



FEB 23 2015

Administrator
Washington, DC 20201

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

Dear Senator Warren:

Thank you for your letter regarding Unique Device Identifiers (UDIs). The Centers for Medicare & Medicaid Services (CMS) supports the Food and Drug Administration's (FDA) goals to improve post-market monitoring and surveillance and product recall capability, and to enhance adverse event reporting and research with respect to high-risk implantable medical devices. We agree that UDIs would aid the FDA in these efforts. I appreciate your bringing your concerns to my attention.

In September 2012, the FDA issued a strategy for establishing a national medical device post-market surveillance system to quickly identify poorly performing devices, accurately characterize and disseminate information about real-world device performance, including the clinical benefits and risks of marketed devices, and efficiently generate data to support premarket clearance or approval of new devices and new uses of currently marketed devices. An important element of this system is the incorporation of unique device identifiers into electronic health information, in particular electronic health records and appropriate medical device and disease registries. CMS agrees with this approach. As we work closely with our colleagues in the Office of the National Coordinator for Health Information Technology in drafting new regulations for the Medicare and Medicaid EHR Incentive Program, we will seek opportunities to further the FDA's goals regarding electronic health records.

In addition to including UDIs in registries, electronic health records and other transactions, some have suggested that collecting UDIs on claims could provide additional, useful information. However, including UDIs on claims would entail significant technological challenges, costs, and risks to normal claims processing for Medicare and other payers. Many others share these concerns including the National Uniform Billing Committee (NUBC) and the National Uniform Claim Committee (NUCC).

On September 23, 2014, the National Committee on Vital and Health Statistics (NCVHS), the statutory advisory committee to the Secretary on health information policy and standards, recommended not mandating the capture, reporting and use of UDI in administrative transactions at the current time. Rather NCVHS recommended that "HHS should continue to work with the Industry to better understand and document the value, benefits and cost of reporting UDI in administrative transactions." This would include "the business reasons for, and costs and benefits of including UDIs in administrative transactions including the added burden for

providers and payers to capture, report and receive/use UDI and the system and workflow changes required” and “the potential post-market surveillance role of payers who receive UDI from providers via administrative transactions.” NCVHS also recommended consideration of implementing pilot tests and working to improve existing mechanisms for post-market surveillance of devices. At a January 2015 meeting of the claims/encounter workgroup of the American National Standards Institute's Accredited Standards Committee (ASC X12), concerns were expressed about the benefits of requiring UDIs to be reported on claims and the issue was referred to a special workgroup.

CMS believes that mechanisms other than claims reporting for collecting UDIs would avoid the significant challenges and risks of collecting UDIs on claims. CMS supports the FDA's engagement with the public to identify registries that could be utilized together with electronic health record information to better leverage real world clinical data to improve post market monitoring and surveillance.

The UDI comprises two pieces, the Device Identifier (DI) and the Production Identifier (PI). The DI is from 16 to 23 characters and is specific to a device version or model. The PI reflects information about the production of the device such as batch or lot number, expiration date or sometimes the serial number. When the DI is combined with the PI, the total UDI size can be 75 characters.

Efforts to collect UDIs on claims would engender many operational challenges. The Health Insurance Portability and Accountability Act (HIPAA) requires the Secretary to adopt standards for electronic health transactions, including health claims. All HIPAA covered entities (e.g., health plans, health care providers, and clearinghouses) use a standardized claim format adopted by the Secretary known as the 837, and can only require information to be reported on claims that is consistent with that form. The Secretary would need to adopt revisions to the 837 for covered entities to be able to report UDIs on claims.

Altering the 837 would involve a lengthy multi-party, multi-stepped process, summarized as follows: (1) ASC X12 would first adopt changes to the standard electronic claims formats and implementation guides to provide space for submission of multiple iterations of the UDI; (2) ASC X12 would then submit changes to the NCVHS; (3) NCVHS would consult with the NUBC, NUCC, Workgroup for Electronic Data Interchange, and the American Dental Association before any changes are adopted (NUBC and NUCC would likewise need to update paper forms); (4) the Secretary would consult with the NCVHS prior to making a decision; (5) the Secretary would issue proposed rulemaking to adopt the new standard, followed later, if the decision were made to finalize the proposed rule, by a final rule. This process typically takes several years.

Changing the claim format to include UDI would also require substantial, expensive, and time-consuming changes to claims processing systems and claims warehouses for all health plans, providers, clearinghouses, and vendors and business associates (e.g., billing services, and repricers). Retrofitting Medicare's legacy claims systems to accommodate UDI reporting would require extensive programming changes and claims edits that could negatively impact the

processing time and adjudication of the more than 1.2 billion claims that Medicare annually processes.

