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Use of UDI in Administrative Transactions

National Committee on Vital and Health Statistics, Subcommittee on Standards

Hearing on HIPAA and ACA Administrative Simplification

June 10, 2014

The Pew Charitable Trusts

Pew is an independent, non-profit research and public policy organization.

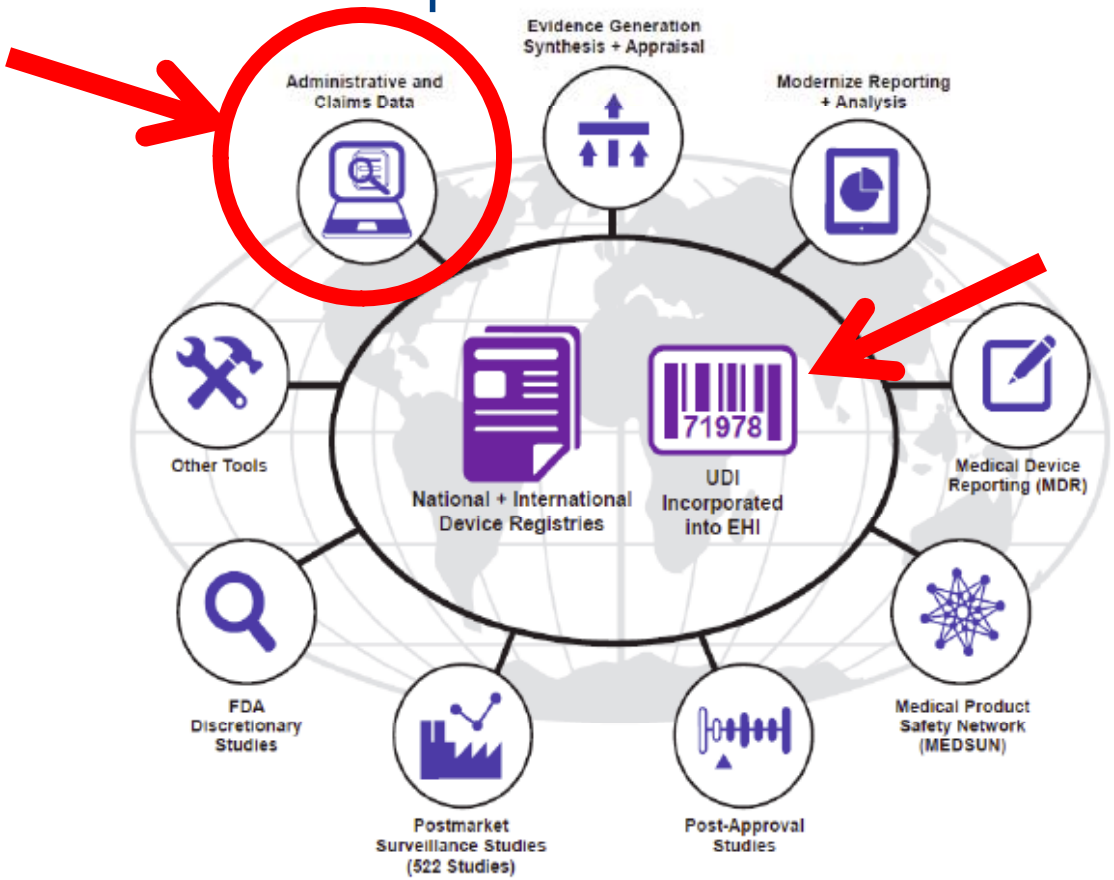
Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

- Unique device identifier (UDI)
- Medical device registries
- Accelerating device innovation

Medical Device Postmarketing Surveillance

- Current problems include:
  - Inability to quickly identify problems with medical devices
  - Incomplete recalls
  - Poor data to establish long-term outcomes
- Medical devices are among the *only* products that do not rely on a standard unique method of identification
- The unique device identifier (UDI) will improve this situation—but only if it is captured in electronic data
  - High-risk devices must have UDIs by September 2014

UDI is Central to Improved Postmarket Surveillance



Strengthening our national system for medical device postmarket surveillance: Update and next steps. U.S. Food and Drug Administration, April 2013.

UDI Capture in both EHRs and Claims are Key

UDI capture in EHRs and claims are complementary, but each insufficient on their own

EHRs

- Provide detailed information on patient care
- Are not interoperable and easily aggregated

Claims

- Larger data sets
- Longitudinal outcomes, especially when different providers involved in care
- Standardized and easily aggregated

Why is UDI Capture in Claims Important?

Major Safety/Quality Advances

- Enables health plans to conduct their own analyses on device performance
- FDA cannot use Sentinel for devices without UDI
- Provides information on the number of devices used in care (denominator data)
- Payors could assist with device recalls

UDI capture in EHRs alone does not yield these same benefits

Claims vs. Attachments or Other Transactions

Claims

- Standardized
- Proven use by payers, Sentinel, researchers and others
- Regularly used to transmit health data

Claims attachments

- Not standardized
- Can include unstructured data, preventing queries from electronic systems
- Used less regularly than the claim

Claims are an existing, standardized, regularly used vehicle to achieve the UDI system's benefits.

Recognition at HHS

FDA

"[I]n-corporation of UDIs into claims data would increase the utility of these data sources for medical device postmarket surveillance, and pilot studies suggest it is both technically feasible and cost-effective."

Sylvia Mathews Burwell, Secretary of Health and Human Services-Designate, in response to confirmation hearing questions from the U.S. Senate

"Incorporating UDIs into claims will be a multi-year effort that will require ongoing engagement with stakeholders… The Sentinel Initiative will ultimately benefit from these efforts by incorporating UDIs into its claims data sources."

Strengthening our national system for medical device postmarket surveillance. U.S. Food and Drug Administration, September 2012. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm

Questions for Ms. Sylvia Mathews Burwell, Secretary of Health and Human Services-Designate, Committee on Health, Education, Labor, and Pensions, U.S. Senate, May 8, 2014.

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Letters of Support for UDI Capture in Claims

The Society of Thoracic Surgeons

PUBLICCITIZEN

NATIONAL PHYSICIANS ALLIANCE

PBGH
PACIFIC BUSINESS GROUP ON HEALTH

amsa
American Medical Student Association

Mercy

CONNECTICUT CENTER FOR PATIENT SAFETY
QUALITY HEALTHCARE IS A RIGHT.

Consumers Union
POLICY & ACTION FROM CONSUMER REPORTS

PREMIER

NATIONAL WOMEN'S HEALTH NETWORK
A VOICE FOR WOMEN, A NETWORK FOR CHANGE

woodymatters

GEISINGER HEALTH SYSTEM

THE LEAPFROG GROUP

NRC FOR WOMEN & FAMILIES

Women Heart
The National Coalition for Women with Heart Disease

fdb™
First Databank

Union of Concerned Scientists

CENTER FOR MEDICAL CONSUMERS

THE TMJ ASSOCIATION TMJA

Trust for America's Health
WWW.HEALTHYAMERICANS.ORG

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… and counting.

Progress To-Date and Next Steps

Pew Submitted Change Request to ASC X12

- Change request submitted in June 2013
- Updated with stakeholder input April 2014
- June 2014: X12 agrees to consider request and convene subgroup to evaluate

Obtained Stakeholder Input

- Commissioned the Workgroup for Electronic Data Interchange (WEDI) Foundation to develop the business case
- Obtained feedback from hospitals, health plans, patients, others
- **Findings:** Recommended UDI capture in claims for high-risk, implanted devices

Thank you

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