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.
[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.