May 31, 2017

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

Dear Mr. Taylor:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing to express our opposition to proposals to add the Device Identifier (DI) portion of a medical device’s Unique Device Identification (UDI) to the institutional and professional claim forms. While we strongly support efforts to reduce existing obstacles to the adequate identification of medical devices, we do not support adding this information to the claims submissions. We believe there are superior alternatives, such as inclusion of UDI in electronic health records (EHRs), to enhance patient safety.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies.

There are many positive benefits of a UDI system once fully implemented, including:

- Facilitating more accurate reporting, reviewing and analyzing of postmarket device data by providing a standard and clear way to document device use in electronic health records, clinical information systems, and registries;
- Generating postmarket data that could be used to support premarket approval or clearance of new devices and new uses of currently marketed devices;
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies; and
- Aiding in the development of an internationally harmonized medical device identification system.

Bringing innovation to patient care worldwide
AdvaMed has worked extensively with the Food and Drug Administration (FDA) to help maximize the usefulness and value of the UDI system as a postmarket tool and to lessen the implementation burdens on industry and the broader healthcare ecosystem. AdvaMed remains committed to working with FDA, hospitals, physicians, and other stakeholders to move forward in implementing an effective UDI system that takes into account the diversity of medical devices and provides information useful to understanding their postmarket performance.

That said, the X12 has advanced a recommendation to add only the Device Identifier (DI) portion of the device’s UDI on hospital claims submissions with the purported goal of improving postmarket surveillance for certain medical devices. The DI portion of a UDI represents an extremely limited data set of the underlying product. In particular, the DI represents only the manufacturer name and device model. More detailed information such as expiration date or serial number is contained in the production identifier (PI) portion of the UDI. Indeed, FDA’s medical device reporting requirements require the DI and PI information for the device to ensure the data set can be fully evaluated and understood. Accordingly, only capturing a device’s DI would not provide sufficient information and could result in wrong scientific conclusions. Furthermore, DI information on the claims forms would not provide a clear picture on the condition of the patient and ultimate benefit of a device to the patient’s wellbeing.

Adding this information to hospital claims submissions ignores tracking, registry and other postmarket data collection requirements already in place for implants. FDA’s rules, for example, require implant manufacturers to track devices through the chain of distribution and to the patient to enable manufacturers to promptly locate devices in commercial distribution. Tracking information may be used to facilitate notifications and recalls ordered by FDA in the case of serious risks to health presented by the devices. Similarly, many implantables are subject to a device registry. If the stated goal of adding DI to hospital claims submissions is to improve postmarket surveillance, there are other avenues to do this that would not open the door for purposes beyond the scope of patient safety. These approaches also are far superior to claims in that they can be real-time and allow for much faster identification and response. Tracking information from claims will not be current, given delays of processing and reporting information from health plans. It will be dated, incomplete, and a highly ineffective and costly tool for surveillance or tracking medical device safety.

With that in mind, it is unclear what purpose inclusion of DI on claims submissions provides from a claims payment standpoint. As you know, the claims form is used for the express purpose of paying for health care services, and current coding systems provide sufficient information to identify procedures involving medical devices for the purposes of reimbursement under existing commercial and public health care payment systems. Adding this information goes beyond the original intent of developing a claims form. At its core, this recommendation advances a policy position that goes beyond a mere change or update of the claims form.

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1 We note that FDA has granted a limited number of exemptions for certain devices to be labeled with only DI information. In such cases, a PI is not present and would not be available for recording. In these cases, FDA acknowledges that it is not technologically feasible to add PI information to the product.
Instead of focusing limited resources on adding information from the UDI to a claims form that will not provide a complete understanding and evaluation of device performance, AdvaMed believes that adding UDI information in EHRs would facilitate more accurate reporting, review and analysis of postmarket data for medical devices. We support inclusion of UDI information in the EHR as a means to increase the availability of UDI information to health care providers involved in the treatment of a patient as well as to strengthen the reliability of the information for the patient’s implantable device(s).

Capture of UDI within the EHR would overcome many of the limitations that would exist if this information is contained within a claims database that is not accessible to physicians and other health care providers caring for patients. The portability of a patient’s EHR is critical as it ensures that the information stays with the patient, regardless of any health plan enrollment changes. As a result, this information would serve as a more robust post-market surveillance tool than a claims submission and can improve coordination among doctors and support medical decision-making.

To accomplish this, the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) should work with EHR vendors to develop and create automatic reporting of UDI and patient information to a uniform database for patient safety and postmarket surveillance.

We believe additional steps can be taken to ensure that this information is appropriately and adequately used to benefit patient safety. For example, ONC could be required to incorporate into the EHR standards for recording UDIs that ensure they have the capability to record and retrieve UDI information for implantable devices and related patient information sufficient to meet the needs of FDA’s Sentinel System. Furthermore, provisions could be added to the Meaningful Use Program that would allow hospitals to use EHRs to report, upon request by the FDA, related patient information to the Sentinel Program.

Finally, efforts should be made to build upon language in legislation signed into law in 2016, the 21st Century Cures Act, which makes improvements to EHRs that would make inclusion of UDI information more impactful. Specifically, the law expedites interoperability among EHRs and encourages the exchange of health information between registries and EHR systems.

AdvaMed stands ready to work with stakeholders to make this achievable.

Thank you for your attention to this matter. If you have any questions or need more information, please do not hesitate to reach out to me.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery