ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

Oral Testimony of

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On Use of UDI in Administrative Transactions

Before the

National Committee on Vital and Health Statistics'

Subcommittee on Standards

Hearing on HIPAA and ACA Administrative Simplification

Operating Rules, ICD-10, Health Plan ID, Attachments

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Good afternoon and thank you for the opportunity to testify before the Subcommittee. My name is Dr. Greg Daniel and I am a Fellow and Managing Director at The Brookings Institution's Engelberg Center for Health Care Reform. Within the Center, I manage a team focused on innovations in pharmaceuticals and medical devices, and how these innovations can inform public policy. The Center's Health Care Innovation and Value Initiative includes a number of projects in collaboration with the US Food and Drug Administration (FDA), such as the development of a Unique Device Identifier (UDI) implementation roadmap. Through this project, we have drawn upon extensive research as well as expert workshops and focused discussions with major stakeholder groups. Our discussions include participation from providers, patients, payers, and manufacturers to help identify major barriers and recommend practical approaches to UDI implementation. While these discussions have informed the recommendations I will put forth today, my comments may not necessarily reflect the opinions of everyone we have engaged during our research.

Incorporation of UDI into administrative transactions can enable a wide array of activities focused on improving the quality of care provided to patients with medical devices. With an increasing focus on improving quality, outcomes, and curbing escalating costs in healthcare,

optimizing the use of UDI will be essential to making sure that patients and their providers have access to the most relevant and timely information on the performance, effectiveness, and safety of medical devices.

Across the healthcare system, data stored from administrative transactions contain data elements that are increasingly being harnessed to support a number of public health and research uses. By linking together pharmacy and medical claims with health plan enrollment files, longitudinal histories based on information from virtually all provider and health care settings a patient passes through can be created to enable examination of important health outcomes associated with many medical interventions at a population level. For example, the FDA's Sentinel Initiative uses health care claims data to assess the safety of drugs and other medical products in large populations of patients in near-real time. This system represents a significant expansion of FDA's tools used to monitor the safety of drugs and many vaccines. Similarly health plans, health services researchers, and epidemiologists routinely use claims data to measure and track the impact of prescription drugs and other interventions on important outcomes in order to identify opportunities to improve the quality and value of health care. Since the claims data today cannot be routinely used to identify unique medical devices, these activities, including the Sentinel Initiative's activities, are rarely conducted for medical devices if at all.

Further, while electronic health record (EHR) data and other sources of clinical data can be a rich source of clinical detail, their limited ability to collect data as patients move from provider to provider across the health care system renders them less useful for population level surveillance and performance tracking when used alone.

Some of the tangible benefits that can be realized soon by incorporating UDIs into administrative transactions include:

- Improving the understanding of utilization, performance, and safety of unique medical devices when used in practice;
- Enabling the ability to conduct health outcomes research for medical devices on a wider and more cost-effective scale;
- Enabling the ability of health plans to play a role in recall management;

- Driving higher quality care by leveraging knowledge of quality and outcomes from medical devices; and
- Better management of costs of care by increasing transparency for payers and patients in the actual devices used during procedures.

Through our research, we have three potential scenarios in which UDI could be incorporated into administrative transactions, each with their own costs and benefits.

The primary scenario is to incorporate UDI into the ASC X12N 837 Institutional and Professional Claims Transaction forms. This would require the creation of a new field and a complementary set of business rules to guide usage. The optimal inclusion of UDI in these forms should exist at the claim line detail level in order to associate the UDI with a particular service or procedure allowing for a greater level of granularity. While there would be a lengthy standards development process, leveraging the existing mechanisms for transferring valuable information between providers and payers seems to be the most feasible and straightforward option that will provide real opportunities to improve care for patients relatively soon.

An alternative option that has been proposed includes incorporating UDIs into the health claims attachment forms often used to supplement primary claim documentation. However, major issues with this scenario include the low penetration of structured electronic health claims attachment forms into provider systems, lack of a final rule regarding standardization, and significant technical extract, transform, and load (ETL) challenges in retrieving UDIs from these forms and using them to maximize benefits outlined above.

