United States Senate
WASHINGTON, DC 20510

August 12, 2015

The Honorable Daniel R. Levinson
U.S. Department of Health & Human Services
Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Levinson:

Congress is currently examining legislation to facilitate medical product innovation. As part of these efforts, we are, we are evaluating ways to improve the postmarket surveillance and safety of medical devices, such as artificial hips, implanted pacemakers and cardiac stents. Your pending investigation on medical devices that are recalled or fail within their expected life cycle may help to inform Congress' efforts to ensure that patients, physicians, regulators, manufacturers and health plans have better data on medical device quality and safety, and the impact of medical devices on patient outcomes.

While medical devices are critical to saving and improving patient lives, occasionally serious problems emerge with these products after approval. For example, malfunctions of two manufacturers' implantable cardiac defibrillator leads—used by hundreds of thousands of patients—caused serious adverse events and death.[1, 2] Researchers have estimated that the failure of just one of the manufacturers' cardiac defibrillator leads could have cost Medicare as much as $1.2 billion.[3]

Similarly, more than 500,000 U.S. patients received a metal-on-metal hip prosthesis, which failed at much higher rates than artificial joints made of other material—problems that were detected first in Australia and Europe.[4] As joint replacement surgery is the most common hospital procedure reimbursed through Medicare, malfunctions of hip and knee implants could cost Medicare—and by extension the taxpayers—billions of dollars, not to mention the significant harm to patients.

Detecting these problems sooner requires a better infrastructure to collect more robust data on the performance of these products after approval or clearance by the Food and Drug Administration (FDA). With FDA's establishment of a unique device identifier (UDI) system, each medical device will receive a code corresponding to its manufacturer and model type. Once this UDI system is incorporated into electronic health data, the FDA, researchers, health plans and other stakeholders will have more robust data to detect problems earlier, alert clinicians to malfunctioning products and ensure patients receive appropriate care before there is a serious adverse event.

In addition to the postmarket surveillance benefits, the incorporation of UDI into insurance claims could also have significant benefits toward improving the efforts of the Centers for Medicare & Medicaid Services (CMS) to detect fraud and recoup payments when devices fail. Under current CMS policies, when devices are recalled or failed before their lifecycle, hospitals can request a credit from the manufacturer of the product. The hospital must then, on the claim form, notify CMS that it received this credit, and Medicare would then adjust reimbursement accordingly.[5] Your office has already investigated this issue, finding last year in a review of 1,859 claims for cardiac implant procedures that Medicare overpaid hospitals $550,000 because either the hospital did not report a manufacturer credit they received or neglected to ask for a credit they could have received.[6] As this investigation covered a very small sample of claims for cardiac implant procedures only, these findings likely vastly underestimate the number of claims and potential savings due to Medicare under existing coverage and reimbursement policies.

UDIs, once integrated into claims data, could support efforts beyond postmarket surveillance to curb fraud and better enforce existing coverage and reimbursement policies, such as those related to recalled or failing devices. The addition of a field on claims transactions for the UDIs of implanted devices could, for example, help Medicare identify all claims associated with a recalled device to then ensure that applicable hospitals both seek manufacturer credits and report them to CMS.

Your office's current investigation into Medicare costs incurred from defective medical devices, including expenses associated with replacing the product and ancillary care, will provide important data to inform the ongoing discussion in Congress on how to utilize the UDI system to improve care while reducing costs.[7] However, the release of your report may come too late to inform this urgent public policy discussion.

To ensure that Congress has the data it needs from your investigation, please provide us with as much information as you are able to disclose by September 1. Specifically:

1) From your research to-date, how many claims have been associated with procedures that could have included devices that are recalled or failed within their expected lifetime? What are CMS' overall costs associated with these procedures?
2) As part of your investigation, what is your estimate for how much Medicare overpaid hospitals for failed or recalled devices? How much of these overpayments are a result of hospitals failing to report a credit versus the hospital not receiving a due credit in the first place?
3) What challenges did you encounter in obtaining and analyzing the data because of a lack of specificity in claims on the devices used?
4) How could UDI in claims support Medicare efforts to better recoup payments and costs associated with defective or recalled devices?
5) How could UDI in claims support overall Medicare efforts to reduce costs and better analyze care provided to seniors?
6) Are the relevant federal agencies providing you with timely and comprehensive assistance to obtain data, analyze the information or otherwise assist the audit?

If you have any questions, please do not hesitate to contact Remy Brim in Senator Warren's office (remy_brim@warren.senate.gov) and Rodney Whitlock in Senator Grassley's office (rodney_whitlock@grassley.senate.gov). Thank you for your prompt response on this matter.

Sincerely,

Elizabeth Warren
United States Senator

Charles E. Grassley
United States Senator

CC:
Sylvia Mathews Burwell, Secretary, Department of Health and Human Services
Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services
Dr. Stephen Ostroff, Acting Commissioner, Food and Drug Administration

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[1] Robert G. Hauser, "Here We Go Again — Another Failure of Postmarketing Device Surveillance," *New England Journal of Medicine* 366, (2012): 873-4, DOI: 10.1056/NEJMp1114695.
[2] Robert G. Hauser, et al., "Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads," *Heart Rhythm Journal* 9, no.8 (2012): 1227-35, DOI: 10.1016/j.hrthm.2012.03.048.
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[4] Joshua P. Rising, Ian S. Reynolds, and Art Sedrakyan, "Delays and Difficulties in Assessing Metal-on-Metal Hip Implants," *New England Journal of Medicine* 367, (2012), DOI: 10.1056/NEJMp1206794
[5] "Medicare Claims Processing Manual: Chapter 3 – Inpatient Hospital Billing," Centers for Medicare & Medicaid Services, last updated Sept. 24, 2014, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.
[6] "Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits," Department of Health and Human Services Office of Inspector General, Oct. 2014, http://oig.hhs.gov/oas/reports/region5/51300029.pdf.
[7] "Fiscal Year 2015 Work Plan Mid-Year Update," Department of Health and Human Services Office of Inspector General, May 2015, https://oig.hhs.gov/reports-and-publications/archives/workplan/2015/WP-Update-2015.pdf.