Congress of the United States

Washington, DC 20510

November 26, 2019

Gary Beatty
Steering Committee Chair
Accredited Standards Committee X12
8300 Greensboro Drive, Suite 800
McLean, VA 22102

Dear Mr. Beatty:

We are writing to provide our comments on the institutional health care claim transaction released for public comment in October 2019. We applaud the committee's recommendation to include a field for the device identifier portion of a medical device's unique device identifier (UDI) on the electronic claim transaction.

Members of Congress have extensively advocated for device identifier information to be collected in both electronic health records and on claims forms,[1] and in October 2019, the committee released a formal recommendation to create the capacity to add the device identifier portion of the UDI of high-risk implantable medical devices to electronic claims transactions.[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

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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.

[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.

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] As a result of these findings, the Inspector General recommended the addition of device identifiers to claims.

Including device identifier information on claims transactions for high-risk implantable devices will greatly improve the health system's ability to identify risks and reach patients who may be affected by device failures. Researchers often rely on claims data because they track nearly every interaction a patient has with the health care system, even when the patient changes providers. As a result, the data can be used to establish population-level correlations between a particular treatment and a long-term outcome or side effect.[5] For example, the Food and Drug Administration (FDA)'s Sentinel Initiative post-market surveillance program primarily uses claims data to monitor the safety of drugs and vaccines; although Congress instructed the FDA to expand the Sentinel Initiative to medical devices in 2012, it is currently unable to effectively do so because of the lack of UDI information on claims forms.[6]

Swift identification of recalled or failed devices not only prevents health risks to patients, but can also save taxpayer funds. A recently proposed rule from the Center for Medicare & Medicaid Services (CMS) would give patients access to their claims data, allowing them to track the details of their past procedures even if they change providers or insurers.[7] Combined with this proposed rule and the use of electronic health records, identifier numbers would facilitate patients and their health care providers ascertaining whether they are affected by recalls or faulty devices and to proactively address potential problems before they negatively impact the patient's health.

Many agencies and stakeholders have worked together for years to develop a process for including the device identifier portion of UDIs in electronic claims forms. We deeply appreciate your work to prioritize and implement this change. We urge you to finalize the recommendation outlined in your October 2019 proposal and work with CMS to develop a final implementation rule as soon as is feasible. We are grateful for your work to support important medical research and improve patient health.

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[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] Ibid.

[5] Pew Charitable Trusts, "Unique Device Identifiers Improve Safety and Quality," June 2016, https://www.pewtrusts.org/-/media/assets/2016/07/udisafety_fs.pdf

[6] Harvard Medical School / Brigham and Women's Hospital / Geisinger Health System, "Transmitting the UDI from the Point of Use to Insurance Claims: Changes In Workflows and Information Systems," Joel Weissman, Dan Krupka, Yasmin Zerhouni, Adam Landman, and Natalia Wilson, May 2017, http://csph.brighamandwomens.org/wp-content/uploads/2018/06/UDI-2-Claims-White-Paper-2017.pdf

[7] Center for Medicare & Medicaid Services, "CMS Advances Interoperability & Patient Access to Health Data through New Proposals," February 8, 2019, https://www.cms.gov/newsroom/fact-sheets/cms-advances-interoperability-patient-access-health-data-through-new-proposals

Please reach out to our offices if you have any questions about this letter. 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