



August 18, 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 information from a medical device's Unique Device Identification (UDI) to the hospital claims form. 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 form. Adding the UDI to the claims form at this time is premature and ignores tracking, registry and other postmarket data collection requirements already in place for implants.

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 FDA (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 system is being phased in gradually and by 2018 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. 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 limited information from a device's UDI to hospital claims forms with the purported goal of improving postmarket surveillance for certain medical devices. This proposal creates unnecessary costs for hospitals and the Medicare system while providing incomplete surveillance data. We believe that collecting UDI information in an electronic health record (EHR) is a better alternative that is more practical, economical, and of value to patients, healthcare providers, industry and the government.

Adding a UDI field to hospital claims forms 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 forms is to improve postmarket surveillance, there are other avenues to do this that would not lead to unnecessary costs and burdens on hospitals, such as maximizing use of the UDI as part of the EHR, as outlined below.

One specific proposal under discussion is to add only the Device Identifier (DI) portion of the device's UDI on the claims form. We understand supporters of this proposal believe this information is sufficient to enhance postmarket surveillance. We do not believe this to be the case, however, because the DI portion of a UDI represents only a limited data set of the underlying product. In particular, the DI represents only the manufacturer name and device model. More detailed information such as lot, batch, expiration date or serial number is contained within 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.<sup>1</sup>

Instead of focusing efforts on modifying the claims form 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). 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 and 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 contact me at (202) 434-7203 / [DMay@advamed.org](mailto:DMay@advamed.org).

Sincerely,



Don May  
Executive Vice President  
Payment and Health Care Delivery Policy

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<sup>1</sup> 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.



**AdvaMed**

Advanced Medical Technology Association

**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