Testimony before the National Committee on Vital and Health Statistics, Subcommittee on Standards

Hearing on HIPAA and ACA Administrative Simplification: Use of UDI in Administrative Transactions

June 10, 2014

Joshua P. Rising, MD, Director of Medical Devices

The Pew Charitable Trusts

Co-Chairmen Suarez and Soonthornsima, and members of the Committee, thank you for the opportunity to provide testimony on the use of the unique device identifier (UDI) in administrative transactions. My name is Josh Rising. I am a physician, and I direct medical device work at The Pew Charitable Trusts. Pew is an independent, non-profit research and public policy organization dedicated to serving the public. Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

The UDI system, developed by the Food and Drug Administration (FDA), will provide each medical device with a code corresponding to its make and model to unambiguously identify devices used in patient care. By this September, the highest-risk implanted devices will have UDIs.

As outlined by FDA in the agency's vision for postmarketing surveillance, achieving the full benefits of this UDI system requires its adoption in electronic health information—including adverse event reports, materials management systems, device registries, electronic health records (EHR) as well as administrative and claims transactions.[1,2]

UDI capture in EHRs and claims provide different and complementary benefits. If the UDI is recorded in EHRs, providers could use this information to identify patients affected by recalls, ensure appropriate care coordination and evaluate product performance in their own facilities. However, the lack of interoperability prevents the aggregation of data across EHRs, which makes it difficult for FDA or payers to use these data to assess whether there are safety problems with a particular device or class of device. Conversely, claims offer large, longitudinal data sets for such analyses—including when patients switch providers or seek care from multiple clinicians. Claims are also standardized and, therefore, easily aggregated. Claims data are already used by payers, FDA and others to evaluate drug performance, but lack information on the specific devices used in care.

There are efforts underway to incorporate UDI into EHRs, which, as stated, is important but insufficient to realize the full benefits of a UDI system.[3,4] Action is now needed to include UDI in administrative and claims transactions.

Benefits of UDI capture in claims

Creating a new field in insurance claims submitted to health plans would greatly enhance the existing medical device postmarket surveillance system to improve patient safety and care quality. Specifically, UDI capture in claims would enable:

- *Analyses by health plans*: Health plans currently pay for procedures, such as hip replacement surgery, but lack any knowledge on the precise device used. Incorporating UDI in claims will provide payers with that specificity and help them to compare outcomes across device models. Given the current challenges of accessing and integrating data from electronic health records, these data are not available elsewhere.
- *Recall assistance from health plans*: Currently, more than half of the highest-risk device recalls conclude with not all products identified or removed from the market.[5] Despite the roles of manufacturers, FDA and hospitals, far too many recalls conclude inadequately, in part because patients' contact information is not up-to-date. Health plans have expressed an interest in assisting with this deficiency by contacting beneficiaries implanted with recalled products to ensure that they receive appropriate follow-up care. Health plans do not have the necessary information without access to UDI data.
- *FDA's Sentinel Initiative*: FDA could also use claims data to conduct robust, longitudinal analyses of device safety. For example, FDA could utilize its postmarket surveillance Sentinel Initiative—which relies predominantly on claims data—to assess device safety, as required by Congress in the Food and Drug Administration Safety and Innovation Act of 2012.[6] FDA has utilized Sentinel to successfully evaluate drug and biologic safety, and the Sentinel primary investigators underscore that using this system to assess device safety is not feasible without adding UDI to claims. Sentinel provides FDA with data unavailable through other postmarket surveillance tools. Adverse event reports, for example, do not provide the agency with information on the total number of products utilized and thus cannot be used to determine the rate of device safety signals.

These business cases have been recognized from multiple sources. In response to questions from her Senate confirmation hearing, Health and Human Services Secretary Sylvia Mathews Burwell commented that the "Sentinel Initiative will ultimately benefit … by incorporating UDIs into its claims data sources."[7] Various stakeholders—including FDA, health plans and health systems—also have expressed their desire to implement these benefits.[8-11] Organizations that have sent letters supporting UDI capture in claims include Mercy health system, Geisinger health system, the Society of Thoracic Surgeons, the American College of Cardiology, Premier, Inc., the Pacific Business Group on Health, AARP, First Databank, Trust for America's Health and the Leapfrog Group. Public letters of support from some of those stakeholders are attached with this testimony.

There is a school of thought that claims are for billing adjudication purposes only. However, health plans—including Medicare and Medicaid—pay billions annually for health services involving devices. As part of paying for services, health plans should know what products they are purchasing. Including UDI in claims would provide health plans with the information necessary to make better coverage and reimbursement decisions.

The proposal under discussion for incorporating UDI into claims already addresses potential concerns that hospitals and information technology vendors would be forced to upgrade some electronic systems to capture and transmit UDI. We support a limited approach where health plans and hospitals would agree to transmit the UDI of a subset of devices. This proposal would not create a new mandate for hospitals.

It is important to emphasize again—contrary to common misconception—that not all device UDIs will be included in claims. As outlined above, the current proposal would result only in UDI capture for a subset of high risk, implanted devices that hospitals and health plans have agreed to include in claims.

Progress to-date and next steps

The work to achieve these benefits has already begun. As previously mentioned, FDA finalized the UDI regulations in September 2013. High-risk devices, including many implants, will have UDIs starting this fall. All devices will have UDIs by 2018.

The Office of the National Coordinator for Health Information Technology (ONC) has proposed new criteria to document the UDIs of implanted devices in patients' EHRs. In parallel, the Health Information Technology Policy Committee, a federal advisory committee, recommended that the Centers for Medicare & Medicaid Services (CMS) develop incentives to encourage hospitals and providers to document in patients' health records the UDIs of implanted devices.[12]

There have also been several recent efforts to incorporate UDI into administrative and claims transactions. Last summer, Pew submitted a change request to the Accredited Standards Committee X12 (ASC X12) to create a new field in claims for UDI. As ASC X12 required additional information to adjudicate this request, Pew commissioned the Workgroup for Electronic Data Interchange (WEDI) Foundation to convene stakeholders and obtain public input to develop a white paper outlining the business case for including UDI in claims. The WEDI Foundation recommended the creation of a new field in claims to support the capture and transmission of the UDI for high-risk, implanted medical devices. This white paper, attached to this testimony, was completed and submitted to ASC X12 in April.

Earlier this month, ASC X12 began considering this topic and voted to continue examining the business case for UDI capture. ASC X12 will now assess how to achieve the stated benefits, and whether UDI capture in claims or another transaction—such as the claims attachment or a different form—is most appropriate. While we are open to considering UDI capture in administrative transactions other than claims, claims are a standardized, proven vehicle for achieving the benefits.

In contrast, claims attachments are not standardized and can include unstructured data, which could prevent electronic systems—such as payers' internal databases and the Sentinel system—from utilizing the UDI. While CMS is required to finalize claims attachment standards, the agency has not issued a proposed rule. Additionally, hospitals submit claims attachments in only a subset of claims. Including a field for UDI on a claims attachment would require providers to submit an additional form that they

may not otherwise transmit, thus increasing the burden. Considering these issues, the actual claim appears more suited to achieve the UDI system's benefits.

In its role as an advisor to the Secretary of Health and Human Services, the National Committee on Vital and Health Statistics (NCVHS) should support the adoption of UDI in claims and administrative transactions. This is an essential next step to develop the data necessary to evaluate device performance in large patient populations and achieve other key benefits.

In addition to recommending UDI capture in claims, you should also support UDI adoption and implementation throughout health care delivery, including in materials management, health records, charge capture, billing and claims systems. Given that UDI integration throughout health care delivery is still in its infancy, the Department of Health and Human Services should—working with providers, device manufacturers, distributors, insurance companies and other health care stakeholders—develop a plan to promote the adoption and nationwide exchange of UDI data to improve patient care. In particular, CMS, which has access to large amounts of data, should participate in the development of this plan, especially regarding UDI integration into claims.

Ultimately, capturing the UDI of a small subset of high-risk, non-dental implants in claims can provide the necessary data to greatly improve patient care, postmarket surveillance and recall resolution in a manner that takes into account implementation challenges.

I thank the committee for its leadership. Should you have any questions, do not hesitate to contact me at jrising@pewtrusts.org or 202.540.6761.

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[1] U.S. Food and Drug Administration. Strengthening our National System for Medical Device Postmarket Surveillance. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/UCM301924.pdf. Accessed February 6, 2014.
[2] Gross TP, Crowley J. Unique Device Identification in the Service of Public Health. N Engl J Med. 2012; 367:1583-1585.
[3] Wilson NA, Drozda J. Value of Unique Device Identification in the Digital Health Infrastructure. JAMA. 2013;309(20):2107-8.
[4] Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; NPRM. 45 Fed Reg 170, 2014.
[5] U.S. Government Accountability Office. FDA Should Enhance Its Oversight of Recalls. GAO-11-468. June 2011.
[6] The Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, 126 Stat. 993. July 9 2012.
[7] 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.
[8] America's Health Insurance Plans. Comments to FDA on the Unique Device Identifier Proposed Rule. November 7, 2012.
[9] Geisinger Health System. Geisinger Direction and Support of UDI on Claims Form. June 3, 2014.
[10] Kaiser Permanente. Comments to FDA on the Unique Device Identifier Proposed Rule. November 7, 2012.
[11] Mercy Health, Inc. Mercy Direction and Support of UDI on Claims Form. April 3, 2014.
[12] Health Information Technology Policy Committee. Transmittal Letter from HIT Policy Committee to the National Coordinator for Health Information Technology. April 1, 2014.