A second alternative that we have heard includes incorporating UDIs into the claim authorization request and response standards, such as the ASC X12 278 transaction set. This scenario, in all likelihood, would severely limit UDI's scope to transactions requiring prior authorization and notification. More importantly, it would necessitate that the provider have foresight into what specific medical device will be used before a procedure is done, which for many surgical procedures, the exact brand/type of implanted device may not be known in the days or weeks prior to the surgery. As a result, the UDIs would not be an accurate reflection of the devices actually used.

Regardless of the specific approach taken to incorporate UDIs into administrative transactions, we find that inclusion of both the static device identifier (DI) portion and the dynamic product identifier (PI) portion of the UDI would be important. If the technical challenges prohibit the inclusion of both, it could be reasonable to start with the DI portion only. Optimizing the use of the DI portion will be bolstered by FDA's maintenance of the Global Unique Device Identification Database (GUDID), which will house and maintain all DIs published by manufacturers and made available to the public.

From our research and expert opinion assessments, our overall recommendation is to incorporate UDIs into administrative transaction systems, as these systems are the primary mode of transferring information, both clinical and financial, between providers and payers. More specifically, we recommend UDI should be incorporated as new field into claim forms such as the ASC X12N 837 Institutional and Professional Claims Transaction at the claim line detail level and as a situational rule. The situational rule would allow providers to coordinate with payers to determine the optimal business rule for the collection of UDI, while ensuring that provider and payer systems have the capacity to incorporate UDI across a breadth of billing situations. Prioritization of which medical devices to capture with UDI should be explored, with high-risk implantable devices as an optimal starting point. We believe this recommendation currently has substantial support in moving through the standards development process and also promises the most feasible option with the widest impact to improve care relative to other administrative transaction scenarios.

The number of challenges facing providers and payers and the vast heterogeneity among their resources and capabilities make giving any qualified assessment and recommendation for UDI implementation difficult. Nevertheless, given the expected impact and current evidence available, UDI inclusion into the administrative transaction process represents a unique opportunity to advance the public health, improve the safety and quality of care delivered to patients, increase operational efficiency, and improve price transparency of medical devices.

Thank you very much for allowing me to provide comments today.

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UDI in Administrative Transactions: June 10, 2014 NCVHS Testimony

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Brookings and UDI

- Charged with producing an UDI implementation roadmap by the FDA

- The process of creating the roadmap has consisted of several expert workshops and focused discussions covering:
  - Opportunities and challenges for including UDI in claims
  - Implementation of UDI in provider electronic data systems
  - UDI as a tool for improved patient engagement
  - Implementation of UDI in administrative transaction systems
  - Implementation of UDI in provider systems

UDI in administrative transactions

- As the nation's health care system is undergoing a paradigm change focused on better outcomes and quality, access to data has become paramount

- Advantages of UDI in administrative transactions include:
  - Improving the understanding of utilization, performance, and safety of unique medical devices when used in practice;
  - Enabling the ability to conduct health outcomes research for medical devices on a wider and more cost-effective scale;
  - Improved recall management through payer involvement;
  - Driving higher quality care by leveraging knowledge of quality and outcomes from medical devices; and
  - Better management of costs of care

UDI in administrative transactions

- Electronic health records currently lack robust capability to track patients across provider settings due to issues surrounding interoperability and data transfer infrastructure and governance
- Administrative transactions represent a clear opportunity to track devices, services, and procedures across provider systems
- FDA Sentinel is a proven example. Uses claims and NDC data to assess safety measures

Three scenarios for UDI in administrative transactions

1. Incorporate UDI in ASC X12N 837 Institutional and Professional Claims Transaction forms at claim line detail level with situational rule
2. Incorporate UDI into the health claims attachment form
3. Incorporate UDI into claim authorization request and response standards, such as the ASC X12 278 transaction set

Current recommendations

- Overall recommendation is to incorporate UDIs into administrative transaction systems
- Incorporate UDI in ASC X12N 837 Institutional and Professional Claims Transaction forms at claim line detail level with situational rule
- Prioritization of which medical devices to capture with UDI should be explored, with high-risk implantable devices as a good starting point

Wrap-up

- Administrative transaction systems are the primary mode of transferring information, both clinical and financial, between providers and payers.

- This approach seems to be the most feasible option to improve care for patients in the near-term.

- Given the expected impact and current evidence available, UDI inclusion into the claims transaction process represents a unique opportunity to advance the public health, improve the safety and quality of care delivered to patients, increase operational efficiency, and improve price transparency of medical devices.