Exploring the Opportunities and Challenges Associated with Capturing UDIs in Claims

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Background and Timeline

- 2007 - Food and Drug Administration Amendments Act directed the FDA to establish a UDI System
- 2010 - Medical Device Epidemiology Network (MDEpiNet) established as a public-private partnership between FDA and academic medical institutions
- 2011 - Chickasaw Nation Industries, Inc. awarded contract from FDA as part of the MDEpiNet initiative to advance innovative methodologies and medical device-specific infrastructure for regulatory science and surveillance
- 2012 - Proposed Rule for UDI System published in Federal Register
UDI Development and Implementation

Affixing/incorporating UDIs during manufacturing

Use of devices that are not uniformly labeled with UDIs (current state)

Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

UDI routinely available for valuable uses

UDI Development Phase

UDI Implementation Phase
UDI Development and Implementation

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Proposed Initial Focus for UDI Implementation Work Group
Meeting Agenda

Overview of Proposed UDI Rule

Overview of Universal Product Number Pilot

Panel 1: Potential Benefits of Including UDI in Claims

Panel 2: Technical Steps Necessary to Create UDI Recording and Transmission Capabilities

Panel 3: Appropriate Policies for Enabling Consistent UDI Recording