May 29, 2014

Karen DeSalvo, MD, MPH, MSc, National Coordinator for Health Information Technology
Margaret Hamburg, MD, Commissioner, Food and Drug Administration
Marilyn Tavenner, RN, MHA, Administrator, Centers for Medicare & Medicaid Services

RE: A new field in claims for the Unique Device Identifier for certain, high-risk implants.

Dear National Coordinator DeSalvo, Commissioner Hamburg and Administrator Tavenner:

We are writing to strongly support the creation of a new field in health insurance claims for capturing and transmitting the unique device identifier (UDI) to health plans from hospitals. Incorporating UDI into claims will deliver significant benefits to providers, health plans and, most importantly, patients.

The UDI system, developed by the Food and Drug Administration (FDA), will provide each medical device with a code corresponding to its make and model to unambiguously identify devices used in patient care. By this September, the highest-risk implanted devices will be marked with UDIs. As outlined by FDA, achieving the full benefits of this UDI system requires its adoption in electronic health information—including adverse event reports, materials management systems, device registries, electronic health records (EHR) and claims transactions.[1,2]

The Office of the National Coordinator for Health Information Technology (ONC) is already taking steps to incorporate UDI into EHRs. This is important but insufficient to realize the full benefits of a UDI system.[3,4] Creating a new field in health insurance claims submitted to health plans would provide the large data sets necessary to assess patient outcomes associated with specific devices to improve patient safety and care quality. Specifically, UDI capture in claims would enable:

- *Analyses by health plans*: Health plans—including Medicare and Medicaid—currently pay for procedures such as hip replacement surgery, but lack knowledge on the precise device used. Incorporating UDI in claims will provide payers with that specificity and help them to compare outcomes across device models.
- *Recall assistance from health plans*: Currently, more than half of the highest-risk device recalls conclude without all products identified or removed from the market.[5] Despite the roles of manufacturers, FDA and hospitals, far too many recalls conclude inadequately, in part because patients' contact information is not up-to-date. Health plans have expressed an interest in assisting with this deficiency by contacting beneficiaries implanted with recalled products to ensure that they receive appropriate follow-up care.
- *FDA evaluations of device safety*: FDA could also use claims data to conduct robust, longitudinal analyses of device safety. For example, FDA could utilize its postmarket surveillance Sentinel Initiative—which relies predominantly on claims data—to assess device safety, as required by Congress in the Food and Drug Administration Safety and Innovation Act of 2012.[6] FDA has utilized Sentinel to successfully evaluate drug and biologic safety, and the Sentinel primary investigators underscore that using this system to assess device safety is not feasible without adding UDI to claims.

These business cases are not hypothetical. Various stakeholders—including FDA, health plans and health systems—have expressed their desire to implement these benefits.[7]

There is a school of thought that claims are for billing adjudication purposes only. However, health plans—including Medicare and Medicaid—pay billions annually for health services involving devices. As part of paying for services, health plans should know what products they are purchasing. Including UDI in claims would provide health plans with the information necessary to make better coverage and reimbursement decisions.

The proposal under discussion for incorporating UDI into claims already addresses potential concerns that hospitals and information technology vendors would be forced to upgrade some electronic systems to capture and transmit UDI. We support a limited approach where health plans and hospitals would agree to transmit the UDI of a subset of devices. Under this proposal, health plans and hospitals could contractually decide to transmit the UDI; this proposal would not create a new mandate for hospitals. Additionally, the proposal does not include UDI capture for all devices, but rather only for a small subset of high-risk, implanted, non-dental medical devices.

It is important to emphasize again—contrary to common misconception—that not all device UDIs will be included in claims. As outlined above, the current proposal would result only in UDI capture for a subset of high risk, implanted devices that hospitals and health plans have agreed to include in claims.

There will be two upcoming discussions on UDI capture in claims. First, the Accredited Standards Committee X12—which helps establish the standards for electronic claims data standards—will evaluate UDI capture. Second, the National Committee on Vital and Health Statistics will hold a June 10 hearing on this topic, and may—as a formal advisor to the Secretary of Health and Human Services—issue a recommendation.

We urge you to develop a coordinated effort across the Department of Health and Human Services to ensure UDI adoption throughout health care delivery. FDA has taken the first step to achieve the benefits of UDI through the release of the final rule; additional steps are necessary from ONC, CMS and potentially other agencies to reap the benefits of this new system.

Ultimately, capturing the UDI of a small subset of high-risk, non-dental implants in claims can provide the necessary data to greatly improve patient care, postmarket surveillance and recall resolution in a manner that takes into account implementation challenges.

Should you have any questions or if we can be of assistance, please contact Josh Rising, director of medical devices at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

American College of Cardiology
First Databank
Mercy

Pacific Business Group on Health
The Leapfrog Group
The Pew Charitable Trusts
Trust for America's Health

[1] U.S. Food and Drug Administration. Strengthening our National System for Medical Device Postmarket Surveillance. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/UCM301924.pdf. Accessed February 6, 2014.
[2] Gross TP, Crowley J. Unique Device Identification in the Service of Public Health. N Engl J Med. 2012; 367:1583-1585.
[3] Wilson NA, Drozda J. Value of Unique Device Identification in the Digital Health Infrastructure. JAMA. 2013;309(20):2107-8.
[4] Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; NPRM. 45 Fed Reg 170 (2014).
[5] U.S. Government Accountability Office. FDA Should Enhance Its Oversight of Recalls. GAO-11-468. June 2011.
[6] The Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, 126 Stat. 993 (Jul. 9 2012).
[7] America's Health Insurance Plans. Comments to FDA on the Unique Device Identifier Proposed Rule. November 7, 2012.

April 7, 2014

Margaret Weiker
Chair, X12N
The Accredited Standards Committee X12
8300 Greensboro Drive
Suite 800
McLean VA 22102

RE: Transmission of the Unique Device Identifier for certain, high-risk non-dental implants.

Dear Ms. Margaret Weiker,

We are writing to voice our support for the effort to create a new situational field in claims for capturing and transmitting the unique device identifier (UDI) to health plans. Creating this field would advance several key public health objectives, including facilitating recalls and identifying high-risk implanted devices with safety problems.

The UDI system, developed by the Food and Drug Administration (FDA), will provide each medical device with a code corresponding to its make and model in order to unambiguously identify devices used in patient care. By this September, the highest-risk implanted devices will be marked with UDIs. Achieving the full benefits of this UDI system, though, requires its adoption in electronic health information—including adverse event reports, materials management systems, device registries, electronic health records (EHR) and claims transactions.[1,2]

There are already steps underway to incorporate UDI into these systems.[3] For example, some hospitals are already integrating UDI into their supply chain management. Additionally, the Office of the National Coordinator for Health Information Technology has proposed new standards that would create a list of implanted devices in patients' electronic health records.[4]

As part of efforts to support UDI adoption throughout the health system, The Pew Charitable Trusts submitted a request to your committee to create a new field to identify devices implanted in patients and pledged to update that request with a more detailed business case. The WEDI Foundation has now developed that business case based on a multi-stakeholder effort to obtain feedback from hospitals, health plans, government regulators, physicians and other health care stakeholders.

Through this process, WEDI identified several business cases for UDI transmission, including:

- *Analyses by health plans*: Health plans currently pay for procedures such as hip replacement surgery, but lack any knowledge on the precise device used. Incorporating UDI in claims will provide payers with that specificity and help them to compare outcomes across device models. The documentation of UDI in claims would offer large, longitudinal data sets for these analyses—including when patients switch providers or seek follow up care from a physician that did not implant a device. Given the current challenges of accessing and integrating data from electronic health records, this data is not available elsewhere.

- *Recall assistance from health plans*: Currently, more than half of the highest-risk device recalls conclude without all products identified or removed from the market.[5] Despite the roles of manufacturers, FDA and hospitals, far too many recalls conclude inadequately, in part because patients' contact information is not up-to-date. Health plans have expressed an interest in assisting with this deficiency by contacting beneficiaries implanted with recalled products to ensure that they receive appropriate follow-up care. Health plans do not have the necessary information without access to UDI data.
- *FDA's Sentinel Initiative*: FDA could also use claims data to conduct robust, longitudinal analyses of device safety. For example, FDA could utilize its postmarket surveillance Sentinel Initiative—which relies predominantly on claims data—to assess device safety, as required by Congress in the Food and Drug Administration Safety and Innovation Act of 2012.[6] FDA has utilized Sentinel to successfully evaluate drug and biologic safety, and the Sentinel primary investigators underscore that using this system to assess device safety is not feasible without adding UDI to claims. Sentinel provides FDA with data unavailable through other postmarket surveillance tools. Adverse event reports, for example, do not provide the agency with information on the total number of products utilized and thus cannot be used to determine the therefore the rate of device safety signals.
- *Enhanced use of registries*: Registries—large databases that contain detailed data on patients and interventions—often only collect information for short periods of time, such as until the patient is discharged from the hospital. Integrating registries with UDI data from claims would enhance long-term analyses of patient outcomes.

