United States Senate
WASHINGTON, DC 20510

December 15, 2022

Denise E. Love and Richard W. Landen
Co-Chairs of the Subcommittee on Standards
National Committee on Vital & Health Statistics
3311 Toledo Road
Hyattsville, M.D. 20782

RE: RFC on X12 and CAQH CORE Proposals

Dear Ms. Love and Mr. Landen,

We are writing to you in support of including the device identifier (DI) portion of a medical device's unique device identifier (UDI) on Medicare claims forms. We applaud the American National Standards Institute's Accredited Standards Committee (X12) for making a formal recommendation to the National Committee on Vital and Health Statistics (NCVHS) calling for this change following years of our engagement.[1] In our June 22, 2022, letter to NCVHS Chair Jacki Monson,[2] we urged NCVHS to promptly evaluate X12's recommendation, provide more information about its review and recommendation, and support the inclusion of DI information on Medicare claims forms in NCVHS's recommendations to the Department of Health and Human Services (HHS) for the next version of standard transactions.[3] We appreciate NCVHS's request for input as it deliberates in developing its recommendation to HHS.

In response to our July 2021 letter,[4] HHS Secretary Becerra noted that, before HHS can take steps to add the DI portion of UDI in Medicare claims, X12 "must first submit formal recommendations on the proposed health care claims transaction standards to the National Committee on Vital and Health Statistics (NCVHS)," and NCVHS must, in turn, "officially recommend to the Department that it should adopt the standards."[5] At this time, X12 has formally submitted their recommendation to NCVHS and stressed that "[i]ncluding device identifier information on claims transactions greatly improves the industry's ability to identify risks and reach patients who may be affected by device failures."[6] X12 further noted that this

[1] Letter from X12 to NCVHS, June 8, 2022, https://x12.org/news-and-events/letter-to-ncvhs.
[2] Letter from Senator Warren, Senator Grassley, Representative Pascrell, Representative Doggett, and Representative Fitzpatrick to Jacki Monson, National Committee on Vital and Health Statistics, Committee Chair, https://www.grassley.senate.gov/imo/media/doc/grassley_et_altonationalcommitteeonvitalandhealthstatisticsdiinfoonmedicareforms.pdf.
[3] NCVHS, "Recommendation Letters," https://ncvhs.hhs.gov/reports/recommendation-letters/.
[4] Letter from Senator Warren, Senator Grassley, Representative Pascrell, Representative Fitzpatrick, and Representative Doggett to HHS Secretary Becerra and CMS Administrator Brooks-LaSure, July 22, 2021, https://www.warren.senate.gov/imo/media/doc/2021.07.21%20Letter%20to%20HHS%20and%20CMS%20re%20UDI%20&%20Claims.pdf.
[5] Letter from HHS Secretary Becerra to Senator Warren, October 28, 2021, https://www.warren.senate.gov/imo/media/doc/2021.11.2%20Response%20to%20Letter%20to%20Becerra%20and%20Brooks-LaSure%20on%20UDIs.pdf.
[6] Letter from X12 to NCVHS, June 8, 2022, https://x12.org/news-and-events/letter-to-ncvhs.

policy "improves patient outcomes and reduces patient health risks and enhances tracking and reporting related to specific devices," while "also [saving] taxpayer funds."[7]

Medical device failures contribute to serious health problems and significant financial costs. In 2017, an HHS Office of Inspector General (OIG) investigation found that recalls or premature failures of just seven faulty cardiac devices resulted in an estimated $1.5 billion in Medicare payments and $140 million in out-of-pocket costs to beneficiaries.[8] Without DI information, OIG had to rely on a "complex and labor-intensive audit" to calculate these costs, which it acknowledged yielded a conservative estimate.[9] As a result, OIG recommended the addition of DIs to Medicare claims forms to better "identify and track the additional health care costs incurred by Medicare resulting from recalled or prematurely failed medical devices," reduce those costs, shield beneficiaries from unnecessary out-of-pocket costs, and improve beneficiary access to appropriate follow-up care.[10]

The inclusion of DIs 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. The data can then be used to establish population-level correlations between a particular treatment and a long-term outcome or side effect.[11] For years, we have called for DI information to be collected in both electronic health records and on claims transactions[12] to help reduce health risks and costs to the Medicare system.

We urge NCVHS to expeditiously assess X12's recommendations to include DI information on Medicare claim forms and to issue an official recommendation to HHS to adopt these standards.

Sincerely,

Elizabeth Warren
United State Senator

Charles E. Grassley
United State Senator

Bill Pascrell, Jr.
Member of Congress

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[7] *Id.*
[8] 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, p. 7, https://oig.hhs.gov/oas/reports/region1/11500504.pdf.
[9] *Id.*, p. 9.
[10] *Id.*, p. 10.
[11] 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.
[12] 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; Letter from Senators Warren and Grassley to Gary Beatty, Chair of Accredited Standards Committee X12, http://ct.symplicity.com/t/wrn/5879b49d5129bd5a44c94261b3cac11e/2057710565/realurl=http://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf.