United States Senate
WASHINGTON, DC 20510

June 1, 2017

VIA ELECTRONIC SUBMISSION

Gary Beatty
Chair
Accredited Standards Committee X12
8300 Greensboro Drive, Suite 800
McLean, VA 22102

Dear Mr. Beatty,

We are writing to provide our comments on the institutional health care claim transaction released for public comment in February 2017. In particular, we applaud the committee's decision to include a field for the device identifier portion of a medical device's unique device identifier (UDI) on the electronic claim form.

We have repeatedly expressed our strong support for the inclusion of device identifier information on medical claims forms. The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) also urged the standards committee to make these changes to the claims form as they developed their latest updates.[1]

Including device identifier information on medical claims forms will help reduce health risks and costs to the Medicare system, and we support X12's decision to include this information on the medical claims form. Poorly-performing medical devices can cause serious health risks and cost seniors and people with disabilities millions of dollars in out-of-pocket spending. Faulty devices can result in additional taxpayer dollars to cover the cost of replacing or upgrading such a device. Yet the limitations of current post-market surveillance systems make it difficult to even track these costs and health risks.

A recent memorandum from the Office of Inspector General (OIG) at the Department of Health and Human Services reported that recalls or premature failures of the seven faulty cardiac devices included in their analysis had resulted in $1.5 billion in Medicare payments to providers and $140 million in costs to beneficiaries in the form of copayments and deductibles.[2] However,

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[1] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, and Robert Califf, Commissioner, Food and Drug Administration, to Gary Beatty, Chair, Accredited Standards Committee X12 (July 13, 2016) (online at: https://pascrell.house.gov/sites/pascrell.house.gov/files/wysiwyg_uploaded/LETTER_FDA%20CMS%20Beatty%20Letter%20on%20UDI%20in%20Claims%207.13.16.pdf).

[2] Memorandum from Daniel R. Levinson, Inspector General, to Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, "Early Alert: Incorporating Medical Device-Specific Information on Claim Forms (A-01-16-00510)" (September 30, 2016) (online at: https://oig.hhs.gov/oas/reports/region1/11600510.pdf).

according to the OIG, the "lack of medical device-specific information in the claims data impedes the ability of CMS to readily identify and effectively track Medicare's total costs related to the replacement of recalled or defective devices."

Although separate from the X12 proposal now out for public comment, we understand that other issues related to the eventual implementation of the device identifier field are also under discussion by stakeholders. Most notably, the FDA has agreed to help coordinate stakeholder work to develop a list of specific, high-risk implantable devices for which reporting on claims will be recommended once the updated transaction is finalized.[3] As this work continues, we urge stakeholders to consider that providers and insurers may have an interest in tracking the performance of a device not included on this recommended list. In other words, development of a list of high-risk implantable devices should not preclude willing trading partners from using the claims form to exchange device identifier information for any device.

Finally, as the committee and other stakeholders continue their work and develop guidelines on the types of devices for which the use of the device identifier field will be most helpful, we urge you to also remain attentive to the fact that the swift identification of recalled or failed devices not only helps prevent health risks, but can also save taxpayer funds by reducing Medicare's financial liability for recalled or poorly performing devices. Even devices that may pose relatively lower levels of risk to patient health if they fail or develop defects can prove costly to patients and taxpayers, and claims data should facilitate efforts to track and reduce these costs.

Thank you for your work to improve and update standards for institutional health care claims transactions, and in particular for your efforts to ensure that these transactions support the post-market surveillance of medical devices. These changes will improve patient health and the integrity of the Medicare system.

If you have any questions about this letter, please do not hesitate to contact Beth Pearson (beth_pearson@warren.senate.gov) in the office of Senator Elizabeth Warren or Karen Summar (karen_summar@grassley.senate.gov) in the office of Senator Chuck Grassley.

Sincerely,

Elizabeth Warren
U.S. Senator

Chuck Grassley
U.S. Senator

CC:
Dr. Scott Gottlieb, Commissioner, Food and Drug Administration
Seema Verma, Administrator, Centers for Medicare and Medicaid Services

[3] American Hospital Association, "Standards Organization Approves UDI Changes," *AHA News Now* (September 20, 2016) (online at: http://news.aha.org/article/160920-standards-organization-approves-udi-changes).