These business cases are not hypothetical. Various stakeholders—including FDA, health plans and health systems—have expressed their desire to implement these benefits. For example, AHIP states in comments on UDI: "*Health plans have long used administrative claims information to evaluate patterns of care, identify missed opportunities, assess effectiveness, and monitor product safety. Given health plans' ability to aggregate administrative claims data and analyze trends using this data, much could be learned about the safety and effectiveness of particular devices with inclusion of UDI information*."[7]

While one way to achieve these benefits may be through direct transmission of UDI to health plans from patients' electronic medical records, these systems cannot currently support this capability and it is unclear how long it would take to build such a capacity. On the contrary, the claims infrastructure is already developed to support the transmission of UDI to payers to achieve these benefits.

We recognize, though, that hospitals would still need to upgrade some electronic systems to capture and transmit UDI and that any approach should account for this challenge. We also believe that the transmission of all device UDIs is not appropriate or necessary. Instead, UDI capture and transmission should be focus on a small subset of high-risk, implanted, non-dental medical devices.

Therefore, we support a limited approach that would require health plans and hospitals to agree to transmit the UDI. Under this situational rule, health plans and hospitals could contractually agree to transmit the UDI. This approach would ensure that each hospital agreed to transmit this data and that health plans desired this information. This situational rule would also support pilot projects where

individual health plans and hospitals interested in UDI transmission will choose to collect this data. There are many ways to draft a situational rule that would accomplish this objective.

Ultimately, capturing the UDI of a small subset of high-risk, non-dental implants in claims can provide the necessary data to greatly improve patient care, postmarket surveillance and recall resolution in a manner that takes into account implementation challenges. A targeted, limited approach that focuses on high-risk implants and supports pilot projects for those interested will meet that goal.

Should you have any questions or if we can be of assistance, please contact Josh Rising, director of medical devices at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

AARP
The Leapfrog Group
The Pacific Business Group on Health
The Pew Charitable Trusts
The Society of Thoracic Surgeons
Trust for America's Health

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[1] U.S. Food and Drug Administration. Strengthening our National System for Medical Device Postmarket Surveillance. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/UCM301924.pdf. Accessed February 6, 2014.
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[3] Wilson NA, Drozda J. Value of Unique Device Identification in the Digital Health Infrastructure. JAMA. 2013;309(20):2107-8.
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[6] The Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, 126 Stat. 993 (Jul. 9 2012).
[7] America's Health Insurance Plans. Comments to FDA on the Unique Device Identifier Proposed Rule. November 7, 2012.

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Deborah Petretich Templeton, RPh, MHA
Chief

GEISINGER
HEALTH SYSTEM

June 3, 2014

ASC X12
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Geisinger Direction and Support of UDI on Claims Form:

For many years, Geisinger has been supporting the adoption and use of GS1 Standards through its collaboration and partnership with the Healthcare Transformation Group. Geisinger has demonstrated that the use of a single standard in healthcare can improve patient safety, and the efficiency of supply chain transactions, and recall management.

A core component of the implementation of the GS1 Standards is a single product identifier, the Global Trade Item Number (GTIN). Last year the FDA released regulations that require manufacturers to apply a Unique Device Identifier (UDI) to their products. Geisinger has advocated that the GTIN be utilized as the UDI and has worked closely with its top 20 suppliers to ensure adoption. Currently all top 20 suppliers are either compliant or have plans to be compliant with the standard.

As application of the UDI in healthcare takes hold and suppliers, providers, and industry partners begin to understand its far reaching value around patient safety, outcomes based analysis, recall management, and device surveillance, another important area is gaining industry attention: UDI on the billing claims form submitted to payors. One reason for this attention is that the billing claims form and the data it contains are common among all providers and inclusion of the UDI would provide a comprehensive dataset that could be used for outcomes based analysis and device surveillance - particularly when combined with clinical data from the electronic health record. One of the challenges that all providers experience is tracking outcomes when a patient is provided care across many networks. Most providers are limited to data within their own network and the data for care provided outside of their network are not available. Claims data bridge that gap and allow providers to see all the care activities provided to a patient.

Geisinger supports and will actively advocate for the use of the UDI on the billing claims form but there are some important considerations with respect to that support:

1. The primary purpose of inclusion of the UDI on the claims form is for outcomes based analysis and device surveillance. It's unclear, at this point in the discussions, how this data will be made available to providers and

Geisinger's support is based on the end goal of available access. Part of the process should include a data rights agreement that has provisions for access.

2. Programmatic changes to provider systems to support the use and transmission of the UDI on the claims form will take time. We recommend a three year period for required adoption by providers.
3. The process and system changes required to support UDI on the claims form will potentially be expensive for providers to adopt. It is our belief that the short term cost of change will be minor compared to long term benefits. The information that will be available will reduce operational cost and enable providers to drive clinical practice toward the highest quality and lowest cost options.

As a provider of health care, Geisinger is committed to initiatives that have the potential to improve the quality of care of those we serve and to lower our operational cost. We see the addition of the UDI on the claims form as such an initiative and we will actively support its adoption in healthcare.

Sincerely,

Deborah Petretich Templeton, RPh, MHA
Chief, Care Support Services

Mercy Direction and Support of UDI on Claims Form:

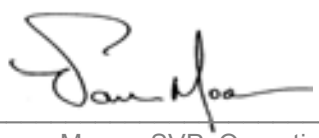
Mercy Health, Inc., ("Mercy") through its collaborative partnership with the Healthcare Transformation Group, supports the adoption and use of GS1 Standards. The use of the GS1 single standard improves the efficiency of supply chain transactions, patient safety and recall management.

A core component of the GS1 Standards is the implementation of a single product identifier, referred to as the Global Trade Item Number ("GTIN"). Last year the FDA released regulations that require manufacturers to apply a Unique Device Identifier (UDI) to products. Mercy requires a GTIN be utilized as the UDI and has worked closely with its suppliers to ensure compliance. Mercy's usage of UDI has shown positive impacts on patient safety, ability to provide outcomes based analysis, monitor recall management, and device surveillance.

Further, the use of a UDI on the billing claims form submitted to payors would allow for a comprehensive dataset. A single UDI, when combined with clinical data, would allow for outcomes based analysis and device surveillance. Providers face significant challenges in tracking outcomes when a patient is provided care across many networks because data is limited to that within their own network. Single use of a UDI allows for a claims data bridge allowing providers to review a complete health record of the care provided to a patient. Mercy supports the use of the UDI on the billing claims form, with the following considerations:

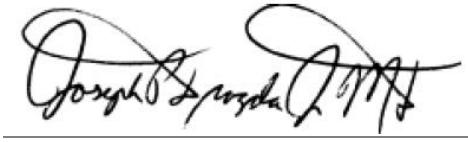
1. The primary purpose of inclusion of the UDI on the claims form is for outcomes based analysis and device surveillance. It is unclear, at this point in the discussions, how this data will be made available to providers. A data rights agreement that has provisions for access should be included.
2. Programmatic changes to provider systems supporting the use and transmission of the UDI on the claims form will required a phased approach. Mercy recommends a three (3) year period for required adoption by providers.
3. The process and system changes required to support UDI on the claims form will require providers to financially invest in infrastructure. Mercy suggests that this cost-benefit analysis provides long term benefits. Information available under the UDI on claims will reduce operational cost and enable providers to drive clinical practice toward the highest quality and lowest cost options.

Mercy is committed to initiatives that improve the quality of care and reduce operational cost. The addition of the UDI on the claims form advances this goal and we support its adoption.



04/03/2014

Vance Moore, SVP, Operations Date
Mercy Health System



04/03/2014

Dr. Joseph Drozda, Dir., Outcomes Research Date
Mercy Health System

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PREMIER TRANSFORMING HEALTHCARE TOGETHER™

April 9, 2014

Ms. Margaret Weiker
Chair, X12N
The Accredited Standards Committee X12
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RE: Transmission of the Unique Device Identifier in Claim

Dear Ms. Weiker:

We are writing to express our support for updated standards to enable the capture and transmission of the new unique device identifier (UDI) system in the claims transaction.

Premier, Inc. (NASDAQ:PINC) is a leading healthcare improvement company, uniting an alliance of more than 2,900 U.S. hospitals and nearly 100,000 other providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Premier, a Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide.

As you are aware, the Food and Drug Administration's (FDA) UDI system will provide each medical device with a code corresponding to its make, model and other clinically relevant information, such as expiration date. This UDI system will significantly improve public health and patient care by enhancing recall resolution and enabling more sophisticated postmarket surveillance. However, the full public health and patient safety benefits of this new device identification system are only possible through UDI capture and transmission throughout healthcare delivery—including in electronic health records, adverse event reports, supply chain systems and claims.

Unlike many other information sources, claims offer large, standardized data sets for analysis. They also support longitudinal analyses on patient outcomes across multiple providers. For example, often,

patients seek follow-up care for implanted devices from providers that did not implant the device. Claims data would capture both the procedure and the patient outcome.

UDI capture in claims is also the most efficient and effective method that will add to the FDA's Sentinel Initiative—post market surveillance system that relies predominantly on claims data—to assess device safety. The FDA has only been able to utilize Sentinel to enhance drug safety, and Congress ordered the FDA in 2012 to use this system for devices.

We urge ASC X12 to support the development of a new field in claims to allow hospitals to transmit the UDIs to health plans, especially for those high-risk implants, which will enable transparency in data necessary to greatly improve patient care and outcomes.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier, Inc.

