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AdvaMed
Advanced Medical Technology Association

September 23, 2016

Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell,

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing to express our concerns with proposals to add a medical device's Unique Device Identification (UDI) to hospital claims submissions. 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 instead urge expediting the inclusion of UDI in electronic health records (EHRs) as a superior alternative 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.

As you are aware, the FDA Amendments Act of 2007 required the Food and Drug Administration to develop a UDI system for medical devices. FDA issued final regulations establishing the UDI system in 2013, and pursuant to those regulations manufacturers began labeling all high-risk implantable devices with UDIs in 2014. The UDI rules are being phased in gradually and by 2016 all class II and class III devices will be required to bear a UDI.

We agree that 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.

AdvaMed has worked extensively with 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 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, proposals have been advanced to add UDI information to hospital claims submissions. Adding a UDI field 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 UDI 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.

In the alternative, a proposal has been advanced to add only the Device Identifier (DI) portion of the device's UDI on 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.[1] Accordingly, only capturing a device's DI would represent a flawed approach.

With that in mind, it is unclear what purpose inclusion of UDI or 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

[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.

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.

Instead of focusing efforts on modifying claims submissions to capture UDI, or partial UDI information, which could lead to inaccurate, incomplete and invalid data, a better approach would be to focus on how UDI information within EHRs could better serve postmarket surveillance efforts. The Office of the National Coordinator for Health Information Technology (ONC) has already made significant progress in this area by requiring capture of UDI for implantable medical devices within EHRs and CMS has required it for meaningful use. In the rule announcing this requirement, CMS concludes that this information is vital to improving the quality of care and ensuring patient safety. We agree.

AdvaMed believes that providing a standard and clear way to document device use from 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. A payer database is unlikely to be retrievable by a physician in the event of a device malfunction and would not provide the necessary clinical information necessary to analyze and determine the patient's outcome related to a medical device. The portability of a patient's EHR with 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.

We urge ONC and CMS to 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.

With these ideas in mind we look forward to working with you and other stakeholders to make this achievable.

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

Sincerely,

Scott Whitaker

Cc:
Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services
Robert Califf, Commissioner, Food and Drug Administration
Vindell Washington, National Coordinator for Health Information Technology,
Office of the National Coordinator