

Unique Device Identification (UDI) Expert Workshop: Exploring the Opportunities and Challenges Associated with Capturing UDIs in Claims

Introduction

As medical devices play an increasingly important role in the ability to provide routine care, treat diseases, and manage a variety of medical conditions, conducting longitudinal tracking of specific device use and associated patient outcomes is imperative. However, the lack of a uniform medical device identification system remains a key obstacle to achieving a number of goals in this area, including understanding whether potential safety concerns are limited to specific devices, initiating efficient communications to providers and patients who might be affected by a recall, and establishing the value of specific medical devices for patients. These activities are more readily conducted for drugs given widespread utilization of the National Drug Code (NDC), which uniquely identifies drugs and acts as a common language for communication across stakeholders. Recognizing the need for an analogous identification system for medical devices, Congress included provisions in the Food and Drug Administration Amendments Act of 2007 (FDAAA), directing the U.S. Food and Drug Administration (FDA) to create a unique device identification (UDI) system that would enable tracking and identification of medical devices. FDA, in developing a plan for an effective system, actively worked to gather and incorporate stakeholder input through public meetings, pilots, and other efforts. These efforts culminated on July 10, 2012, in the release of the Proposed Rule for a Unique Device Identification System in the *Federal Register*.¹

The Proposed Rule, which was available for comment through November 7, 2012, includes in its provisions that UDIs will be developed and included by manufacturers on labels for relevant medical devices and that accompanying device information will be made available to the public through the Global UDI Database (GUDID).² The GUDID, which is currently under development by FDA, will contain a set of standardized attributes submitted by manufacturers, such as make, model, and clinically relevant size. Once the GUDID is operational, any interested party will be able to use a UDI to look up important information about a medical device. In addition to significantly enhancing the detail and quality of device information available to the public, the GUDID is intended to serve as an important resource to health systems, researchers and other stakeholders invested in using UDIs to improve the supply chain, better understand device effectiveness, and conduct a range of other activities.

Currently, manufacturers are at various stages in their readiness for the upcoming UDI labeling and device-information submission requirements, with only some manufacturers fully incorporating UDIs into their labeling and tracking mechanisms. This current lack of uniformity in device labeling has made it challenging, if not impossible, for other stakeholders to derive significant value from the available UDIs. Thus, while the Proposed Rule provides an important step toward ensuring medical devices are consistently labeled, the true value of a UDI system clearly lies in its broad adoption and use by manufacturers, distributors, payers, providers, patients, and other stakeholders with important roles throughout the medical device lifecycle.

The Engelberg Center for Health Care Reform at Brookings is collaborating with FDA and Chickasaw Nation Industries, Inc., to explore the potential promise of broad, stakeholder-driven UDI implementation and address the challenges it may face. To accomplish this, 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, this UDI Implementation Work Group met

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>.

² An amendment to the Proposed Rule was issued on November 19, 2012, as a result of amendments made by the Food and Drug Administration Safety and Innovation Act (FDASIA) to the Federal Food, Drug, and Cosmetic Act. More information can be found here: <https://www.federalregister.gov/articles/2012/11/19/2012-28015/unique-device-identification-system>.

for an initial, in-person kick-off meeting to outline major priorities for successful UDI implementation; materials and a summary from that discussion can be found on the [event page](#). One of the recurring themes from this discussion was the importance of ensuring that UDIs are consistently and accurately recorded in electronic data sources as part of the routine delivery of care, with emphasis placed on the important role of incorporating UDIs into electronic health records (EHRs), hospital and provider administrative data systems, and health insurance claims. While considering claims data, participants suggested that enriching such data with UDIs could facilitate a host of research and surveillance activities for medical devices. However, despite acknowledging these potential benefits, participants also recognized that the task of overcoming the associated technical and motivational challenges is not trivial and will require broad stakeholder input and focus.

On October 15, 2012, Brookings convened an expert workshop on the topic of “Exploring the Opportunities and Challenges Associated with Capturing UDIs in Claims.” This workshop brought together a diverse set of stakeholders to discuss the potential barriers and paths forward for capturing UDIs in health insurance claims. Over the course of the day, participants discussed the key benefits for various stakeholder groups, associated technical and motivational challenges, and potential approaches to achieving effective capture of UDIs in claims. Key themes from the discussion are summarized below.

Benefits

Participants identified an array of enhanced capabilities that could arise from successfully incorporating UDIs in claims. Throughout the discussion, benefits specific to three stakeholder groups—payers, health care providers and health systems, and the public—were identified as particularly important and are summarized below.

Payers

Participants described UDI as a tool for payers to access a variety of important information. Currently, in the case of reimbursement for drugs, a payer has access to the NDC provided on a pharmacy claim and can adjudicate appropriately based on that information. In contrast, for medical devices, payers must request an attachment to a medical claim from the provider in order to uniquely identify a device since existing codes, such as the Healthcare Common Procedure Coding System Level II (HCPCS Level II), only aggregate devices into broad categories based on use and common physical characteristics. This claims attachment process is largely manual and hampers many of the activities (e.g., active safety surveillance, effectiveness research, evaluations of patterns of care) that electronic claims data are currently being used for with regards to drugs. Additionally, the level of granularity provided by these mechanisms for identifying devices in claims is not sufficient to quickly and specifically understand device use. Access to device information facilitated by UDI could help payers better understand the types of devices being used by providers, evaluate outcomes associated with specific devices, and make appropriate reimbursement decisions based on that information. Payers specifically highlighted the utility of UDI with regard to implantable devices. Because of the elevated risks associated with implantable devices and the potential need for additional care, especially in the event of a device recall, participants emphasized that payers could significantly benefit from more complete access to specific data regarding the use of these devices. With better access to specific device information and a data infrastructure supportive of ongoing evaluation of patient outcomes once a new device reaches the market, payers may also have greater confidence when granting initial coverage for promising new devices. Additionally, participants discussed some potential financial benefits for payers. Specifically, participants highlighted that by capturing UDIs in claims, payers would have access to better data regarding value associated with medical devices, which could then be used to inform more appropriate bundled payment agreements between payers and providers.

Health Care Providers and Health Systems

For health care providers and health systems, capturing UDIs in claims could enable a host of benefits in three major areas: clinical, operational, and financial. Participants indicated that if UDIs were required as part of the reimbursement process, this would drive consistent recording of UDI at provider sites. To the extent that UDI was also captured in other electronic data systems, such as EHRs and supply chain management systems, this could help unlock an array of benefits for health systems and providers. From a clinical perspective, UDIs would add important information to patient records, which may be useful to inform downstream care decisions. From an operational standpoint, UDIs could allow providers and health systems to more efficiently manage purchased medical devices, understand what products are currently in their inventory, and more effectively identify and remove expired or recalled products. This streamlining of the supply chain could significantly reduce wasted resources in the system and

allow for more of those resources to be allocated to the provision of care. Additionally, UDI could be used as a link across systems, from the internal supply chain through billing and clinical data systems, enabling more efficient communication within a care delivery site. Participants also discussed a number of financial benefits for providers and health systems that could accrue if UDIs were captured in claims. By creating a consistent mechanism for recording UDIs, providers could distinguish themselves to consumers by demonstrating increased access to device information to inform patient and provider decision-making, the ability to efficiently communicate with patients regarding recalls, and, possibly, the availability of additional automated features such as patient information portals or triggers for follow-up care after a surgery.

Public

Participants highlighted several ways in which capturing UDIs in health insurance claims could improve capabilities for assessing and acting on public health concerns related to medical devices. Particularly, participants emphasized that payers have a distinct view of patients' medical encounters across providers. As a result, payers are uniquely positioned to leverage claims data containing UDIs to enable post-market safety surveillance and effectiveness evaluations. Programs such as FDA's Sentinel Initiative are already conducting safety surveillance for drugs by making use of the NDC in claims and creating a link to safety outcomes. In addition to enhancing device surveillance activities, participants indicated that including UDIs in claims could make possible significant advances in comparative effectiveness research by enabling researchers to link device use to patient outcomes. This new research could eventually allow clinicians and patients to make more informed point of care decisions regarding appropriate devices.

Technical Approaches to Incorporating UDI into Claims

In order to achieve the benefits described above, a series of technical processes must be considered. Participants discussed previous models and pilot projects that shed light on approaches to capturing UDIs in claims, associated technical challenges, and potential paths forward. Prominent themes from this discussion are summarized below.

Previous Models

Genetic Testing

Participants discussed a model implemented by a leading pharmaceutical distribution and health care information technology company to identify, catalog, and appropriately crosswalk a wide array of genetic and molecular tests to only a handful of current procedural terminology (CPT) codes that describe a particular diagnostic service. This company began by creating a five-character unique identifier for each genetic and molecular test, analogous to the UDI. Using this identifier, the company built upon the existing payment framework of CPT and HCPCS Level II codes, enabling payers to map the new supplemental tracking codes for each molecular and genetic test to the existing more general billing codes. With several hundred new genetic and molecular tests a year, and fewer new CPT codes, participants indicated that an analogous model might be used to create a system of unique claims-based identifiers for UDIs. Each of the new UDI-linked claims-based identifiers would be reported with an appropriate, but more general CPT or HCPCS code. Thereafter, claims data repositories would be searchable for utilization analytics and recall notices.

Physician-Administered Drugs

The gradual reporting of NDCs for physician-administered drugs on medical claims was another model raised by participants. Claim standards for inpatient, outpatient, and professional claims were developed to allow for the reporting of NDCs for physician-administered drugs as an optional reporting element, however, their use was not mandated. Initially, providers were required to submit the appropriate HCPCS Level II codes but no unique identifier for physician-administered drugs was required. In implementing the NDC reporting requirement for physician-administered drugs, states, in coordination with the Centers for Medicare and Medicaid Services (CMS), allowed for a period of voluntary reporting, in which providers were encouraged to begin reporting NDCs for physician-administered drugs, but no claims were denied for lacking the code. In 2005, reporting NDCs for certain physician-administered drugs became mandatory as part of the federal Deficit Reduction Act (DRA) of 2005. The DRA expanded the Medicaid Drug Rebate Program to include physician-administered drugs. As such, Medicaid providers were required to report the NDC on outpatient and professional claims. State Medicaid programs use NDCs to reimburse claims, track utilization, and collect rebates from manufacturers; participants noted that each of these activities was enhanced with the availability of NDCs in claims, contributing to significant cost savings. Participants indicated that the initial voluntary use of NDCs on medical claims allowed providers who were ready to begin reporting NDCs for physician-

administered drugs the opportunity to do so while allowing providers who needed time to build the capabilities and workflows to report NDCs adequate flexibility. Such a phased strategy could also be successful for UDI reporting in claims.

Pilot Projects

Universal Product Number Pilot

Participants also considered the approach taken as part of a recent pilot project, the Universal Product Number (UPN) Pilot, which examined the potential for capturing UDIs in medical and pharmacy claims for certain medical supplies. Through this pilot, the California Department of Health Care Services (DHCS) sought to test the feasibility and cost-effectiveness of UDI, formerly known as UPN, as an alternative to HCPCS Level II codes, the current Health Insurance Portability and Accountability Act (HIPAA) coding standard for medical supplies. Over the course of two years, UDIs were recorded in a segment of the claim form that serves as a general product identifier field and is currently only allowed for reporting NDCs for drug identification. The medical claim form includes a separate data element that allows for the reporting of HCPCS Level II codes. During the pilot, over seven million claims were processed with UDIs, for a total of over \$600 million in provider reimbursements for devices from the following medical product categories: diabetic supplies, enteral nutrition, incontinence, ostomy, tracheostomy, urologicals, and wound care. The pilot found that UDI helped lower program costs, improve the quality of data collected, and improve patient safety along with demonstrating the potential to reduce fraud and abuse.

Despite these benefits, the pilot also found a series of challenges associated with capturing UDIs as part of claim transactions. These challenges include the lack of a single authority for UDI generation, complex and inconsistent labeling formats, lack of a federal mandate for standardized UDI use and labeling, and variable lengths and formats of existing unique identifiers. Participants indicated that many of these issues would likely be mitigated with the release of the final UDI regulation. At the close of the pilot, an evaluation was conducted to determine whether UDI met the federal criteria for adoption as a HIPAA coding standard. The evaluation found that UDI fully met eight out of 10 criteria and partially met the other two. As a result, California submitted a recommendation to the Secretary of the Department of Health and Human Services (HHS) to adopt UDI as a situational data element on institutional, professional and pharmacy claim forms to be directed for use in cases where UDI needed to be more specifically identified. HHS denied this request indicating that UDIs lacked the maturity and widespread use necessary for consideration as a HIPAA standard.

