United States Senate
WASHINGTON, DC 20510

November 8, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Washington, DC 20201

Dear Administrator Verma,

We write to express our interest in the inclusion of device identifier information on Medicare claim forms. We urge you to follow the recommendation of the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) and act to ensure that Medicare is better able to track poorly performing medical devices.

In September 2017, the HHS OIG released a report analyzing costs to Medicare associated with a set of seven medical devices that failed prematurely or were recalled.[1] The OIG found that Medicare spent $1.5 billion on the medical services incurred in order to replace these poorly performing devices between 2005 and 2014. Medicare beneficiaries whose devices were recalled or failed also paid an additional $140 million in out-of-pocket costs.

In addition to finding that poor performance of medical devices comes at significant cost to the Medicare program and to Medicare beneficiaries, the OIG's analysis concluded that Medicare claim data does not currently support the identification and tracking of recalled or prematurely failed medical devices. Because current Medicare claim forms do not include a field for recording a medical device's "device identifier" (DI) number, Medicare does not collect any medical device-specific information about the products implanted in Medicare beneficiaries. Indeed, the OIG was only able to determine the cost to Medicare associated with the poor performance of seven cardiac devices by undertaking "complex audit procedures" and engaging in a "labor-intensive process" involving the manual review of device recipients' medical records.

In order to reduce Medicare costs and protect beneficiaries, the OIG recommended that the Centers for Medicare and Medicaid Services (CMS) "continue to work with the Accredited Standards Committee X12 to ensure that the DI is included on the next version of claim forms." The OIG's recommendation echoes the June 2017 assessment of the Medicare Payment Advisory Commission, which stated: "requiring device identifiers on administrative claims for certain devices could improve the

[1] Department of Health and Human Services Office of Inspector General, *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (September 2017) (online at: https://oig.hhs.gov/oas/reports/region1/11500504.pdf).

information available to conduct post-market surveillance, which is critical to ensure device quality."[2]

We have long supported this recommendation, repeatedly urging stakeholders, including CMS, to support the inclusion of device identifiers on the Medicare claim form.[3] In June, we also submitted public comments to X12 on the institutional health care claim transaction that they released this spring. Our comments strongly supported the draft claim form released by the standards committee, which included a field for collecting device identifier information.[4] We shared these public comments with you when we submitted them to X12.

In response to the OIG's recommendation that CMS work with X12 to ensure that device identifier information is collected on the next version of claim forms, you stated: "Similar to other policies under review by the new Administration, this policy is also under consideration. CMS will carefully evaluate the potential that this policy would impose burden on physicians unnecessarily."[5]

However, the physicians who implant many of these devices already support the inclusion of device identifier information on Medicare claim forms. The American Academy of Orthopedic Surgeons, the American College of Cardiology, and the Society of Thoracic Surgeons have all expressed their support for this policy, saying it would "equip patients, clinicians and researchers with better data to prevent harm and reduce cost," and urging you "to continue advancing this critical policy that has support across the healthcare system."[6]

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[2] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System (June 2017) (online at: http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf), p. 234.

[3] Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services (December 22, 2014); Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Daniel Levinson, Inspector General, Department of Health and Human Services (August 12, 2015) (online at: https://www.grassley.senate.gov/sites/default/files/news/upload/2015.08.06%20UDI%20Letter%20to%20OIG.pdf); Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Sylvia Matthews Burwell, Secretary, Department of Health and Human Services (March 8, 2016) (online at: https://www.grassley.senate.gov/sites/default/files/news/upload/2016_03_09%20CEG%20to%20HHS%20regarding%20UDI.PDF); Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Gary Beatty, Chair, Accredited Standards Committee X12 (August 29, 2016) (online at: https://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf); "Senators Warren and Grassley Comment on HHS Report on Medicare Savings from Inclusion of Medical Device Identifiers on Claim Forms" (October 4, 2016) (online at: https://www.warren.senate.gov/?p=press_release&id=1270).

[4] Letter from Senator Elizabeth Warren and Senator Chuck Grassley to Gary Beatty, Chair, Accredited Standards Committee X12 (June 1, 2017) (online at: https://www.warren.senate.gov/files/documents/2017-6-1_Letter_to_X12.pdf).

[5] Department of Health and Human Services Office of Inspector General, *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices* (September 2017) (online at: https://oig.hhs.gov/oas/reports/region1/11500504.pdf).

[6] Letter from stakeholders to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, and Scott Gottlieb, Commissioner, Food and Drug Administration (May 17, 2017) (online at:

Your comments in the OIG's report appeared to conflict with prior support from CMS for the collection of device identifiers on claims forms. In a July 2016 joint letter to X12, CMS and FDA had asked the standards committee to "support capturing on the claim form the device identifier (DI) portion of the unique device identifier for implantable devices."[7]

We were encouraged by your statement issued shortly after the OIG report. You stated that such a step could help CMS "more effectively identify and track Medicare's aggregate costs related to recalled or prematurely failed devices, reduce Medicare costs by identifying poorly performing devices more quickly, facilitate device recipients' chances of receiving timely follow up care, and protect beneficiaries from unnecessary costs."[8] However, on October 31st, during testimony before the Senate Committee on Health, Education, Labor, and Pensions, CMS Chief Medical Officer Kate Goodrich responded to a question about whether CMS agreed with the OIG recommendation by saying, "[A]t this time, I don't have anything else to offer [. . .] because, as is customary for new administrations, we are still reviewing this policy."[9]

CMS will play an important role in ensuring the integrity of the Medicare system and reducing health risks and costs to Medicare beneficiaries as the claim form undergoes its periodic update. X12's draft institutional health care claim transaction is currently undergoing final review, before being sent to other standards organizations. When these organizations approve X12's proposed update, CMS will be responsible for reviewing this recommendation and issuing regulations that will begin the process of implementing use of the updated claim transaction.

Poorly-performing medical devices cause serious health risks for seniors and people with disabilities and cost Medicare beneficiaries millions of dollars in out-of-pocket costs associated with replacing these devices. Taxpayers also bear the costs when medical devices fail prematurely or are recalled and need to be replaced. Past reviews by the HHS OIG have found that Medicare overpaid hospitals millions of dollars because hospitals did not obtain manufacturer credits for recalled devices or failed to pass those

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http://www.sts.org/sites/default/files/content/On%20the%20Record/051717_Multi-stakeholderFDACMSUDI.pdf).

[7] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, and Robert Califf, Commissioner, Food and Drug Administration, to Gary Beatty, Chair, Accredited Standards Committee X12 (July 13, 2016) (online at: https://pascrell.house.gov/sites/pascrell.house.gov/files/wysiwyg_uploaded/LETTER_FDA%20CMS%20Beatty%20Letter%20on%20UDI%20in%20Claims%207.13.16.pdf).

[8] David Pittman, "ONC Talks up Progress on Goals," *Politico Morning eHealth* (October 3, 2017) (online at: http://www.politico.com/tipsheets/morning-ehealth/2017/10/03/onc-talks-up-progress-on-goals-222614).

[9] "Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology," Senate Committee on Health, Education, Labor and Pensions (October 31, 2017) (online at: https://www.help.senate.gov/hearings/implementation-of-the-21st-century-cures-act-achieving-the-promise-of-health-information-technology).

savings on to CMS, as required by federal regulations.[10] Improved surveillance of recalled devices through the use of device identifiers would enable Medicare to better track where these credits are due and collect them from hospitals. In summary, it is essential that the Medicare system support the post-market surveillance of risky medical devices, both to improve patient care and to support program integrity.

In order to clarify our understanding of your position on the inclusion of device identifiers on the Medicare claim form, we ask that you respond to the following questions, no later than December 1, 2017.

1. Does CMS support capturing on the Medicare claim form the device identifier portion of the unique device identifier for implantable devices?

2. Will CMS follow the recommendations of the HHS OIG and MedPAC and work with the Accredited Standards Committee X12 to ensure that the DI is included on the next version of claim forms?

3. If CMS's position on the inclusion of DI on the Medicare claim form is still under review, what exact issues are under review, and what is the timeline for completing this review?

If you have any questions about this letter, please do not hesitate to contact Beth Pearson in Senator Warren's office (beth_pearson@warren.senate.gov) or Karen Summar in Senator Grassley's office (karen_summar@grassley.senate.gov).

Sincerely,

Elizabeth Warren
United States Senator

Chuck Grassley
United States Senator

[10] Department of Health and Human Services Office of Inspector General, "Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits" (October 2014) (online at: https://oig.hhs.gov/oas/reports/region5/51300029.pdf). Department of Health and Human Services Office of Inspector General, "The Medicare Contractors for Jurisdiction E Overpaid Claims for Replaced Cardiac Medical Devices When Hospitals Had Not Reported Manufacturer Credits" (March 2016) (online at: https://oig.hhs.gov/oas/reports/region9/91502029.pdf).