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March 28, 2014

Margaret Weiker
Chair, X12N
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RE: Transmission of the unique device identifier in claims.

Dear Ms. Margaret Weiker,

As members of the Patient, Consumer, and Public Health Coalition, which includes groups representing physicians, scientists, consumers, and patients, we are writing to express our strong support for updated standards that will enable the capture and transmission of the new unique device identifier (UDI) system in the claims transaction.

The Food and Drug Administration's (FDA's) UDI system will provide each medical device with a code corresponding to its make, model, and other clinically relevant information. This UDI system will significantly improve public health and patient care by enhancing recall resolution and enabling more sophisticated postmarket surveillance.

However, the full public health and patient safety benefits of this new device identification system are only possible through UDI capture and transmission throughout the healthcare delivery system (including in electronic health records, adverse event reports, supply chains, and claims).

Unlike many other information sources, claims records offer large, standardized data sets for analysis. They also support longitudinal analyses on patient outcomes across multiple providers. For example, patients often obtain follow-up care for implanted devices from providers that did

not implant the device. Claims data would capture both the procedure and the patient outcome (such as whether and when a patient needed revision surgery). Thus, the FDA, payors and clinicians can utilize UDI data captured in claims to improve information about device safety and efficacy.

UDI capture in claims is an efficient and effective method to utilize FDA's Sentinel Initiative to assess device safety. The FDA's Sentinel postmarket surveillance system relies predominantly on claims data. Without UDI data, the FDA has only been able to utilize Sentinel to evaluate drug safety, but not device safety. However, Congress ordered FDA in 2012 to use Sentinel for devices and is requiring devices to have UDIs.

UDI capture in claims will allow health plans to conduct robust analyses on device quality and ensure that beneficiaries obtain appropriate follow-up care in the event of a recall. America's Health Insurance Plans cited these benefits in comments to FDA, and Kaiser Permanente has stated that UDI should be utilized as a more precise alternative to the Healthcare Common Procedure Coding System.

Also registries currently collect detailed data on patients for initial, short-term outcomes. Adding UDI to claims will make it easier for registries to track long-term patient outcomes associated with specific technologies.

While the public health and business benefits are clear, UDI capture should be prioritized for higher-risk and implantable devices first. This approach would minimize the burden on hospitals while ensuring that the benefits of UDI are achieved for patients receiving devices that inherently have higher risks.

We strongly urge ASC X12 to support the development of a new field in its claims records to allow hospitals to transmit the UDIs of higher-risk and implanted devices to health plans. This decision will have major implications for the health of individual patients, for public health, and for the efficiency and effectiveness of our healthcare system.

American Medical Student Association
Center for Medical Consumers
Connecticut Center for Patient Safety
Consumers Union
National Physicians Alliance
National Research Center for Women & Families
National Women's Health Network
Public Citizen
The TMJ Association
Center for Science and Democracy at the Union of Concerned Scientists
WomenHeart
WoodyMatters

For more information, contact Paul Brown at (202) 233-4000 or pb@center4research.org

Unique Device Identifiers:
Facilitating the Capture and Transmission of UDI

April 7, 2014

Prepared by:

NOTICE: The project that is the subject of this report was approved by the Workgroup for Electronic Data Interchange Foundation (The WEDI Foundation). The WEDI Foundation, formed in 2004, is a multi-stakeholder charitable non-profit dedicated to scientific research and education in order to foster the improvement of administrative and clinical healthcare information exchange.

Additional copies of this report are available from Leanne Cardwell at lcardwell@wedi.org.

For more information about the Workgroup for Electronic Data Interchange Foundation, visit the WEDI home page at: www.wedi.org

Acknowledgments

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Contents

Executive Summary

Medical technology and devices deliver remarkable advances in the health and care of individuals; however, the full risks and effectiveness of medical devices are not completely known because of the lack of a robust postmarket surveillance system in the United States. Without an effective system to gather and share the unique identification of devices, conducting recalls or understanding device performance is difficult.

To address this problem, the U.S. Food and Drug Administration (FDA) is establishing the new unique device identifier (UDI) system, which will provide each device with a unique number corresponding to its make, model, and other clinically relevant information, such as lot number and expiration date. Manufacturers of high-risk implantable devices will begin including the UDI on product packaging in September 2014. In a phased approach over the next several years, labels on virtually all devices will be required to contain the UDI. The true benefits will be realized with the capture and transmission of UDI throughout healthcare to evaluate device performance and conduct device recalls.

The medical device postmarket surveillance system should quickly identify poorly performing devices, accurately characterize and disseminate information about real-world device performance, including the clinical benefits and risks of marketed devices, and efficiently generate data to support premarket clearance or approval of new devices and new uses of currently marketed devices (FDA, 2012). Unfortunately, the current system does not accomplish any of these objectives.

CHALLENGE

Determine the best option for transmitting the UDI for non-dental high-risk implants among stakeholders to achieve the full benefits of a quality medical device postmarket surveillance system without adding significant cost and complexity

To address this challenge, WEDI conducted a series of meetings involving multiple stakeholders from the healthcare industry to discuss the many facets of postmarket surveillance with particular focus on the transmission of UDI from providers to payers. The focus of these discussions was high-risk implanted devices only[1]. UDI transmission is not cost-effective, nor necessary, for all devices. Only those devices that are prone to failure and would cause substantial harm to patients should have the UDI transmitted. High-risk, implanted medical devices fit that definition.

The outcome of the discussions was recognition that a hybrid approach would be the optimum solution to enable the UDI to become an integral component of the postmarket surveillance system in the United States.

[1] Refers to non-dental devices

This hybrid approach would include:

- Developing provider system capabilities to capture and electronically integrate the UDI into their internal systems so the UDI is available within their clinical systems, supply chains, and administrative systems

- Implementing reporting registries to consolidate device information, including UDI, from facilities

- Adding UDI as an optional field, via a situational rule to the ASC X12N standards, to enable providers and payers to transmit and use the UDI of high risk implants on a voluntary basis

- Deploying pilots with support of the Food & Drug Administration (FDA) that test and demonstrate UDI being transmitted between the critical entities (e.g., provider to payer, provider to registry, etc.) to evaluate the transmission methods.

Background

Legislative and Regulatory History

In 2007, Congress passed legislation that directed the FDA to issue regulations establishing a UDI system for medical devices to provide early detection of defective devices and facilitate device recalls to enhance patient safety and reduce medical errors. In 2013, the FDA issued regulations establishing this UDI system. The stated purpose of the regulations was to initiate improvements in the postmarket surveillance program for medical devices by assigning a unique identifier to each medical device. The UDI legislation required the publication and storage of UDI medical device information in a single FDA database accessible to the public. The Global UDI Database (GUDID) administered by the FDA will be used to meet this requirement. The labeler of the device, which in most cases is the device manufacturer, is required to submit data on the device to the GUDID to serve as a reference catalog for every product with an identifier. GUDID will not contain any information on patients or providers. The FDA intends for the GUDID to operate in a manner similar to the National Drug Code (NDC) database and to provide many of the same benefits.

Components of UDI

The UDI is a code on each device label, package, and/or device itself that is comprised of two parts. The first part is the device identifier (DI). The DI is static and identifies the version or model of the device, and will be included in the GUDID. The second part is the production identifier (PI). The PI is dynamic and distinguishes the device by listing the lot or batch number, serial number, manufacturing date, and expiration date.

UDI numbers will be assigned by issuing agencies accredited by the FDA (e.g., GS1, Health Industry Business Communications Council (HIBCC), and the International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA)) and created and maintained by the manufacturer of the device.

The UDI will be both human readable and encoded in automatic identification and data capture (AIDC) technology. To ensure maximum efficiency and to reduce errors associated with manual recording of the lengthy field, the UDI should be scanned and transmitted electronically.

Overview of FDA's Sentinel Program

The FDA developed the Sentinel Initiative to comply with the Food and Drug Administration Amendments Act of 2007, which required the FDA to collaborate with public, academic, and private entities to develop methods for obtaining access to disparate healthcare data sources and to analyze healthcare safety data. In 2012, Congress directed the FDA to expand Sentinel to include devices.

Sentinel is built upon a secure network portal that enables the FDA to issue requests to participating health plans and aggregate the data—primarily from claims—that are returned. The source data gives access to 382 million person-years of observation time, 3.7 billion dispensings, 4.1 billion unique encounters, 46 million acute inpatient stays, and 24 million people with one or more laboratory test result.

By working with the participating payers, Sentinel was used to successfully investigate safety concerns with drugs. For example, FDA used Sentinel to assess reports and risks of serious bleeding events regarding the anticoagulant Pradaxa (dabigatran) (FDA, 2012). Through the Sentinel analysis of insurance claims, the FDA was able to issue a safety announcement on this drug. Similarly, using Sentinel, the FDA conducted an analysis of the rotavirus vaccine that resulted in approval of revisions to

the prescribing information and patient information for RotaTeq (FDA, 2013). Because Sentinel relies on claims data from payers, including the UDI in the claim could enable the FDA to utilize Sentinel to conduct assessments and analyses on medical devices and outcomes in a manner similar to the analyses conducted on Pradaxa and RotaTeq.

Existing UDI Pilot Projects

Pilot projects attempting to utilize existing device data are underway in several payer and provider organizations, including a payer that is conducting a pilot specifically focused on device recalls where information on the device implanted is sent from the provider to the payer. As the payer will be publishing the results of the pilot, the company has chosen not to be named at this time.