Participants suggested that broader efforts to map HCPCS codes to UDIs should begin now and emphasized the importance of this pilot in helping to establish the value and feasibility of incorporating UDI into claims processing systems. Participants discussed the possibility for UDI to be included as a situational element and the scenarios that may arise for its use. Throughout the discussion, however, it was clear that stakeholders with important roles to play in this effort would need to come together to articulate the value of UDI recording, its uses, and the situations in which UDI would need to be captured in order for successful implementation to occur.

Potential Paths Forward and Challenges to Be Considered

Incorporating UDI as a Standard within Claims

To drive adoption of UDI recording, participants put forth the possibility of incorporating UDI into the standards for claims reporting. Specifically, participants highlighted the potential for UDI recording to be included within the standards developed by the Accredited Standards Committee X12 (ASC X12). Participants stated that the industry would have to clearly articulate the business cases and uses for UDI recording within claims in order for any progress to be made in this regard. Participants outlined the three possibilities for UDI to be reported within claims and a broad timeline associated with each one. First, UDI could be reported with claims as ancillary data. This scenario would require minimal changes to the standards and could be completed within a few years. Another possibility would be if UDIs were needed as part of the claims process to reflect information important to the remittance advice. This option would require significant changes to the remittance advice and could take upwards of five to seven years to take effect. Finally, participants presented a situation in which UDI was critical to eligibility and services review determinations, in which case, UDI would need to be added as a primary coding standard within those transactions. This scenario would take the longest time to implement and would require the most significant push from industry to move it forward. In any of these situations, participants indicated that if industry clearly expressed a strong desire for UDI to be captured in claims, ASC X12 would in turn create clear, concise requirements from the articulated business

cases and present them to the Designated Standard Maintenance Organization for review. This body could then put forth a recommendation to the Secretary of HHS.

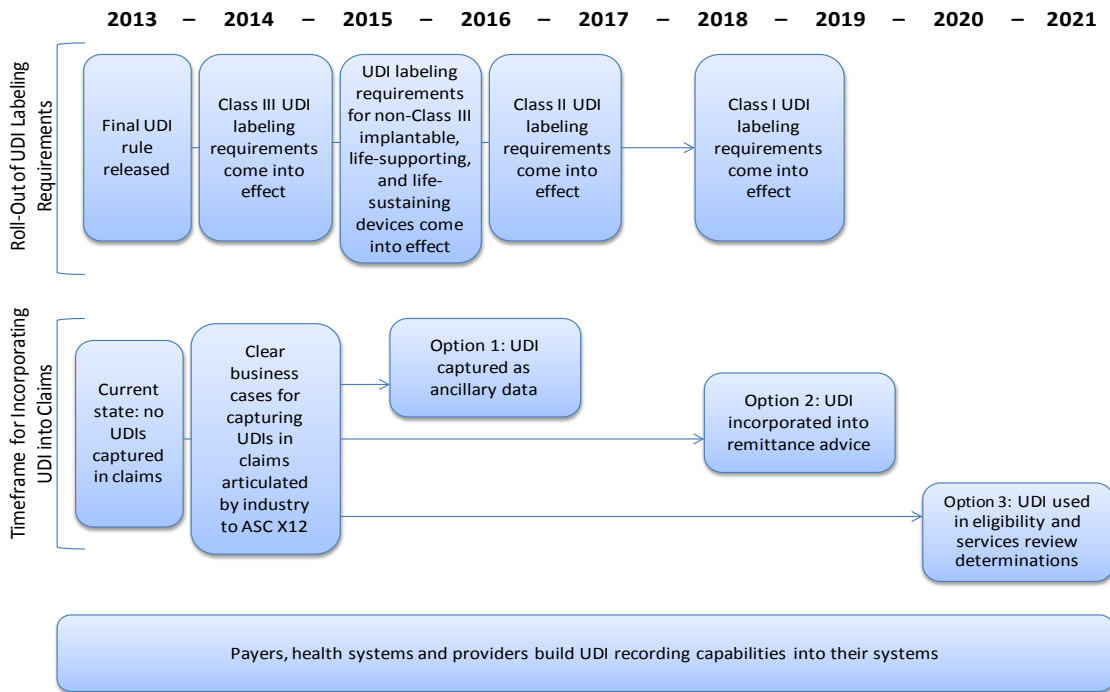
Incorporating UDI into Payer and Provider Systems

