

Exploring the Opportunities and Challenges Associated with Capturing Unique Device Identifiers in Claims

Workshop Background

Medical devices augment the ability to predict, prevent, diagnose, and treat many conditions in vital ways. Each day, medical devices are used for these purposes by health care providers, patients, and caregivers in a variety of settings. As medical devices have become more sophisticated and care delivery sites have become less centralized, the need for an effective monitoring system to better understand medical device use and the associated outcomes patients experience has become critical. Despite significant steps toward creating effective monitoring capabilities for drugs, medical device monitoring has been hampered by the lack of a standardized identification system that would be analogous to the National Drug Code, which provides a common language for identification of specific drugs. Without such a standardized identification system for medical devices, it is much more challenging, if not impossible, to understand whether potential safety concerns are limited to specific devices, initiate efficient communications to providers and patients who might be affected by a device recall, and conduct a range of other activities that rely on specific information regarding device use.

In response to growing calls for the development of a standardized medical device identification system, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA mandated that the U.S. Food and Drug Administration (FDA) create a unique device identification (UDI) system that would enable tracking and identification of medical devices across the medical device lifecycle (i.e., from production through use in clinical practice). To effectively establish this system, FDA sought stakeholder input by organizing public meetings and workshops, conducting pilot studies, working to understand global UDI activities, and issuing calls for comments related to key aspects of UDI development. FDA incorporated the input gathered from these efforts, and, on July 10, 2012, released its [Proposed Rule](#) for a Unique Device Identification System in the *Federal Register*.¹

The Proposed Rule, which will be available for comment through November 7, 2012, outlines a number of public health objectives that could be achieved through UDI implementation and describes provisions surrounding the establishment of a UDI system. Some of the public health objectives enumerated include reducing medical errors and providing rapid identification of medical devices with adverse events. The Proposed Rule outlines the features of the UDI system, describing the two main components of the UDI itself (i.e., production identifier and device identifier) and how the UDI should be generated and displayed (i.e., via plain-text and automatic identification and data capture formats). It also describes the establishment and anticipated role of the accompanying Global Unique Device Identification Database as the gateway for stakeholders and the general public to access detailed device information. Other important provisions of the Proposed Rule include a device class-based timeline for UDI adoption by manufacturers, labeling requirements, and important exemptions and exceptions associated with UDI.

¹ U.S. Food and Drug Administration, Unique Device Identification; Proposed Rule. *Federal Register*. Retrieved August 22, 2012, from <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001>.

While the release of the Proposed Rule is an important step forward, its proposals, if adopted in the Final Rule, only ensure that UDIs will be developed and included by manufacturers on labels for relevant medical devices and that accompanying device information will be available to the public. The true value of a UDI system, however, lies in its broad adoption and subsequent use by manufacturers, distributors, payers, providers, and other stakeholders with important roles throughout the medical device lifecycle. To this end, the Engelberg Center for Healthcare Reform at Brookings is collaborating with FDA and Chickasaw Nation Industries, Inc., to explore the potential promise of broad, stakeholder-driven UDI implementation and the obstacles it may face. With this in mind, Brookings assembled a group of expert stakeholders with interests that span the medical device lifecycle to advise on issues related to the implementation of UDI, explore potential strategies for resolving them, and identify topics in need of further exploration. On July 16, 2012, the UDI Implementation Work Group met for an initial, in-person kick-off meeting to outline major priorities for successful UDI implementation. More information about this meeting can be found on the Engelberg Center [website](#).

During the kick-off meeting, participants discussed a range of topics related to UDI implementation. One of the recurring themes was the importance of ensuring that UDIs are consistently and accurately recorded in electronic data sources as part of the routine delivery of care. As part of this discussion, participants emphasized how valuable it would be if UDIs were captured in administrative claims. As electronic claims data are used increasingly for a range of activities related to drugs, including active safety surveillance, effectiveness research, and evaluation of patterns of care, participants indicated that enriching claims data with UDIs could facilitate a host of new research and surveillance activities for medical devices. Despite acknowledging the potential benefits of including UDIs in claims, participants also recognized that the task of overcoming the associated technical and motivational challenges is not trivial and would require broad stakeholder input and focus.

Workshop Objectives and Overview

This workshop is intended to create an opportunity for a diverse set of stakeholder groups, with unique and important perspectives, to weigh in on the potential barriers and paths forward for capturing UDIs in administrative claims. In bringing together payers, providers, academics, medical device manufacturers, and other relevant stakeholders, a meaningful discussion around the overall benefits, associated technical challenges, and appropriate policies surrounding capturing UDIs in claims can emerge. To facilitate the conversation on these topics, this workshop is organized into three interactive sessions in which a few lead discussants will start the conversation with remarks, followed by an open discussion among participants in the room.

Panel 1: Potential Benefits of Including UDI in Claims

Stakeholders from across the medical device lifecycle have identified a wide array of enhanced capabilities that could arise from successful UDI implementation. In many cases, stakeholders linked the ability to realize these benefits with the inclusion of UDIs in claims and their subsequent use by relevant stakeholders. This panel will allow participants to investigate the short- and long-term promise of UDI reporting in claims. Potential discussion questions may include the following:

- How can stakeholder groups (e.g., third-party payers, providers, regulatory agencies) benefit from including UDIs in claims?
- Are financial benefits likely to be the primary driver of UDI reporting in claims? If not, what are the most important non-financial benefits?
- What circumstances maximize the benefits of reporting UDIs in claims? What practical trade-offs may need to be considered (e.g., recording every device used or recording the primary device used)?

- If UDIs are consistently reported in claims, how might this benefit efforts to efficiently collect specific device information in registries?
- What advantages can pilot projects convey regarding UDI inclusion in claims?

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

Along the path to attaining many of the collective benefits that arise from UDI inclusion in claims, a series of technical processes must be considered. This panel will allow participants to examine those considerations, with particular attention to methods to overcome potential technical hurdles and strategies for developing a system in which UDI recording and transmission capabilities are enabled.

Potential discussion questions may include the following:

- What changes need to be made to the uniform billing (UB) format to accommodate UDI submission on claims?
- Are there fields currently available in existing claims transaction systems in which UDI could be included?
- If UDIs were submitted by providers for reimbursement, how would they be reported on claims? For example, in the case of bundled payments, would UDI be reported as a line item?
- What standards can facilitate UDI recording in claims?
- In the coming years, what other changes to claims are anticipated that may focus resources away from UDI incorporation into claims?

Panel 3: Appropriate Policies for Enabling Consistent UDI Recording

Although creating the technical capability to capture UDIs in claims is a fundamental step toward achieving many of the expected benefits of UDI, realizing these benefits requires that UDIs are actually recorded and used by stakeholders across the medical device lifecycle. This panel will give participants a chance to explore some of the potential incentives that may promote consistent UDI recording and the obstacles that may be associated with each incentive. Potential discussion questions may include the following:

- What might be the advantages and disadvantages of tying UDI reporting to payment?
- In the context of payment reform and bundled payments, how might UDI reporting in claims be promoted?
- If multiple devices are used in one procedure, how might reporting of their UDIs on claims be prioritized?

This meeting is intended to be highly interactive, and all participants are encouraged to consider a wide variety of possibilities for strategies to address the key technical and motivational challenges associated with including UDI in claims. This meeting will be a success if by the end of the meeting, participants can emerge with a potential path forward for successfully implementing UDIs in claims.