Congress of the United States

Washington, DC 20510

November 26, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
750 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

We write to encourage you to support bipartisan efforts to improve the safety and quality of care for millions of patients that rely on medical devices by advancing the inclusion of the device identifier portion of a medical device's unique device identifier (UDI) on electronic claim transactions This change will empower patients and improve the quality of the health care system by better tracking information on crucial medical implants, such as cardiac stents and artificial joints.

Members of Congress have extensively advocated for electronic health records and claims to include the UDI system, which provides each medical device with a code corresponding to its manufacturer and model.[1] Last month, the X12 committee, which is responsible for claims transactions, released draft recommendations to add new capabilities to claims transactions to incorporate the device identifier portion of the UDI of high-risk

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[1] Letter from Senator Elizabeth Warren and Senator Charles E. Grassley to Sylvia Matthews Burwell, Andy Slavitt, and Robert Califf, March 8, 2016, 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 Charles E. Grassley to Gary Beatty, Accredited Standards Committee X12, August 29, 2016, https://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf; Letter from Senator Elizabeth Warren and Senator Charles E. Grassley to Gary Beatty, Accredited Standards Committee X12, June 1, 2017, https://www.warren.senate.gov/files/documents/2017-6-1_Letter_to_X12.pdf; Letter from Senator Elizabeth Warren and Senator Charles E. Grassley to CMS Administrator Seema Verma, November 8, 2017, https://www.warren.senate.gov/files/documents/2017_11_08_Letter_to_CMS_re_UDI_and_claims.pdf; Letter from Senator Elizabeth Warren and Senator Charles E. Grassley to FDA Commissioner Scott Gottlieb, June 12, 2018, https://www.warren.senate.gov/imo/media/doc/2018.06.12%20Letter%20to%20Gottlieb%20on%20UDI%20and%20claims.pdf.

implantable medical devices.[2] This overdue change will help to reduce health risks and costs to the Medicare system. Including this information in claims transactions will enhance post-market surveillance of potential faulty devices and streamline the process of identifying affected patients when problems arise.

Although medical device failures are rare, when they do occur, they can create serious health problems and significant financial costs. A 2017 investigation by the Office of the Inspector General at the Department of Health and Human Services found that recalls or premature failures of just seven faulty cardiac devices resulted in $1.5 billion in Medicare payments to providers and $140 million in out-of-pocket costs to beneficiaries.[3] Moreover, the report was not able to examine the total cost of all device failures because of the lack of information about specific devices in claims data. The examiners were able to assess the impact of the seven devices included in the report only through a "complex and labor-intensive" audit.[4] Given the findings of this audit, the Inspector General recommended the addition of device identifiers to claims.

The Trump administration has advanced the use of claims data in several ways. For example, CMS has taken several steps to equip patients with their Medicare and private health plan claims data through the Blue Button 2.0 program.[5] In addition, CMS has increasingly made Medicare, Children's Health Insurance Program, and Medicaid claims data available to facilitate research that can inform medical decisions.[6] Finally, the President issued an executive order in October that calls for new policies to "use Medicare claims data to give health providers additional information regarding practice patterns for services that may pose undue risks to patients."[7]

The addition of device identifiers to claims would build on all these efforts to generate the same benefits for the millions of patients that rely on medical implants to improve and sustain their lives. The Administration has recognized this benefit through its budget request for the Food and Drug Administration (FDA) calling for the addition of UDIs to claims among other data sources to improve the information available on devices once marketed.[8]

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[2] X12, "X12 Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Institutional (837)," October 2019, http://forums.x12.org/007030-change-logs/X324-change-log-2.pdf, pg. 84.

[3] 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, https://oig.hhs.gov/oas/reports/region1/11500504.pdf

[4] *Id.*

[5] Centers for Medicare & Medicaid Services, "Speech: Remarks by Administrator Seema Verma at the Blue Button Developer Conference," July 30, 2019, https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-blue-button-developer-conference

[6] Center for Medicare & Medicaid Services, "Speech: Remarks by CMS Administrator Seema Verma at the HIMS18 Conference," March 6, 2018, https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-himss18-conference

[7] Executive Order on Protecting and Improving Medicare for Our Nation's Seniors, Donald J. Trump, October 3, 2019, https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/

[8] Department of Health and Human Services, Fiscal Year 2020 Budget, https://www.fda.gov/media/121408/download

Many agencies and stakeholders have worked together for years to develop a process for including the device identifier portion of UDIs in electronic claims transactions—an effort that recently advanced through the X12 proposal. We urge CMS to support the finalization of the recommendation by X12 to enable the addition of device identifiers of medical implants to claims transactions. In addition, given that claims transactions are considered standard transactions under the Health Insurance Portability and Accountability Act,[9] both public and private health plans would not be able to use this new capability prior to its adoption by CMS via rulemaking; we urge you to promptly promulgate regulations to implement this change.

We look forward to working with your office to advance this common-sense, bipartisan policy change. Thank you for your consideration.

Sincerely,

Elizabeth Warren
United States Senator

Charles E. Grassley
United States Senator

Lloyd Doggett
Member of Congress

Brian Fitzpatrick
Member of Congress

Bill Pascrell, Jr.
Member of Congress

[9] Center for Medicare & Medicaid Services, "Transactions Overview," July 26, 2017, https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Transactions/TransactionsOverview.html