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Unique Device Identifier

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Overview of UDI

- Importance of UDI in identifying problems with medical devices.
 - Surveillance & Safety
 - Premature failure
 - Recalls
 - Longitudinal Studies
- Existing revenue cycle billing systems are not designed for handling manufacturer number nor production lot numbers.
- Need to design an effective and practical solution.
 - Efficient
 - Capable of meeting the needs in a cost-effective manner.
 - X12 Standards are simply designed as a cross walk from internal systems mapped to a common electronic format.
 - Again hospital internal billing systems do not currently exist to accommodate the UDI.



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Why the Claim Standard is Wrong

- On the surface it seems simple – add it to the electronic billing transaction.
 - Realities are that doing so would involve enormous costs.
 - Development of a new charge master system capable of managing this level of detail within the hospital.
 - Nothing like this exists today. Who will pay providers for undertaking such changes and the ongoing maintenance?
 - Federal government
 - Health plans
- Any action to add this to the HIPAA claim standards should be mindful of the Administrative Procedures Act.



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The Claim is designed for Reimbursement

- Reimbursement does not change because of UDI reporting.
- Existing mechanisms within the claim are already in place to identify a device that fails prematurely.
- Health plans already require pre-authorization of scheduled surgeries.
- Most health plans follow a prospective payment model for reimbursement to providers.
- Meaningful Use – Stage III calls for UDI in the EHR.



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Attachment Transaction

- Need to look toward the attachment transaction.
- Attachment transaction works with information from the EHR.
- Attachment standard is designed to supplement the claim information – where business rules are specific.
 - High risk surgical procedures with device implants (e.g., stents, hip replacement, etc....).
 - Easily identified by ICD procedure codes.
 - Can include the production/lot number portion of the UDI.



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- The NUBC which oversees the institutional data components for claim reporting - opposes adding the UDI to the Claim transaction.
- Importance of “checks and balances” when new reporting requirements are being introduced – process matter.
- Role of the four organizations in HIPAA legislation
 - Safeguard design of the ANSI standards.



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