In addition to the payer pilot focused on device recalls, two other pilot projects that have results regarding the technical feasibility, business value, and cost effectiveness of capturing and transmitting UDI are:

- Mercy Health System UDI demonstration project
- California Medicaid UDI pilot project

Mercy Health System UDI Demonstration Project

In 2012, Mercy Health System began a demonstration project to implement a coronary artery stent UDI-based surveillance system using the electronic health records (EHRs) in a multi-hospital system. Mercy initially created its own internal UDI using the manufacturer and device code numbers, since manufacturers are not required to implement UDI until September 2014.

Mercy found the following benefits by capturing UDI in their EHR, billing, and supply chain systems (Drozda, 2013):

- The ability to determine the most effective stents in different patient situations
- Operational efficiencies in the various departments that use device data in the integrated technology systems by using scanning devices to reduce manual entry and by having the device data readily available within each department for use and analysis by the medical staff
- Cost savings through the reduction of the medical devices inventory and the use of automated re-ordering

California Medicaid (Medi-Cal) UDI Pilot Project

In June 2009, the California Medicaid Program (Medi-Cal) commenced a two-year pilot that required participating providers to submit the universal product number (UPN), a unique number that a manufacturer assigns to its products, as part of the claim for reimbursements. The UPN was used for the Medi-Cal project because the UDI did not yet exist. For this project, Medi-Cal used the HCPCS code field in the ASC X12 claim transaction with a situational provision to transmit the UPN. The HCPCS field cannot be used to transmit the UDI in the future, because the field is not large enough to hold the UDI, and the situational provision was only approved for this Medi-Cal pilot.

During the pilot, Medi-Cal processed seven million claims and $600 million in provider reimbursements that resulted in the following (DHCS, 2011) (Watson and Rivera, 2012):

- $30 million savings in supply contracting

- Lower operational costs for Medi-Cal and providers because of faster, more accurate adjudication and elimination of the need to request additional information on claim attachments
- Enhanced identification of claims data by specific product attributes, such as manufacturer name and product functionality
- Better control in the determination of medical necessity, rate setting, establishment of utilization controls, preparation of fiscal reports, and monitoring of healthcare outcomes
- Greater accountability with the providers and manufacturers
- Improved identification and removal of defective products from Medi-Cal's list of covered benefits

Acknowledging that costs would be incurred with changing processes and systems to include UDI, the experiences from pilot projects indicate that the potential benefits for providers and payers outweigh the costs.

Surveillance Challenge

The full risks and effectiveness of medical devices are not completely known because of the lack of a robust postmarket surveillance system in the United States. Without an effective system to gather and share the unique identification of devices, conducting recalls or understanding device performance is difficult.

The medical device postmarket surveillance system should (FDA, 2012):

- Quickly identify poorly performing devices
- Accurately characterize and disseminate information about real-world device performance, including the clinical benefits and risks of marketed devices
- Efficiently generate data to support premarket clearance or approval of new devices and new uses of currently marketed devices

The current postmarket surveillance system is flawed, but UDI will provide a new tool for strengthening existing data sources that are or could be used to assess device safety and to recall products. In some cases, additional actions are needed to integrate UDI into these data sources.

Given the deficiencies in device postmarket surveillance and the new opportunity afforded by the new UDI regulations to generate improvements, the WEDI Foundation assessed the current strengths and weaknesses of various data sources and analyzed how to effectively integrate UDI through its capture and transmission.

Postmarket Surveillance

There are four primary data sources that are or could be used to conduct device postmarket surveillance:

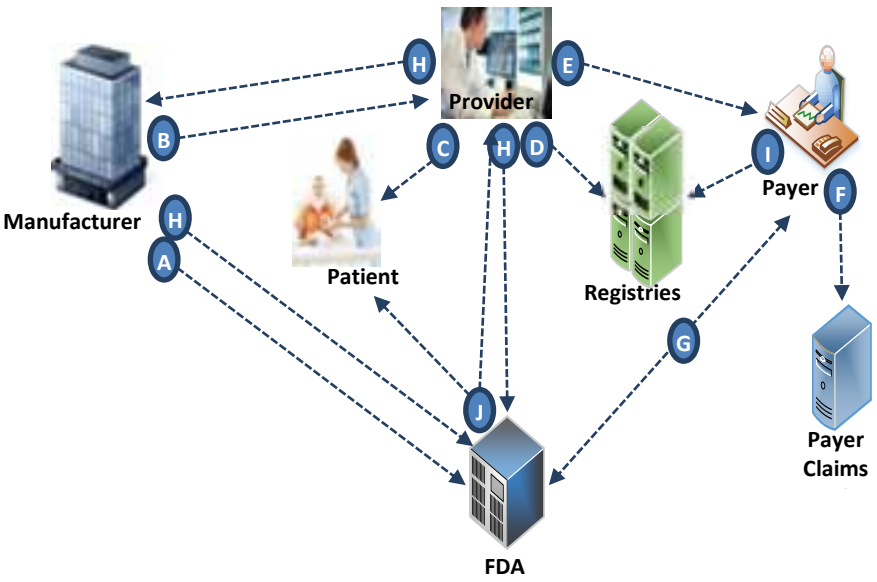
- Adverse Event Reporting System (AERS) is a combination of voluntary reporting of health event issues and the mandatory reporting of possible device-associated serious injuries, deaths, and malfunctions.

- EHRs contain patient data at the individual provider level. Most EHRs currently lack information on devices used in patient care, though there are early-stage efforts to include UDIs in patient records to support recall resolution and care coordination.
- National and international device registries are created and maintained on specific devices of interest by private organizations. An example of such a registry is the National Cardiovascular Data Registry operated by the American College of Cardiology.
- Claims and administrative transactions transmitted from provider to payer may be accessed and aggregated through the FDA Sentinel System (for drugs and biologics) and for analysis by each payer individually. Today, claims lack information on the device used and therefore cannot be utilized for postmarket surveillance. An existing example of using claims is the work currently done assessing drug safety.

Each of these potential sources serves a specific role within the postmarket surveillance system and has its own strengths and weaknesses, which are identified in the following table.

SOURCE	AERS	EHRs	REGISTRIES	CLAIMS
ROLE in POSTMARKET SURVEILLANCE	Identifies some safety concerns for FDA	Identifies patients with recalled devices; could be used in other analyses, but significant interoperability challenges exist	Assesses questions associated with specific procedures involving medical devices	Tracks patient longitudinal records and analysis of large data sets to identify safety signals
STRENGTHS	A process currently exists FDA receives a large number of reports Patients and providers can submit reports	Most large medical centers currently use EHRs Detailed clinical information on patients is maintained No time lag exists for providers to access this data	Contents include very focused and detailed information on the product, procedure, and patient Each registry addresses a very specific focus Registries consolidate data from individual reporting institutions	A transmission process currently exists for providers to send data to payers, payers to store data in claims database, and payers to send data to the FDA Sentinel system There is a process to aggregate data across very large numbers of patients There is a successful history in using claims data for postmarket surveillance of pharmaceuticals
WEAKNESSES	Often reports are not submitted in a timely manner Reports only identify problems, not total number of devices in use Not all problems are reported Many reports do not readily identify the problem or device for the FDA	Not all EHRs have added fields for tracking UDI data It is difficult to share and aggregate data across providers, which poses significant issues when the patient is being treated by a provider who did not implant the device Large data sets and longitudinal records are not readily available Currently not included in any certification program	Registries do not exist for every high-risk medical device, and are currently not conducting device surveillance Registries are expensive to develop and maintain No standardized exports exist from EHRs Recording of data into registries is manual There are no existing standards or regulations regarding the data, formats, protocols, procedures, and governance across registries	Claims information is not as detailed as other data sources, specifically EHRs and registries Often there is a time lag between the completion of the procedure and the submission of the claim The standard claim transaction has to be changed to include the UDI Provider systems need to be modified to capture the UDI using AIDC technologies and make it available to the claim process Claims and administrative transactions maintained by health insurance payers are accessed and aggregated through the FDA Sentinel System for drugs and biologics, but not currently for devices

The following exhibit depicts a macro-level view of how the elements of UDI could potentially interact.



UDI Process Flow Events

A. Manufacturer sends UDI information to FDA database
B. Manufacturer ships device to provider and provider captures device UDI information
C. Provider issues medical information with UDI to patient
D. Provider submits UDI information to registries
E. Provider files claim with payer
F. Payer stores UDI in claims database
G. FDA Sentinel gathers claim data from payers
H. Provider and manufacturer report adverse events
I. Registries utilize claims data from payers
J. FDA alerts provider and patient of recall

Discussion on UDI Transport and Storage

The goal of UDI transport and storage is to better understand and evaluate device performance and assist with device recalls. There are systems that could contain UDI data and other systems that could analyze this information to assess device performance or locate patients with recalled devices.

Data sets that contain or could contain UDI data include EHRs (housed by providers) and claims (housed by payers), if they contain a specific field to document the UDI. Systems that could analyze these data include FDA's Sentinel Initiative, registries run by third-party organizations, internal systems used by health plans to assess the quality of care of their beneficiaries, and all-payer claims databases.

The challenge is to establish the most efficient and cost-effective method to transmit UDI data from a system that contains UDI to one that can analyze UDI. The two potential methods for transmitting the UDI utilize EHRs and claims.

