities are critical for implanted medical devices, as problems might not emerge for several years and patients may seek care in facilities that did not perform the implant procedure. California Department of Health Care Services (DHCS)—which administers the state's Medicaid program—concluded a pilot program to determine whether the capture of device identifiers could yield benefits beyond the current Healthcare Common Procedure Coding System (HCPCS), which does not distinguish between specific devices. As a national UDI system for all devices had not yet been implemented, DHCS evaluated the capture in claims transactions of Unique Product Numbers for durable medical equipment and products sold in retail pharmacies. DHCS found that documenting device identifiers in claims transactions yielded several benefits, including more precise identification and payment for medical supplies; additional detail to enable rebate collection from manufacturers; streamlining claims processing procedures; reducing fraud and abuse; increasing data quality to provide enhanced payer control over rate setting and other business processes; and improving patient care by ensuring that products meet quality standards. Lastly, documenting UDIs in claims transactions will also support the FDA's postmarket surveillance Sentinel Initiative to evaluate the safety of medical devices once they are approved, a capability that Congress also directed in the statute mandating the development of the device identifiers system. By proactively monitoring data rather than relying on spontaneous reporting from manufacturers and health care providers, Sentinel can more systematically and quickly identify safety and quality issues. Sentinel—which relies heavily on claims transactions—currently accesses safety information on drugs and biologics by querying data on more than 100 million patients. However, without device identifiers in claims transactions to track the products used, Sentinel cannot effectively evaluate patient outcomes following the utilization of specific devices. Establishing a way to exchange the UDI in EDI may achieve some of the benefits documented above.

We recommend the exploration of ways to exchange the UDI via electronic data interchange (e.g, X12, HL7, etc…).

http://crbrowser.x12.org/

Thank You