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.