March 28, 2014

Margaret Weiker
Chair, X12N
The Accredited Standards Committee X12
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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

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