ASC X12®

The Accredited Standards Committee

Panel 6: Unique Device Identifier(UDI) and its Relationship to Administrative Transactions

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- The content should not be construed as legal advice.
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BACKGROUND

- Universal Product Number (UPN) – generic term used to reference various types of UPIs
- Multiple standards used by manufacturers
  - GS1 Global Trade Item Number (GTIN)
  - Health Industry Bar Code (HIBC)
  - National Health Related Items Code (NHRIC)
  - Universal Product Code (UPC)

BACKGROUND

- The US Food and Drug Administration (FDA) Amendments Act of 2007 includes language related to the establishment of a Unique Device Identification System, which will require the label of a device to bear a unique identifier.
- In 2007, the US Department of Defense initiated a pilot to test the GS1 Global Data Synchronization Network (GSDN) and the Global Trade Identification Number (GTIN) for patient safety and cost-containment purposes related to medical supply purchase and distribution.

HISTORY

- ASC X12 Version 4010A1 Professional Claim (837) accommodated the UPN as a line level situational billed/reported item/supply
    - Only allowed use for Medicare/Medicaid programs
    - Supported HIBC and UPC numbers

HISTORY

- ASC X12 Version 5010A1 Professional Claim (837) accommodates the UPN as a line level situational reported item/supply
    - Only allowed uses:
        - HHS approved pilot projects
        - Government regulation mandates medical and surgical supplies reported with UPNs
    - Supports Customer Order Number, HIBC, UCC-12, EAN/UCC-8, EAN/UCC-13, GTIN numbers

HISTORY

- DSMO Change Request 1093 submitted December 2009
    - Requested existing code qualifiers in the ASC X12 and NCPDP be brought forward in the next version
    - Add any other product qualifiers to support the UDI regulation currently in development by the US Food and Drug Administration (FDA)

- DSMO Change Request 1093 Recommendation:
  - Disapprove. The DSMO determined that the change request to add the capability for unique device identification to the transactions needs to be done at the same time as the request for a new HIPAA code set is submitted. The submitter is invited to resubmit a change request to the DSMO and is requested to include clear business justification and specific usage for the use of UDI in each transaction in the request in conjunction with identifying the code set(s) being used for UDI under HIPAA.

    In addition, as the FDA has not yet issued its regulations for unique device identification (UDI) and has indicated that UPN is outdated terminology, and has requested to discuss with SDOs any changes necessary to support their UDI initiative, we see this request as premature.

FUTURE

- UDI
  - External Code Source addition
    - Source
    - Available From
    - Abstract
  - Identify impacted standard transactions
    - Qualifier added to standard that identifiers the code
    - Usage Rules
      - Will code be used for billing/payment or reporting only?
      - Situational rule

FUTURE

- UDI
  - Use Errata process to modify existing HIPAA adopted transactions to support new code set
    - ZZ qualifier
  - Use of new qualifier and associated code source will require adoption of a new version of the HIPAA adopted transactions

FUTURE

- UDI Other Items
  - Editing and Metadata
    - Structure of number
    - Effective and expiration date

Thank You

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