Participants also discussed the potential challenges and paths forward for building UDI recording capabilities into payer and provider systems. For payers, participants indicated that a number of factors are important to consider when building in any new data element. Latency, or the time it takes to distribute data, is an important consideration as payers think about how to dispense UDI data to the end users to enable many of the benefits described above. Additionally, time for processing the data was another important factor raised by participants to ensure that claims with UDIs are processed in a timely manner and that no information is lost in the process. Participants also stressed the importance of ensuring accuracy in the capture of UDI and careful thought regarding storage of UDI in a way that is system-readable and useful. Given large variability across payers, participants noted that payers’ implementation of UDI may not occur at one time.

Provider and health system-specific considerations for enabling UDI recording and transmission capabilities were also discussed. Participants highlighted the importance of a high-fidelity system that does not introduce data entry errors into the process. Automatic identification and data capture technology (e.g., barcodes, RFID) was cited as an important component of this effort. Additionally, participants underscored that in order for UDI to be effectively captured in claims, providers would need to adapt workflow processes to accommodate the recording. These efforts would likely involve a diverse group of stakeholders providing input to create support for such a measure and eventually facilitate its success.

The importance of these efforts happening concurrently was also discussed. Figure 1 shows an approximate potential timeline for incorporation of UDI into claims based on the meeting discussion. As shown, based on the business cases articulated by industry for capturing UDIs in claims, one of three options could be taken. Because each option will require a different length of time, it will be important to understand these associated timelines in relation to the Final Rule’s roll-out of the UDI labeling requirements and ongoing improvements to UDI recording capabilities within provider and payer systems.

Figure 1. Potential Parallel Efforts for Incorporating UDI into Claims



* Assuming release of Final UDI Rule in May 2013

Appropriate Policies for Enabling Consistent UDI Recording

Stakeholders also considered potential approaches to achieving the goal of consistent UDI recording in claims. Key points from the discussion are summarized below.

Parallel Claims and EHR Tracks

Participants emphasized that there is a primary need to find UDI a generic home within electronic data sources and suggested that claims may not be the only optimal medium to ensure UDIs are consistently recorded and can be leveraged for future use. While acknowledging the variety of benefits that UDI incorporation into claims offers, participants added that EHRs and other clinical data sources may be another important vehicle to consider in striving toward achieving the full potential of successful UDI implementation. Participants stressed the need to simultaneously pursue incorporation of UDI into claims and EHRs to ensure widespread UDI adoption by stakeholders across the medical device lifecycle. To advance this, convening a multi-stakeholder initiative on UDI to gather input for these parallel efforts was suggested.

Meaningful Integration

In order to achieve the benefits associated with UDI implementation, participants underscored the importance of enabling meaningful integration across systems. Under current system configurations at many health care delivery sites, if UDIs were included in one system there would be limited ability to transfer that information to other systems (e.g., supply chain system to EHR). Additionally, participants suggested that this lack of integration could potentially create redundancies in the system and opportunities for the introduction of errors, as UDIs would get re-entered into various systems with little to no communication within or among care delivery sites. Participants emphasized that by integrating across systems, the value of UDI implementation would be more easily demonstrated, which could assist in creating broad stakeholder support.

Next Steps

This meeting was the first of several important conversations around the potential benefits, challenges, and strategies for successful UDI implementation. Throughout the meeting, participants identified the importance of capturing UDIs in a host of data sources, including health care claims, EHRs, and other databases. The full benefits of UDIs, however, will not accrue unless broad adoption and implementation occurs across the spectrum of stakeholders. Through a variety of activities, including expert workshops and webinars, Brookings will continue to facilitate stakeholder dialogue on this topic. With input from these activities, Brookings will begin developing a framework for the UDI Implementation Roadmap, which will eventually be available for use by a range of stakeholders to support UDI implementation efforts.