The time and expense to update CMS's systems when claims standards change varies depending upon the scope of the change. The recent claim form update from version 4010 to version 5010 took 5 years, at a total combined cost to CMS (for Medicare and Medicaid) of \$700 million, with other payers bearing additional costs. Without knowing the requirements for a UDI standard, it would not be possible to estimate implementation costs, but the systems changes required to accept the full UDI would likely make it a much more complicated change than that associated with the change from version 4010 to 5010.

Information reported on claims needs to be verified to ensure that it is valid. CMS is concerned that collecting UDIs on claims would be prone to errors because there are an estimated 300,000 UDIs just for high-risk implantable medical devices, multiple UDIs may need to be reported on a claim, UDIs vary in format depending on the UDI-assigning entities, the UDI is more than 10 times longer than an ICD-10 code, and the data are not essential to adjudicate claims. Without validity checks, simple errors could lead to improper identification of products and patients. Since a database that contains all full UDIs is not available, payers would not be able to validate that UDIs submitted on claims were actual assigned UDIs.

Some have suggested that, in lieu of reporting the full UDI, reporting just the DI portion of the UDI on claims would suffice. However, in addition to involving all the steps to change claims, claims edits would also be needed to: (a) verify that a valid DI was reported on a claim; (b) validate that the DI was appropriate for the claim billing unit (e.g., a DI for implantable infusion pump was not reported on a hospital claim for pacemaker insertion); and (c) identify claims for which a DI should have been reported but was not. Developing, applying, and continually updating claims edits would be expensive and challenging. For example, considering just high-risk implantable medical devices, 300,000 UDIs would need to be cross-walked to device dependent Medicare Severity Diagnosis Related Groups (MS-DRGs), Ambulatory Payment Classifications (APCs) and procedure codes for related physicians' services. While the FDA's Global Unique Device Identification Database (GUDID) could be used to verify DIs, claims edits would be needed to associate DIs with each different payment code used in every payment system by each payer. Claims edits would need to be continually updated to reflect new DIs. Moreover, there could be inconsistency in the quality of claims edits developed and applied among many different payers. The challenge of developing claims edits would increase when as many as 4 million UDIs covering all classes of medical devices (and involving an unknown lesser number of DIs) are phased-in over the next few years pursuant to the FDA's compliance dates for UDI requirements.

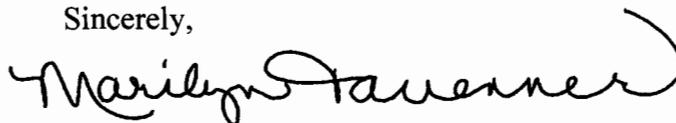
An additional technical issue is that the multiple entities that assign the UDIs currently do not use a standard format, with at least one assigning entity employing special characters in its UDIs. The use of special characters is a particularly difficult problem in a claims transaction, as special characters have specific and limited uses such as element delimiters (separators), segment terminators, and/or file terminators. While we understand that this issue is being addressed, until it is adequately dealt with, having a special character embedded in the UDI could cause major systems errors for payers expected to accept the UDI on claims transactions.

There is also an issue about whether payment systems are the best method to track devices. Patients change commercial insurance plans relatively frequently and there is no legal obligation for a plan to maintain contact with a formerly insured individual. This would hinder recalls. Moreover, some believe that many previously recalled devices had not yet reached patients, but, instead, remained in inventories along the supply chain, in which case reporting UDIs on claims would not yield a benefit.

We believe that collecting UDI information could be a valuable resource for many uses. These uses could include: improving the effectiveness of product recalls; assessment of long-term outcomes (by registries and others); assessment of patient safety as well as post-market monitoring and effectiveness research on devices; making public aggregate information on Medicare utilization and payments for medical devices; making available information to patients; and curbing fraud and abuse activities. Because of the extensive concerns about collecting UDI data via claims, however, we believe that collection mechanisms other than claims would best facilitate accurate reporting of valid UDIs. Such non-claims collection mechanisms would also allow collection of robust information (additional to UDI) that could not be collected on claims but could be helpful to these activities. For example, information on patient status, laboratory and imaging results, medication use, and surgical details are often used to evaluate post-market safety and in effectiveness research but cannot be captured on claims.

Thank you for sharing your perspective on the use of UDIs. I appreciate your interest in this important issue as we work toward our mutual goal of strengthening the Medicare program for all beneficiaries. Please do not hesitate to contact me if you have any further thoughts or concerns. I will also provide this response to Senator Charles E. Grassley.

Sincerely,

A handwritten signature in black ink that reads "Marilyn Tavenner". The signature is written in a cursive, flowing style with a large, sweeping flourish at the end.

Marilyn Tavenner