

United States Senate  
WASHINGTON, DC 20510

April 19, 2021

Stephanie Fetzer  
Chair, Board of Directors  
X12  
1405 S Fern St #92957  
Arlington, Virginia 22202

Dear Chair Fetzer:

We are writing to request an update on the institutional health care claim transaction released for public comment on October 2019.<sup>1</sup> We applaud X12'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 and are interested in learning when the transaction will be finalized.

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 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 and \$140 million in out-of-pocket costs to beneficiaries.<sup>2</sup> Furthermore, the Inspector General was not able to examine the total cost of all device failures because of the lack of information about specific devices in claims data. Instead, OIG examiners were forced to engage in a "complex and labor-intensive audit" to assess the impact of the seven faulty devices.<sup>3</sup> As a result, the Inspector General recommended the addition of device identifiers to claims.<sup>4</sup>

Including device identifiers on claims transactions would greatly improve the health system's ability to identify risks and reach patients who may be affected by device failures. Researchers can rely on claims data to track patients' interactions with the health 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.<sup>5</sup>

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<sup>1</sup> MedTechDive, "Key committee pitches adding UDIs to payer claim forms, called 'huge step,'" David Lim, October 17, 2019, <https://www.medtechdive.com/news/key-committee-pitches-adding-udis-to-insurance-claim-forms-called-huge-st/565200/>.

<sup>2</sup> 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, pg. 7, <https://oig.hhs.gov/oas/reports/region1/11500504.pdf>.

<sup>3</sup> Id.

<sup>4</sup> Id., pg. 10.


<sup>5</sup> Pew Charitable Trusts, "Unique Device Identifiers Improve Safety and Quality," July 5, 2016, <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/07/unique-device-identifiers-improve-safety-and-quality>.

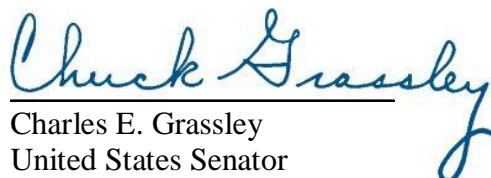
We have extensively advocated for device identifier information to be collected in both electronic health records and on claims transactions,<sup>6</sup> and in October 2019, the X12 Accredited Standards Committee released a formal recommendation to create the capacity to add the device identifier portion of the UDI of high-risk implantable medical devices to electronic claims transactions.<sup>7</sup> This overdue change will help to reduce health risks and costs to the Medicare system, and we joined our colleagues in applauding the committee's recommendation when it was released.<sup>8</sup>

Today, we write for an update on the status of the October 2019 formal recommendation. Specifically, we request information on when X12 plans to publicly release a final new version of the electronic claims transaction and whether that electronic claims transaction will include the device identifier portion of the UDI of high-risk implantable medical devices. If the new version of the claim transaction will include device identifiers, please provide us with the full details on its use, such as restrictions on when device identifiers can be included in claims and the number of device identifiers permitted per claim. Finally, we also request information on when X12 intends to recommend the adoption of the new version of claim transactions for formal adoption by the Centers for Medicare & Medicaid Services for use in health care.

We would appreciate a response, in writing, no later than May 3, 2021, and request that you expedite the release and implementation of this critical change that will improve patient care.

Sincerely,

  
Elizabeth Warren  
United States Senator

  
Charles E. Grassley  
United States Senator

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<sup>6</sup> See Letter from Senator Warren, Senator Grassley, Representative Doggett, Representative Fitzpatrick, and Representative Pascrell to Gary Beatty, Steering Committee Chair, Accredited Standards Committee X12, <https://www.warren.senate.gov/oversight/letters/in-bipartisan-letter-warren-grassley-doggett-fitzpatrick-and-pascrell-advocate-for-unique-device-identifiers-udi-information-to-be-added-to-electronic-health-insurance-claims-forms>.

<sup>7</sup> MedTechDive, "Key committee pitches adding UDIs to payer claim forms, called 'huge step,'" David Lim, October 17, 2019, <https://www.medtechdive.com/news/key-committee-pitches-adding-udis-to-insurance-claim-forms-called-huge-st/565200/>.

<sup>8</sup> Letter from Senator Elizabeth Warren, Senator Charles E. Grassley, Congressman Lloyd Doggett, Congressman Brian Fitzpatrick, and Congressman Bill Pascrell, Jr., to Gary Beatty, Steering Committee Chair, X12 Accredited Standards Committee, November 26, 2019, <https://www.warren.senate.gov/imo/media/doc/2019.11.26%20Comment%20letter%20to%20X12%20Committee%20re%20UDIs.pdf>.