UDI Transmission via EHRs

An option to achieve the goal of improved data for postmarket surveillance and recalls is to transmit UDI via EHRs. However, there are limitations that prevent the EHR from being the primary source of reporting UDI. These limitations include limited interoperability and data sharing capabilities between EHR systems, and an inability for EHRs to export UDI data to external systems. It will not be possible in the foreseeable future for EHRs and related registries to be used in such a way for postmarket surveillance.

UDI Transmission via Claims

The stakeholder working group convened by WEDI explored another source of UDI data—claims databases (submitted data from providers via claim transactions). Since it will not be efficient in the

near future for EHRs and device registries to be utilized for postmarket surveillance, an advantage of transmitting UDI in claims is that the existing infrastructure can be leveraged, with some modifications.

Expanding existing transactions to accommodate UDI in the claim via a situational rule[2] for reporting purposes would create opportunities for providers to voluntarily extract UDI data from institutions and consolidate data within payers. UDI could potentially be accessible for postmarket surveillance sooner than what could occur via EHR transmissions and registries.

Options for the Transmission of UDI

Based on these sources of data, the stakeholder working group identified the following options regarding the capture and transmission of UDI:

1. Maintain the status quo and do not enable providers and payers to transmit UDI
2. Enhance EHR functionality to enable UDI to be transmitted directly from EHRs to registries, payers and other data systems
3. Modify the claim to allow for reporting of UDI to payers

Option 1: Maintain the status quo and do not enable providers and payers to transmit UDI

Currently, the means of evaluating device performance are inadequate. There are no standardized exports between providers and payers. The FDA Adverse Event Reporting System (AERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. AERS currently is the only system for reporting adverse events, but this channel of communication is not consistent among all providers and manufacturers.

The current adverse event reporting system requires manufacturers to report problems to the FDA; however, once the provider receives the device, the manufacturer rarely receives information regarding the patient or device to report problems. Providers submit the required mandatory reports on device use to the FDA. These reports may not be useful, if the patient receives treatment from a provider other than the one who performed the implant procedure. Since the manufacturer and often the treating physician do not have specific, reliable information regarding the performance of all of their devices, relying on the AERS for postmarket surveillance will not enable the intended UDI benefits to be achieved.

Benefits to Option 1 include:

- No additional burdens would be placed on providers or payers

Shortcomings to Option 1 include:

- Quality and outcomes data of medical devices would neither be tracked nor analyzed
- Identification of patients affected by medical device problems or recalls would only be possible by individual providers on a case-by-case basis
- Cost effectiveness of devices and associated procedures would not be determinable
- The ability to conduct postmarket surveillance would improve only marginally beyond the capabilities that currently exist

[2] According to ASC X12, "*Required means the item must be present in all data transactions. Situational means the usage depends on an associated business rule which is specified in the implementation guide and which clearly and unambiguously states the requirement designation…*"

Option 2: Enhance EHR functionality to enable UDI to be transmitted directly from EHRs to registries, payers and other data systems

The second option would be to transmit the UDI directly from the EHRs to other stakeholders, including registries, FDA, and payers. Within providers, EHRs contain large amounts of data for clinical purposes (e.g., patient recovery observations, complications, and follow-ups) and will require the addition of UDI functionality. To be used for postmarket surveillance, systems would need to be established to receive the UDI directly from EHRs. In addition, the EHRs would need to be modified to include functionalities and capabilities to transmit the UDI directly to new systems, such as registries.

Benefits to Option 2 include:

- Specific characteristics and metrics could be determined and tracked for each device type
- Registry owners or payers could have detailed medical device databases
- Entities within healthcare focused on specific fields of medicine, such as orthopedics or cardiology, could include UDI into existing registries, each of which would have its own purpose, criteria and guidelines
- Only providers who practice in the specific fields of medicine pertaining to the registry would participate
- Providers could develop a single transmission mechanism from their EHRs to send UDI to multiple recipients and force the receiving systems to agree to receive the data via the same mechanism and in the same format

Shortcomings to Option 2 include:

- Providers would have to make changes to their EHRs to capture and transmit UDI data to the appropriate registries and/or payers
- Payers would have to develop new medical device databases and establish new systems and processes within their quality and outcomes divisions
- The current Sentinel system could not be utilized to evaluate device safety, as Sentinel relies predominantly on claims data
- Registries would have to be developed, if they do not exist, or existing registries would have to be modified for each type of medical device
- The infrastructure for each registry would have to be developed with each provider
- The expense of developing and managing registries is significant, therefore adding new types of medical devices would be cost prohibitive; however, as data become more easily accessible, these types of registries may be more viable in the future
- Providing data to registries is usually burdensome on providers, because duplicative work can be required
- Governance of state-level registries would have to be established to conduct postmarket surveillance of medical devices (there are models for performing this governance, such as the Physician Quality Reporting System (PQRS) program administered by CMS, but there would be significant regulatory changes required to address such a framework in the future)

Option 3: Modify the claim to allow for reporting of UDI to payers

The third option would involve modifying the Accredited Standard Committee (ASC X12) claim transaction to carry structured UDI data for specific non-dental, high-risk implants such as hips, knees, and coronary artery stents. This option would incorporate UDI data into electronic transactions between providers and payers. Each provider and hospital would agree to transmit the UDI for a limited and

defined set of devices. The UDI will be used for reporting the unique device identifier when a health plan and hospital mutually agree to transmit this information or as deemed by the provider to enhance claim reporting. This approach would be completely voluntary for providers, and not require providers that are not capable of transmitting the UDI to include it in claims data. Essentially, this approach would enable providers and payers to establish pilot projects for capturing and transmitting the UDI.

To accomplish this option, providers would need to evaluate their EHR or inventory management systems and ensure that appropriate linkages are in place with their billing systems. This integration would include modification of existing hospital charge master systems in order to accommodate the finite lists of high-risk, implantable devices for which each hospital has agreed to transmit the UDI. The charge master systems typically have a single entry to contain the device type and the amount the hospital charges for that device. Incorporating UDI would require a separate entry in the charge master system for every UDI. For example, a hospital that performs stent implants today may have one entry in the charge master system for a stent. With UDI, there would be an entry for every stent type from every manufacturer, which would significantly increase the number of the entries in a hospital charge master system.

This option could provide expanded insight into medical device performance for patients, providers, payers, and manufacturers. Outcomes and associative data would greatly improve the holistic view of a patient, since performance of a medical device would be considered. A holistic view is particularly desirable considering the span of use of some devices and the potential for patients to move geographically and to have multiple providers. Additionally, Sentinel—which has access to a critical mass of patient data from major payers—has successfully assessed drug performance and could be similarly utilized for devices.

While the current claims infrastructure would be sufficient to assess device outcomes with the addition of UDI, to improve on this option, industry could develop an all-payer claims database in which to store UDI data. With this all-payer claims database, the patient information would also be tracked, if the patient did not remain with the same payer. Should the patient switch to a different payer, the information in the patient's former payer claims database would be available. This all-payer claims database would also allow private payers to share data with other payers and back to submitting institutions to enhance their own quality efforts.

Benefits of Option 3 include:

- Many of the postmarket surveillance goals for medical devices would be achieved
- Payers could conduct their own quality analyses on devices and assist with locating patients implanted with recalled devices
- Registries could link with claims to enhance longitudinal analyses of devices
- The FDA's Sentinel system, which relies predominantly on claims data, could be utilized to assess device performance as is currently done with drugs
- Pilot programs could transmit UDI for interested providers and health plans
- Collaborating providers and payers would decide which implants would involve transmission of the UDI
- Costs are anticipated to be less than Option 2 while significant benefits could be achieved
- If developed, all-payer claims databases would be able to incorporate UDI for analysis and evaluation across multiple payer datasets

Shortcomings to Option 3 include:

- Participating providers would have to make changes to their respective systems to:
  - capture and transmit UDI data as part of the claim
  - receive and process UDI data as part of the claim
  - analyze UDI data and provide the data for postmarket surveillance
- Patients that change payers would not be tracked longitudinally, unless those payers participated in Sentinel or participated in all-payer claims databases; however, the magnitude of data available from claims would lessen the impact
- A situational rule could become a requirement for payment by a payer
- Clinical and administrative data capture typically occurs in two different systems and would require integration
- Adding UDI to the claim will add a level of burden and cost to providers who will have to modify their systems to move the UDI from their EHR/clinical systems to billing systems

Business Case for the Transmission of UDI to Payers as Part of a Hybrid Approach

Through our research, it was determined that a blended solution (hybrid approach) could serve as an effective strategy to build a repository of UDI data to enhance postmarket surveillance.

In this approach, it is recommended that EHRs should both collect UDI data and develop exports to payers, public registries, and billing systems in order to address “short-term” and “long-term” goals in collecting UDI. Since EHRs will not be capable of this type of export in the foreseeable future and due to the associated challenges with creating device registries, it is suggested that ASC X12 modify the claim transactions to accommodate the transmission of UDI.

Many benefits could result from the transmission of UDI to payers as part of a hybrid approach:

- Payers could assist with recalls by using UDI data to more quickly and efficiently reach the patient than the healthcare facility in which the procedure was performed, which in many cases could have been several years prior. Currently, many of the highest risk recalls end without all devices accounted for and identified, partially because hospitals and manufacturers lack up-to-date contact information. Health plans, on the other hand, are another stakeholder that can contact the patient and often will have more recent contact information.

