

April 27, 2015

Stephen Ostroff, MD  
Acting Commissioner  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

**RE: Docket No. FDA-2012-N-0359**

Dear Acting Commissioner Ostroff:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to provide comments on the National Medical Device Postmarket Surveillance Planning Board's (Planning Board) report "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System" released in February 2015. It is also our pleasure to have the AMA's Kathleen Blake, MD, MPH, Vice President of Performance Improvement, serving on the Planning Board. In brief, the AMA applauds the Planning Board's mission of creating a "National Medical Device Postmarket Surveillance System (MDS) that supports optimal patient care by leveraging the experiences of patients to inform decisions about medical device safety, effectiveness, and quality in order to promote the public health." The main objective of this surveillance system must be to provide the patient with the best health outcomes possible.

We appreciate the thorough way in which the Planning Board explored the current medical device safety surveillance system, the roles of the many "actors" within the system, and the implementation of the Unique Device Identifier (UDI) as a resource for safety surveillance. Because of the criticality of patient safety, we believe that health care organizations must focus their UDI implementation efforts on medical device safety surveillance at this time. Therefore, we strongly support the Planning Board's statement that the MDS' primary function is to facilitate timely and reliable safety surveillance. Although health care organizations may wish to utilize UDI for secondary purposes, such as internal cost analysis for example, these uses should not be considered or initiated until implementation of the UDI for safety surveillance is complete.

A number of stakeholders have posited that the best strategy for post-market surveillance would be the inclusion of the UDI into electronic claims data. This activity was addressed by the Planning Board which noted in the report that, "...some Planning Board members oppose the inclusion of UDIs in claims data as a component of the adoption strategy." We agree with those on the Planning Board who oppose this effort. Several characteristics of a health plan-based model of UDI reporting limit its efficacy for optimal patient-centered safety surveillance.

First, patients are annually given the option to change their health plans—through their employer or the health insurance exchange—and they do. In addition, many employers change health plans frequently in

an effort to control health care costs. As a result, a patient's health plan at the time of the device implant may no longer be the same as it is at the time of a device problem, failure, recall, or explant—particularly because devices often only show evidence of malfunction years after the original implant and submission of a claim. Where a patient changes health plans, the payer at the time of device implantation could have minimal to no ability to contact the patient or their treating physician regarding a problem or recall.

Reporting the UDI in the health care claim will also not provide all of the clinical information necessary to analyze and determine the patient's outcome related to a medical device. The limitations of administrative data for analysis of care quality and outcomes have been widely acknowledged in the health care industry, and any review of device performance based only on claims data would be similarly incomplete and inadequate. Additionally, a model that establishes health plans as the recipients of UDI data will make it difficult for physicians and providers to access this information. When a device malfunctions, it is critically important that the UDI and other information be accessible by physicians at the point of care. Such information, if stored in a payer's database, is unlikely to be retrievable by a physician.

Besides not advancing the central goal of supporting patient-centered sentinel reporting, inclusion of the UDI in health care claims imposes substantial burdens on the healthcare system because it will require investment of resources by physicians and other health care providers that should be directed toward patient care. The Planning Board acknowledged the importance of minimizing the burden and costs to providers in data capture several times in its report and stated that "the long-term sustainability of the system is questionable if reporting data is a substantial burden." We agree with this assessment. Adding UDI to administrative transactions at this time will only detract from the main goal of strengthening the safety surveillance system.

The addition of the UDI to the claim or other administrative transactions will be a costly and cumbersome undertaking for physician practices and other health care provider organizations. In order to enable the proper tracking of UDI, a functional link between the supply chain, inventory management, electronic health record (EHR), and claims revenue systems would need to be created. Currently, no provider organization has linked all of these components, meaning that this necessary work would be untested and potentially inefficient. We are aware of one health care system that has integrated UDI into its supply chain management and EHR systems, but not its revenue cycle system. It is also important to note that this system's integration costs were externally funded by a Food and Drug Administration (FDA) grant. Therefore, the true implementation cost for this highly committed provider and for other health systems cannot be determined.

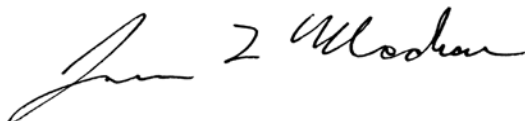
A key principle of the Health Insurance Portability and Accountability Act's (HIPAA) administrative simplification provisions is to reduce burden on health care organizations through electronic standards. The introduction of additional administrative requirements into HIPAA transactions such as the claim—particularly items that are not required for payment purposes—runs contrary to the regulatory intent. Inclusion of the UDI in claims transactions may also disrupt timely provider payments. For claims processing, payer identification and validation of the UDI and implant would be necessary in order for the claims data to be as accurate as possible for subsequent data analysis efforts. Accordingly, any failure of claim edits due to UDI would result in claim rejection, and the subsequent rework by the payer and provider could cause significant delays in the health care revenue cycle.

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While there are a number of shortcomings to relying upon the inclusion of the UDI in electronic claims transactions, there are a number of significant benefits to inclusion of the UDI in the EHR. The Notice of Proposed Rulemaking for the 2015 Edition Health Information Technology (Health IT) Certification Criteria includes the recommendation for the EHR to include functionality to record and access UDIs. We are supportive of this criterion and believe that the UDI and other implanted device information should be stored in an EHR where it will be accessible to physicians and other health care providers caring for patients, along with other relevant clinical information about the patient. We are committed to seeing widespread interoperability among EHRs and the utility of UDIs in EHRs will be far better realized there than in siloed payers' databases. We also support the capture of UDIs in clinical registries where it can be used in the evaluation of a specific population of patients with implanted devices.

Finally, before a new system for reporting UDIs is implemented, we strongly urge the FDA and other willing stakeholders to pilot projects to assess the usability and functionality of the proposed new process(es). The pilot projects should also identify costs and benefits and to which organizations, by type, that the benefits accrue. It stands to reason that those that receive the greatest financial benefits would also be those that would bear the largest share of the implementation costs. In summary, as a result of the limitations of reporting UDIs to payers for the purposes of patient safety and post-market surveillance, we recommend that the MDS not pursue UDI reporting on health care administrative transactions. Alternatively, we recommend that the resources that would otherwise have to be spent working to enable the transmission of the UDI to payers be redirected toward enhancing the capabilities of EHR and registry platforms. Thank you for the opportunity to comment on the Planning Board's report. Should you have any further questions, please contact Nancy Spector, Director of Electronic Medical Systems, at [nancy.spector@ama-assn.org](mailto:nancy.spector@ama-assn.org) or 202-789-4586.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD

cc: Thomas P. Gross, MD, MPH