

Exploring the Opportunities and Challenges Associated with Capturing UDIs in Claims

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The Brookings Institution • Washington, DC Monday, October 15, 2012

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



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



Affixing/incorporating UDIs during manufacturing

Incorporating UDI into data collection fields and provider workflow



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Affixing/incorporating UDIs during manufacturing

Incorporating UDI into data collection fields and provider workflow

Developing methods and data infrastructure



(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



Incorporating UDI into Affixing/incorporating Developing data collection fields **UDIs** during methods and data and provider workflow manufacturing infrastructure Use of devices Routine that are not Use of devices **UDI** routinely capture of UDI with UDIs in available for uniformly labeled in electronic with UDIs clinical practice valuable uses data sources (current state) **UDI** Development **UDI** Implementation Phase Phase Proposed Initial Focus for UDI Implementation Work Group



Meeting Agenda

Overview of Proposed UDI Rule

Overview of Universal Product Number Pilot

Panel1: 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