- FDA's Sentinel system has successfully evaluated drug safety. Sentinel, though, lacks access to data on device quality and the specific devices used in care. UDI transmission to the health plan would enable Sentinel evaluations of device quality. Richard Platt, MD, MSc, Professor and Chair of the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute and the Sentinel Program Lead, stated that transmitting the UDI in the claim is the least burdensome method for using Sentinel with devices (Platt, 2013).

- Payers would have access to detailed device information to conduct their own analyses on device quality and performance. As payers currently lack any information on the specific devices used, this information would provide them with previously unattained data to assess the care of beneficiaries. This information would support longitudinal analyses when patients see multiple providers or obtain follow-up care from a physician that did not conduct the initial procedure. As stated in the comments from the America’s Health Insurance Plans (Bocchino, 2012) and Kaiser Permanente (Ferguson, 2012) submitted in response to the FDA UDI Rule, the presence of

the UDI in the claim would enable patients, procedures, costs, and devices to be related, analyzed, and evaluated based on outcomes.

- Both existing and new registries could link with claims data to provide longitudinal analyses on medical devices. As registries often only house short-term outcomes data, this capability would ensure long-term data collection linked to detailed patient information.

- As proven successful in the Medi-Cal pilot project, providing a mechanism for providers to transmit the UDI to payers could result in many operational and financial benefits. The transaction and situational provision used for Medi-Cal cannot be used with UDI because:
    - The HCPCS field is not large enough to hold the UDI
    - The situational provision was only approved for the Medi-Cal pilot

To achieve these goals, a situational rule such as the following could be appropriate:

SITUATIONAL RULE

The suggested language for a proposed situational rule for providers and payers to include UDI in the claim as optional for reporting purposes is the following:

The UDI will be used for reporting the unique device identifier when a health plan and hospital mutually agree to transmit this information or as deemed by the provider to enhance claim reporting.

Including the UDI in the claim with the proposed situational rule makes the inclusion of UDI voluntary, meaning providers would not be required to report it and payers would not be required to collect it, unless they have both agreed to do so. Providers would need to make changes to their charge master and billing systems to include UDI (both DI and PI). The UDI pilot projects have made these changes, or are in the process of making these changes, because their evaluations indicated that the potential benefits and costs savings outweigh the costs of the changes.

Ultimately, through this situational rule, providers, payers, registries, and the FDA could compare the efficacy of similar devices to:

- Determine quality based on actual results in large patient populations
- Identify poorly performing devices and safety risks
- Assess differences in the performance of devices to improve competition among manufacturers and ensure that patients use the highest quality and most appropriate technologies for their conditions
- Assist with device recalls to ensure that all patients affected by failing technology receive appropriate follow-up care

Payers and providers would be able to work together to identify the best-performing and cost-effective medical devices. Patients and providers would be able to make decisions regarding specific medical

devices and procedures based on historical, factual data. Providers and patients would be able to make informed selections of medical devices best suited for each patient's situation.

ASC X12 Elements for Including UDI in the Claim with a Situational Rule

To be clear, the situational rule would apply to the institutional claim transaction and would not be mandatory. Through the proposed rule, UDI transmission would be voluntary for both providers and payers, who would need to mutually agree to collect and transmit the UDI for certain products that they identify. This approach would support pilot projects that any health plan (including Medicare) or providers would like to conduct and would ensure that providers without the capability to transmit UDI would not be required to send device data. Recent health IT initiatives, such as Meaningful Use, also create opportunities to enhance the capture and usage of UDI. Currently, UDI is being discussed for inclusion in the draft standards for Meaningful Use Stage 3, which will drive adoption by EHR vendors.

The WEDI Foundation's stakeholder group assessed the option to develop the elements for including UDI in the claim with a situational rule. The suggested language for a proposed situational rule is:

- The UDI will be used for reporting the unique device identifier when a health plan and hospital mutually agree to transmit this information, a pilot project developed by a hospital and health plan requires the transmission of this data, or as deemed by the provider to enhance claim reporting.
- Since the UDI will be included for reporting purposes, a HIPAA code set is not required at this time.

Structure of UDI Data and Fields

Devices

The claim transaction would be used to transmit the UDI for high risk implants such as knees, hips, and cardio stents. It is not the intent of the healthcare industry to transmit UDI for the very large volume, low risk medical devices such as wound dressings.

When a medical device is implanted, the UDI for that medical device should be reported. The ability to transmit multiple UDIs is necessary for procedures that utilize multiple high-risk components per procedure. For example, if a hip transplant is performed on a patient that uses the bundled hip package as it was manufactured and labeled by the manufacturer, then the one UDI for that hip implant is transmitted. If pieces of one hip from one manufacturer/ type (e.g., titanium) and pieces from another manufacturer/type (e.g., ceramic) are used to construct a complete hip, then the UDIs for the high-risk, implanted components are transmitted. Similarly, in a procedure involving many small implants (such as screws), the high risk implanted components could be transmitted or not at all if the screws were not deemed high risk and worthy of transmission by the payer and provider. Conversely, if those screws could represent significant risk to the patient and the payer and provider agree to transmit their UDIs, then that information would be included in the claim.

UDI

The entire UDI comprised of the device identifier (DI) and production identifier (PI) is to be transmitted in the claim transaction.

Field Type

A single medical procedure can involve multiple UDIs to comprise the entire implanted medical device; therefore, the claim transaction should have the ability to include the UDI as a structured field at the claim line level.

Embedding the UDI within an attachment would place it inside of an unstructured document (such as large PDF documents) that would not provide the format and standardization necessary for extraction, reporting, and analysis. Additionally, attachments are large documents that would occupy much more hard drive space than structured fields.

Furthermore, the lack of consistency and uniformity in the use and handling of attachments between providers and payers would not readily enable the UDI to be available for postmarket surveillance.

Additional Area for Further Consideration

The ASC X12 278 transaction set is called the Health Care Services Review Information. A healthcare provider will send a 278 transaction to request an authorization from a payer. The transaction may also be used by the payer to respond to this request for an authorization. Thus, the 278 can be used either as a one-way transaction, or as a two-way "request/response" type of transaction. The ASC X12N Subcommittee developed three unique implementation guides based on the 278 transaction set. Of these, the Health Care Services Review and Response guide was mandated by HIPAA as the standard format for EDI transmissions of authorizations and referrals.[3]

In 2012, the CR8 segment of the 278 transaction was modified to accommodate the reporting of all implant types from its previous usage of just a pacemaker. The CR8 segment only captures the type of implant, make, model, series number, and warranty but it does not include the UDI. The WEDI TAC did not discuss using the 278 Notification (278N) transaction as a means to report the UDI. The TAC did discuss prior authorization and the 278 (HIPAA mandated transaction) but decided not to include it at this time. The 278N is a different business purpose of the 278 transaction than the 278 Prior Authorization Request and Response. Very few entities have implemented the 278N to date and this transaction requires further research as another possible avenue for transmitting UDI.

[3] http://www.1edisource.com/learn-about-edi/transaction-sets/tset/278#axzz2y2ERTz7E

Conclusion

There is general consensus among healthcare stakeholders that having UDI available for postmarket surveillance has enormous potential for improving public health and device safety. Each of the pilot projects involving providers and payers that has been completed or is underway has yielded positive financial and efficiency results.

The hybrid approach is optimum to enable UDI to be accessible for postmarket surveillance and is comprised of the following combination of initiatives:

- The UDI should be added to the claim with a situational rule to enable interested providers and payers, on a voluntary basis, to transmit and use the UDI for high-risk implants
- Providers should work to capture and electronically integrate the UDI into their internal systems so the UDI is available within their clinical systems, supply chains, and administrative systems
- Registries should be modified to add UDI and work to consolidate data from facilities
- All-payer claims databases should be modified to add UDI and work to consolidate data from multiple all-payer claim databases
- Further research should be done to evaluate if UDI should be included in the preauthorization transaction to enable interested payers and providers, on a voluntary basis, to transmit and use the UDI for high-risk implants
- With support of the FDA, pilot projects should be developed that demonstrate UDI being transmitted between entities (e.g., provider to payer, provider to registry, etc.)

This approach uses existing infrastructure and minimizes the burden on any individual stakeholder and enables each stakeholder to utilize UDI along its own timeline.

EHRs should eventually be able to transmit the UDI from providers to registries, payers, and other stakeholders; however, that capability will not be realized until well into the future. Achieving the benefits of UDI in the foreseeable future requires the inclusion of UDI in claims. The proposed situational rule establishes a voluntary approach to achieve the goals of postmarket surveillance to improve device safety and public health with minimal additional costs, complexities, and burdens.

