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

November 15, 2017

Dear Administrator Verma:

We are writing regarding the recent response of the Centers for Medicare & Medicaid Services (CMS) to a report from the Office of the Inspector General (OIG) of the Department of Health and Human Services on the costs to taxpayers and patients resulting from recalled and faulty medical implants. As organizations that include or represent healthcare providers—such as physicians, clinics, hospitals and others—we support OIG's recommendation to add device identifiers to claims forms. Detecting medical device failures sooner, including through claims data, will both improve patient safety and reduce costs.

In a report released earlier this month, the OIG found that the failure and recall of just seven cardiac implants cost CMS $1.5 billion to provide follow-up care to patients affected by the faulty products, and Medicare beneficiaries an additional $140 million in out-of-pocket expenses. Given the limited scope of the investigation, the costs to both taxpayers and patients is assuredly higher when considering other products, including hip and knee implants.

OIG found that claims data lacked the necessary information to detect device failures. To address this gap, OIG recommended adding device identifiers (a portion of the unique device identifier, or UDI, which Food and Drug Administration regulations require each device to have) to claims to indicate the brand and model of device used. Claims data, in turn, could supplement other data sources—such as registries—to provide more robust data on product performance and detect device failures sooner, which is important to both prevent problems sooner and provide assurances to organizations that participate in alternative payment models that the products they use are high quality.

The OIG recommendation echoes support for device identifiers in claims from a wide array of healthcare stakeholders, including clinical societies that represent physicians that implant these products, hospitals, the Medicare Payment Advisory Commission, and many other organizations.

In CMS' response to the recommendation, you indicated that the agency would examine the potential burden to healthcare providers of the addition of device identifiers to claims. As healthcare provider organizations, we believe the benefits of adding device identifiers to claims of improved patient safety and reduced costs far outweigh any limited additional effort required. Once device identifiers exist in healthcare data sources—such as supply chain systems or electronic health records (EHRs)—transmitting that information electronically to claims is straightforward as research has shown.[i] Therefore, the primary effort required to document device identifiers will occur regardless of their inclusion in claims; as healthcare organizations will already be making that effort, they should experience as many benefits as possible, which can only happen through the inclusion of device identifiers in claims.

In addition, we understand that you may also be considering other factors, including the role of claims data in postmarket surveillance. Postmarket surveillance for devices relies on a broad range of data—including clinical trial databases, adverse event reports, registries and other data sources. Each of these data sources has its strengths and limitations. One of the strengths of claims data is that they provide

longitudinal information (such as revision surgery to remove an implant) on patient outcomes from thousands—even millions—of patients in ways that other data sources may not be able to provide. Incorporating device identifiers in claims would enable them to supplement—not replace—other sources of information for postmarket surveillance and would fill critical gaps in the availability of longitudinal data on large numbers of individuals. In fact, CMS has recognized the utility of claims data for analysis and the creation of a learning healthcare system.

Additionally, you may also be considering whether the entire UDI or just the device identifier portion is required in the claim to obtain benefits. Having only the device identifier in claims—as included in draft recommendations by X12, the private organization that administers the claims standard—provides substantial benefits over existing data. Adding the device identifier will provide claims with information on the brand and model of device, so that researchers—including within some of our organizations—can evaluate the quality of specific devices. Further, many challenges with device safety affect the entire product line; as a result, having the brand and model from the device identifier is sufficient for analyses and the production information contained in the rest of the UDI is not needed.

Finally, some have suggested utilizing EHRs or attachments in lieu of claims. While we support adding UDIs to EHRs, EHR data are not standardized in a manner to support analyses from many providers and across millions of patients. Claims, on the other hand, are standardized and are already used for those kinds of analyses. Similarly, claims attachments are not standardized. Even once they are, the data may not be structured, thereby inhibiting their use for research to evaluate device performance.

In conclusion, as organizations that include or represent healthcare providers, such as physicians that implant these products, doctors' offices and hospitals, we support the addition of device identifiers in claims data. We do not believe this would introduce an undue burden. We urge CMS to support OIG's—and many others'—recommendation to add device identifiers to claims to enable hospitals and clinicians to obtain better data on product performance to improve safety and reduce costs for our patients.

Should you have any questions, please contact Courtney Yohe, Director of Government Relations, The Society of Thoracic Surgeons, at cyohe@sts.org or 202-787-1222.

Sincerely,

Alliance of Community Health Plans
American College of Cardiology
American College Health Association
American Joint Replacement Registry
American Medical Group Association
Geisinger
Intermountain Healthcare
Oregon Health & Science University
Premier Inc. healthcare alliance
The Society of Thoracic Surgeons
Adil Haider, MD, Adam Landman, MD, Joel S. Weissman, PhD, representatives from the Center for Surgery and Public Health, Brigham and Women's Hospital, Harvard Medical School

[i] Brigham and Women's Hospital, "Transmitting the UDI from the Point of Use to Insurance Claims: Changes in Workflows and Information Systems" (2017) http://www.brighamandwomens.org/Research/labs/CenterforSurgeryandPublicHealth/Research/PPOPP/UDI2Claims_Whitepaper.pdf