United States Senate
WASHINGTON, DC 20510

March 8, 2016

Sylvia Matthews Burwell
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Andy Slavitt,
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Robert Califf, MD, MACC,
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Burwell, Acting Commissioner Slavitt, and Commissioner Califf,

We are writing to inquire about the progress the Department of Health and Human Services (HHS), Center for Medicare and Medicaid Services (CMS), and Food and Drug Administration (FDA) have made on the addition of the unique device identifier (UDI) of medical devices to health insurance claims forms in order to improve post market surveillance and curb waste in the Medicare program.

Congress has recognized that a tracking system for medical devices is a critical tool to better detect adverse events, facilitate product recalls and enable robust post market surveillance. In 2007, Congress required the FDA to create the UDI system and then in 2012 required that the Sentinel Initiative—a large electronic database comprised of primarily insurance claims data designed to evaluate the safety of drugs and biologics—be expanded to medical devices. Active post-market surveillance of medical devices can help to track product safety and performance, which is critical to public health and safety.

To reap the numerous benefits that UDI can provide, it must be incorporated into electronic health data sources – including insurance claims. We wrote to CMS Administrator Marilyn Tavenner on December 22, 2014 asking how the addition of UDI on the insurance claims form could improve patient safety and evaluation of medical devices, and what actions CMS planned

to take to make this important update. CMS replied at the time, and has continued to express, opposition to adding UDI to the claims form solely because of the technological challenges associated with the change.

In addition to the patient safety benefits that the inclusion of UDI in claims can provide, inclusion may also help to protect the integrity of the Medicare program. We are enclosing a letter from the Office of Inspector General in response to our request for feedback on a study they are conducting that outlines the costs that Medicare incurred due to recalled or poorly performing devices. Their preliminary findings indicate that recalls of defective products have likely resulted in millions of claims for monitoring, replacement and follow up care at significant costs. Inclusion of UDI in claims would allow for faster identification of poorly performing and recalled devices, and ensure that hospitals, device manufacturers, and CMS are all receiving proper reimbursement.

Continued opposition by CMS is contrary to the statements made by Secretary Burwell on the record for the HELP Committee. It is also contrary to recent comments from Commissioner Califf and CMS officials in the enclosed *Wall Street Journal* article that the addition of UDI in claims is a priority for the FDA in their efforts to establish a national evaluation system for medical devices and that CMS is "generally supportive" of placing UDI on claims.

Although the next version of the claims form is not scheduled to be implemented until approximately 2021, the window to make changes is rapidly closing. Given the importance of this issue, we hope you will ensure that CMS works collaboratively with FDA and other stakeholders to ensure that the next update of the claims form will incorporate UDIs.

If you have any questions, please do not hesitate to contact Remy Brim in Senator Warren's office and Karen Summar in Senator Grassley's office. Thank you.

Sincerely,

Elizabeth Warren
U.S. Senator

Charles E. Grassley
U.S. Senator

Senate Confirms Cardiologist Robert Califf as FDA Commissioner

New commissioner says top priorities will include using electronic data as early-warning systems

THOMAS M. BURTON
Updated Feb. 24, 2016 6:25 p.m. ET
Wall Street Journal

WASHINGTON—The new commissioner of the Food and Drug Administration said Wednesday his top priorities will include using databases and electronic medical records as early-warning systems to pinpoint safety lapses of drugs and medical devices.

Dr. Robert M. Califf, confirmed overwhelmingly by the Senate on Wednesday, said in an interview that such electronic data should help the federal agency generate "pretty good information about how a product is performing." The idea is that the agency could more actively discern such problems, as opposed to more passively waiting for reports.

The Senate vote was 89-4.

Dr. Califf, a cardiologist with a background at Duke University, said such early-warning information can be derived from medical records and company registries that show how products are performing.

He said he is adamant as well about the use of identification numbers on medical devices that will enable the FDA to spot whether device issues are minor glitches or major safety-endangering malfunctions. The use of such ID numbers in federal Medicare billing records is something the FDA has urged for years, but which the federal Medicare agency has been slow to embrace because of its cost.

"It is going to get done," said Dr. Califf. "The question is when. It's a very high priority for the FDA." Officials at the Centers for Medicare and Medicaid Services, the agency that oversees the program, said they generally support putting medical-device ID numbers on Medicare bills, but they didn't say when it might happen.

Dr. Califf, a multiyear veteran of supervising clinical studies of drugs for the pharmaceutical industry, said he also is intent on enhancing the technical expertise of the FDA workforce to deal with complex biotechnology issues. He has been the FDA's deputy commissioner for medical products and tobacco since early 2015.

Widely viewed as an expert on the intricacies of clinical-trial design, Dr. Califf won the support of both Sen. Lamar Alexander (R., Tenn.) the chairman of the Senate Health, Education, Labor and Pensions Committee, which considered his nomination, and the panel's top Democrat, Sen. Patty Murray of Washington.

"We are fortunate to have a man of this distinction accept this position," Mr. Alexander said on the Senate floor during debate Tuesday.

Some who opposed Dr. Califf did so for a range of reasons. Sens. Joe Manchin (D., W.Va.) and Edward J. Markey (D., Mass.) opposed the nomination over what they contend is the FDA's too-lax approval of narcotic painkillers that have led thousands of people to become addicted and even to die.

The four no votes in the Senate came from Messrs. Manchin and Markey as well as Richard Blumenthal (D., Conn.) and Kelly Ayotte (R., N.H.)

In the interview, Dr. Califf said senators and the public should be upset and concerned about opioid painkillers.

"This is a complex set of issues." He promised the agency will be more flexible in trying to respond to issues of painkiller abuse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

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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

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

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.