Appendix A: Stakeholder Meeting Participants

The participants in the UDI project were:

Organization	First Name	Last Name
AAHAM - Chennai Chapter	Maya	Mohan
Abbott	John	Terwilliger
Aetna	Michele	Lanzetta
Aetna	Phillip	Lerner
Aetna	Sally	McDonald
Akin Gump	Emily	Strunk
Allscripts	Eric	Grindstaff
Allscripts	Danielle	Jones
Altarum Institute	Tim	Borchert
American Dental Association	Jean	Narcisi
American Health Information Management Association	Meryl	Bloomrosen
American Health Insurance Plans	Tom	Meyers
American Hospital Association	George	Arges
American Hospital Association	Chantal	Worzala
American Medical Association	Bob	Poiesz
American Medical Association	Nancy	Spector
Applied Policy	Jim	Scott
Applied Policy	Melissa	Andel
Arizona Medicaid	Melanie	Lopez
Azuba	Bart	Carlson
Blue Cross Blue Shield Alabama	Tony	Benson
Blue Cross Blue Shield Arizona	Cindy	Bell
Blue Cross Blue Shield Arizona	Jennifer	DiChiara
Blue Cross Blue Shield Arizona	Sheri	Jackson
Blue Cross Blue Shield Association	Gail	Kocher

Organization	First Name	Last Name
Blue Cross Blue Shield Florida	Tab	Harris
Blue Cross Blue Shield South Carolina	Jim	Daley
Blue Cross Blue Shield South Carolina	Tonya	Dorsey
Brookings Institution	Greg	Daniel
CareFirst	Marilyn	Collins
CareFirst	Nurzetty	Rahim
CareFirst	Tamara	Tromblay
Cerner	Patricia	Chism
Cerner	R	Lantz
Centers for Medicare and Medicaid Services	Matthew	Albright
Centers for Medicare and Medicaid Services	Jason	Jackson
Centers for Medicare and Medicaid Services	Marc	Wynne
Clinical Trials Transformation Initiative	Bray	Patrick-Lake
Cognosante	Susan	Ackley
Community Health Systems	Laurie	Holtsford
Consumers Union	Lisa	McGiffert
Deloitte	Renu	Pandit-Pant
Delta Dental of New Jersey, Inc.	Joe	Stanton
Dignity Health	Nancy	Cahill
Dignity Health	Channin	DeHaan
Dignity Health	Joseph	Dysko
Dignity Health	Tran	Le
Dignity Health	Kelley	Moore
Dignity Health	Penny	Thurman
Dignity Health	Nataiya	Waller
Dignity Health, St. Bernardine Medical Center	Daryl	Cannon
Edifecs	Basil	Pais
Edifecs	Prasad	Pavuluri

Organization	First Name	Last Name
Edifecs	Gregg	Prothero
Edifecs	Ruby	Raley
Emblem Health	Frank	Bacchus
Emdeon	Kelly	Butler
Enclarity, a LexisNexis Company	Michele	Cleary
Epic	Mukesh	Allu
Epic	Kenny	Jackelen
Express Scripts	Ashley	Maples
Faulkton Area Medical Center	Heather	Bode
Federation of American Hospitals	Samantha	Burch
Federation of American Hospitals	Jayne	Chambers
Food and Drug Administration	Jay	Crowley
Food and Drug Administration	Thomas	Gross
Food and Drug Administration	Behnaz	Minaei
Food and Drug Administration	Terrie	Reed
GE Healthcare	Michael	Dahlweid
Geisinger Center for Health Research	Jove	Graham
Geisinger Health System	Kevin	Capatch
Geisinger Health System	Sam Anson	Herbert
Geisinger Health System	Don	Masser
Geisinger Health System	Deb	Templeton
GNYHA	Stewart	Presser
Harvard Pilgrim	Joanne	Cochran
Harvard Pilgrim	Richard	Platt
Health and Human Services	Scott	Douglas
Health and Human Services	Erin	Rubens
Health Care Services Corporation	Durwin	Day
Health Transactions, Inc.	Sue	Miller

Organization	First Name	Last Name
Healthcare Supply Chain Association	Frank	Moore
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Highmark	Suzann	Bottaro
Highmark	Doug	Renshaw
Highmark	Karen	Shutt
Highmark	Robert	Twining
Hoag Memorial Hospital Presbyterian	Quality	Reps
Independent Consultant	James	Kaneski
Indian Health Service (HIS), HHS	Charolett	Melcher
Intermountain Healthcare	Erin	Selin
John Hopkins Health System	Bonnie	Aumann
John Hopkins Health System	Shenean	Lee
Kaiser Permanente	Michael	Innes
Kaiser Permanente	Anthony	Rizzi
Kaiser Permanente	Jim	Whicker
Kaiser Permanente	Megan	Zimmermann
Knapp Consulting (President)	Paul	Knapp
Legacy Health	Denyce	Campo
Mayo Clinic	Laurie	Darst
McKesson	Kathy	Hayden
McKesson Technology Solutions	Mike	Marchlik
Medical Group Management Association	Robert	Tennant
Medical Mutual	Randy	Cloesmeyer
Medicity, a Healthagen Business	Saurabh	Mathur
MedImpact Healthcare Solutions, Inc.	Carol	Germain
Mercy	Joseph	Drozda
Mercy	Curtis	Dudley
MN Dept Labor & Industry, Workers Comp Division	Lisa	Wichterman

Organization	First Name	Last Name
Moda Health	Patricia	Van Dyke
NALC Health Benefit Plan	Anita	Lutrario
National Research Center for Women & Families Cancer Prevention and Treatment Fund	Paul	Brown
National Council for Prescription Drug Programs	Lynn	Gilbertson
National Council for Prescription Drug Programs	Kay	Morgan
National Council for Prescription Drug Programs	Sue	Thompson
NextGen	Gloria	Davis
National Institutes of Health	John	Kilbourne
National Women's Health Network	Kate	Ryan
Office of E-Health Standards and Services, CMS	Gladys	Wheeler
Office of E-Health Standards and Services, CMS	Kamahanahokulani	Farrar
Office of the National Coordinator	Nayan	Jain
Office of the National Coordinator	Behnaz	Minaei
Office of the National Coordinator	Sandra	Rausch
Optum	Tammy	Banks
Optum	Patrick	Sauer
OTB Solutions	Chris	Gilbert
OTB Solutions	Shelly	McDermot
PracticeFusion	Richard	Loomis, MD
Premier Healthcare Alliance	Lauren	Choi
Premier Healthcare Alliance	Cheryl	Fahlman
Presbyterian Healthcare Services	Andrea	Kinsley
Public Employees Health Program	Lance	Toms
PwC	Ginger	Parker
QuadraMed, Inc.	Elizabeth	Cramer
RelayHealth	Denise	Oviatt
RelayHealth	Trebba	Putnam
Sentry	William	Kirsh

Organization	First Name	Last Name
Sentry	Lisa	Tonkinson
Siemens Healthcare	Valdez	Ladd
Siemens Healthcare	Kathleen	Ochal
Southcoast	Manny	Mello
St. Joseph Health	Cathy	Mesnik
State of Utah	P	Buck
Systems Made Simple	Andrew	Underhill
TM Floyd & Company	David	Arnold
TM Floyd & Company	Terry	Floyd
TM Floyd & Company	John	Starmack
The Pew Charitable Trusts	Ben	Moscovitch
The Pew Charitable Trusts	Josh	Rising
The Rybar Group, Inc.	Claudia	Garabelli
The Weiker Group	Margaret	Weiker
UnitedHealthcare	Nancy	Berger
University of Utah Hospitals and Clinics	Amy	Mitchell
University of Washington	Sarah	Lucas
WEDI	Leanne	Cardwell
WEDI	Samantha	Holvey
WEDI	Devin	Jopp
WellPoint	Christol	Green
WPS Insurance	Laurie	Burckhardt
Xerox State Healthcare, LLC	Maggie	Ramey
Zirmed	Juliana	Sorbo

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Glossary

278 – Electronic data interchange standard transaction for requesting authorization and services review

278N – Electronic data interchange standard transaction to exchange notification data

Adverse Event Reporting System (AERS) – A database containing information on adverse events and medication error reports submitted to the FDA

Automatic identification and data capture (AIDC) – The process for identifying objects, collecting data about them, and entering those data into a data store without human intervention

All-payer claims databases – Databases designed to contain de-identified health insurance eligibility and claims information from all healthcare payers within a state

Accredited Standards Committee (ASC) X12 – Standards organization for electronic data interchange

Centers for Medicare & Medicaid Services (CMS) – An agency of the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards

Device identifier (DI) – A mandatory, fixed portion of the UDI that identifies the labeler and the specific version or model of a device

Electronic Health Record (EHR) – Computer software used to maintain health information and demographics about patients

Food and Drug Administration (FDA) – An agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary products

Global UDI Database (GUDID) – An FDA database that includes a standard set of basic identifying elements for each device with a UDI

HIPAA – Health Insurance Portability and Accountability Act

Medi-Cal – California’s Medicaid healthcare program

National Drug Code (NDC) – A unique product identifier used in the United States for drugs intended for human use

Production identifier (PI) – A conditional, variable portion of a UDI that can identify the lot or batch number, serial number, expiration date, manufacture date, and distinct identifying codes of a medical device

Postmarket surveillance – The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market

Registry – A repository for a predefined purpose that contains a defined set of health, demographic, and medical device data for patients with specific health characteristics

Sentinel Initiative – The FDA's national electronic system that aims to develop and implement a proactive system that will complement existing systems that are in place to track reports of adverse events linked to the use of its regulated products

Situational rule – An ASC X12 rule that depends on an associated business rule which is specified in the implementation guide and which clearly and unambiguously states the requirement designation

Unique device identifier (UDI) – A unique numeric or alphanumeric code that consists of a device identifier and a production identifier

Universal product number (UPN) – Identifier for medical/surgical products assigned by the manufacturer/labeler and represented in both human readable and bar code formats on the product