September 28th, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, DC 20201

Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Administrator Verma and Commissioner Gottlieb:

The following organizations strongly support the implementation of the Unique Device Identifier (UDI) through electronic health records (EHRs) and clinical registries in order to achieve the congressional intent of promoting patient safety by ensuring all patients and their healthcare providers as well as public health officials and researchers have accurate and complete information on medical devices, in a timely manner. In light of the limited resources (including funding and human resources) to effectively implement the UDI, we are also opposed to the recommendation to add the Device Identifier (DI) portion of a medical device's UDI to health insurance administrative claims forms. This would impose additional costly administrative burdens on health care providers and would provide no clearly identifiable benefit to patient safety or the health care system.

Our organizations are strong proponents of efforts to enhance medical device safety. We support a system that effectively integrates the UDI into clinical practice so that physicians and their patients are well-positioned over time to have ready access to the full UDI when safety issues arise. In addition, we strongly support strategies that enable earlier detection of patterns suggestive of safety concerns. It is for these reasons we strongly support the inclusion of the full UDI information in a patient's EHR, which when coupled with a more robust data analysis architecture, would facilitate more accurate reporting, as well as review and analysis of medical device performance over time. Unlike the addition of DI to an administrative claim, including the UDI in the EHR would place the identifier in the context of the clinical information necessary for a complete understanding and evaluation of device performance. The portability of a patient's EHR with this information would serve as a more effective post-market surveillance tool than using administrative claims and can improve coordination among physicians and supports medical decision-making. (In contrast, when patients change insurance companies during the annual election period or when they change employers, for example, the link between patients and payer claims is broken.) The process to include the UDI in EHRs has already begun and the certified EHR is required to include UDI in the next update.

However, the recommendation to include the DI on the administrative claims form would not meet the stated intent of improving device safety monitoring and would not serve to promote patient safety. 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. Only capturing a device's DI would not provide sufficient information and could result in faulty 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.

Health insurance claims forms are used to obtain payment for health care services rendered, and current coding systems provide sufficient information to identify procedures involving medical devices for the purposes of reimbursement. Adding the DI portion of a medical device's UDI goes beyond the original intent of a claims form. Thus, it is unclear what purpose inclusion of this information on claims submissions provides from a claims payment standpoint.

Attaching the DI to claim forms would also create undue provider burdens. Providers would need to make investments to update their internal systems to adequately relay DI information onto the claim. Furthermore, any errors in cataloging DI information could result in delaying claim payment. The current Administration has prioritized reducing regulatory burdens. Given the provider and payer burden associated with adding DI information to the claim forms, this is an opportunity by the Administration to prevent a burdensome regulation from being implemented.

Thank you for your attention to this matter. Please do not hesitate to reach out to us if we can be of further assistance.

Sincerely,

Advanced Medical Technology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Otolaryngology Head and Neck Surgery
American Association for Homecare
American Association of Neurological Surgeons
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
College of Neurological Surgeons
Medical Device Manufacturers Association
National Venture Capital Association
North American Spine Society
Society for Cardiovascular Angiography and Interventions