DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Administrator
Washington, DC 20201

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

July 13, 2016

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

Dear Mr. Beatty:

The Department of Health and Human Services (HHS) appreciates the role of the Accredited Standards Committee X12 (ASC X12) and its members in enabling the development of consensus based standards in order to promote administrative simplification in health care transactions.

As voting members of the ASC X12 Unique Device Identifier (UDI) Special Appointed Committee and other ASC X12 workgroups, the Centers for Medicare & Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) are writing to request that ASC X12 revisit the current business requirements to support capturing on the claim form the device identifier (DI) portion of the unique device identifier for implantable devices. CMS and FDA are hopeful that ASC X12 can complete its work on the next version of the claims form (version 7030) for the relevant transaction standards[1] to permit the DI for implantable devices to be included in the claims form. We understand these standards are currently anticipated to be released December 1, 2016. CMS and FDA are committed to working with other ASC X12 members to advance this request through the normal ASC X12 consensus based process.

HHS is committed to improving the quality and safety of health care provided to all Americans, and believes that monitoring medical device product safety and performance is critical for ensuring public health and safety. HHS supports adding the DI portion of the UDI to claims for implantable devices if sufficient funding and resources are provided to make the necessary Medicare claims processing system changes.

There are several benefits to collecting the DI on claims forms for implantable devices. Collecting the DI would:

- Allow for evaluation of product performance and identification of safety concerns for devices at the model level;

[1] The Health Care Claim: Professional (837P) and Health Care Claim: Institutional (837I), among others.

- Facilitate the collection and analysis of patient data for devices at the model level that would be helpful in surveillance efforts and device innovations;

- Help providers and certain payers to calculate and compare total costs and outcomes based on the device model used; and

- Support program integrity by providing better information to link the patient and implanted device to help track rebates from manufacturers back to the payer or provider.

We recognize that collecting the DI is complex and involves providers changing their workflow and billing systems as well as requiring public and private payers, entities that bill for providers, clearinghouses, and other entities to change their claims processing systems. CMS also needs to modify numerous legacy computer systems to collect DIs for implantable devices on Medicare claims, which would require additional funding and resources.

Accordingly, HHS is committed to working collaboratively with our colleague stakeholders on the ASC X12 and is committed to a process that collects the DI on claims on a timeline and in a manner that minimizes the impact on state Medicaid agencies, health plans, small physician practices, and hospitals in rural areas. Stakeholder education and outreach, especially for clinicians and hospitals, is critical to making this implementation successful. We want to engage our colleague stakeholders on the ASC X12 who we know share our goals and collaborate to overcome barriers that may exist.

ASC X12's work to develop a consensus based standard is an important first step in enabling the collection of DI information for implantable devices on claims. We believe that a new change request resulting in a technical solution that supports adding the DI to health care claims for implantable devices would improve device oversight and monitoring and support more robust research.

We look forward to working with ASC X12 to assist in the development of this consensus-based standard. If you have any questions regarding this letter, please contact Terrie Reed at Terrie.Reed@fda.hhs.gov or Diane Kovach at Diane.Kovach@cms.hhs.gov.

Sincerely,

Andrew M. Slavitt
Acting Administrator

Robert M. Califf, M.D.
Commissioner Food and Drugs