DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

SEP - 1 2015

The Honorable Charles E. Grassley
United States Senate
Washington, DC 20510

Dear Senator Warren and Senator Grassley:

I am writing in response to your letter dated August 12, 2015, regarding the impact on patient safety and the cost to the Medicare program of medical devices that are recalled or fail during their expected life cycle. As you are aware, the Food and Drug Administration Amendments Act of 2007 charged the U.S. Food and Drug Administration (FDA) with creating a unique device identifier (UDI) system that will give each medical device a code corresponding to its manufacturer and model type to better detect adverse events, improve product recalls, and enable robust post-market surveillance. We, too, recognize the prospective benefits of incorporating the UDI into registries, electronic health records, and health insurance claims data, both to protect beneficiaries from adverse events and the Medicare trust funds from significant losses, and we believe collecting UDI data on claims forms would add significant long-term value and benefit.

Beneficiaries adversely affected by recalled or failed devices incur adverse health events and/or unnecessary costs. Further, Medicare trust funds are jeopardized by the significant financial liability for defective medical devices. This liability includes additional monitoring, hospitalization, surgeries, imaging, postacute care, and physician costs.

In 2007, the Centers for Medicare & Medicaid Services (CMS) expressed its concerns about the impact of additional health care costs and Medicare expenditures associated with defective medical devices.[1] CMS stated that it would develop a plan to address this issue; CMS has not developed that plan to date.

The establishment of a UDI system is a great first step to assist in identifying the total costs to Medicare for defective medical devices, ensure patient safety, and safeguard the Medicare trust funds. To realize the significant long-term value and benefit from the creation of the UDI system from a program integrity standpoint, it would be beneficial to include the UDI on claims forms.

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[1] 72 Fed. Reg. 66222, 66327 (Nov. 27, 2007).

In your letter, you asked OIG to respond to six questions; the answers to those questions are enclosed. We are unable to fully respond to some of your questions because Medicare claims forms insufficiently identify Medicare beneficiaries who received a recalled or defective device. Therefore, we cannot readily determine the number of Medicare beneficiaries affected by medical device recalls and failures or assess the financial impact on Medicare. However, we have identified over 200 FDA recalls for cardiac devices alone since early 2010 that we believe have significantly increased Medicare costs. There have also been numerous orthopedic-related recalls within the past 5 years that we believe have significantly increased Medicare costs.

We appreciate the opportunity to respond to your concerns and questions. If you have any questions, please contact me or your staff may contact Christopher Seagle, Director of External Affairs, at (202) 260-7006 or Christopher.Seagle@oig.hhs.gov.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Inspector General

Enclosure:
HHS OIG's Response to Senator Warren's and Senator Grassley's Questions

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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's overall costs associated with these procedures?*

As explained in our letter, we are not able to provide a specific number of claims that resulted from these recalls because the information collected on the Medicare claims form is insufficient. Nevertheless, research indicates that recalls of defective medical devices have likely resulted in millions of Medicare claims for monitoring services and device replacement-related procedures and services. In addition, research also indicates that beneficiaries have incurred unwarranted expenses, including copayments and deductibles, and suffered exposure to significant health risks.

For instance, Medtronic's Sprint Fidelis defibrillator wire or "lead" was recalled in October 2007 after 268,000 of them were implanted.[1] For months, Medtronic and the FDA lacked the data to gauge the extent of the danger to recipients;[2] subsequent research studies done by two independent groups estimate that Medicare incurred costs exceeding $1 billion due to this recall alone.[3]

While we cannot precisely determine CMS's overall costs associated with fixing and monitoring problems caused by defective devices, based on our work and work of other researchers, we believe that Medicare, and by extension the taxpayers, has most likely spent several billions of dollars on monitoring, hospitalization, surgeries, imaging, postacute care, and physician costs. To underscore the materiality and help us fully examine this issue, we have initiated a review of the Medicare costs incurred due to seven cardiac devices with high failure rates that have been implanted into numerous beneficiaries.

We expect to make recommendations that will facilitate the identification of the total Medicare costs incurred due to defective medical devices.

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?*

Because the information collected on the Medicare claims form is insufficient, we are not able to estimate the total Medicare overpayments to hospitals for failed or recalled devices for any

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[1] Recall announcement number Z-0068-2008, dated October 25, 2007.

[2] "FDA to Require ID Numbers for High-Risk Medical Devices," *Wall Street Journal*, September 20, 2013

[3] *Examining the Sprint Fidelis Effect on Medicare Costs*, H. Dennis Tolley, PhD, ASA and *Medtronic Sprint Fidelis lead recall: Determining the Initial 5-year management cost to Medicare,* Heart Rhythm Center in the Section of Cardiology, Department of Internal Medicine, University of Chicago, Chicago, Illinois and Electrophysiology Section, Northwestern University, Chicago, Illinois.

specified period. However, our compliance reviews at specific hospitals[4] have identified approximately $10 million in overpayments to the hospitals for device manufacturer credits that were received but not reported by the hospitals to Medicare (about 75 percent of the $10 million) or for credits that were available under the terms of the manufacturers' warranties but not obtained by the hospitals (about 25 percent of the $10 million). It is important to note that the regulations regarding medical device warranty credits only address the amount due back to Medicare for credits that providers receive from device manufacturers. The cost of the replacement device represents only a relatively small portion of the total costs incurred by Medicare, which include monitoring, hospitalization, surgeries, imaging, postacute care, and physician costs.

3) *What challenges did you encounter in obtaining and analyzing the data because of a lack of specificity in claims on the devices used?*

Because claims forms do not include device-specific information, we were unable to discern from the claims data alone the device manufacturer and model and whether the revision was due to a defective device that was recalled and warrantied, as opposed to, for instance, a medically necessary device upgrade. Furthermore, although there is a field on the claim that will permit the use of two condition codes to identify whether a device has failed within its life cycle or has been recalled, hospitals rarely utilized this field. We are also unable to determine the additional related healthcare costs for the subsequent services provided to beneficiaries as a result of receiving device replacements due to defects or recalls.

4) *How could UDI in claims support Medicare efforts to better recoup payments and costs associated with defective or recalled devices?*

Including the UDI on claims forms could be an important step in the process to identify the manufacturer/model type of a device that has been recalled or has a high failure rate, which might be one way to determine the aggregate 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?*

Incorporating the UDI into claims forms could allow quick identification of poorly performing devices and alert relevant stakeholders earlier when defective devices need to be replaced or monitored. As a result, beneficiaries implanted with recalled products could receive appropriate follow-up care more quickly. Finally, CMS could use the data to make better coverage and reimbursement decisions.

[4] For our reviews at 145 hospitals nationwide, we selected about 200 claims per hospital and determined the hospitals' compliance with Medicare billing requirements for several high risk areas, including credits for defective cardiac devices.

6) *Are the relevant Federal agencies providing you with timely and comprehensive assistance to obtain data, analyze the information or otherwise assist the audit?*

FDA has been cooperative in providing data, and its efforts were instrumental in the selection of the recalled devices in our current review. FDA also supplied valuable background information on its device approval processes and monitoring mechanisms. Moreover, OIG has independent access to timely Medicare claims data. CMS support and assistance is crucial to this effort and we look forward to working with CMS to obtain the necessary information to complete our work.