

Congress of the United States

Washington, DC 20515

June 22, 2022

Jacki Monson, JD
Committee Chair
National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782

Dear Ms. Monson,

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 Now, we urge you to promptly evaluate X12's 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.²

In response to our July 2021 letter,³ 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."⁴ 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." X12 further notes that this policy "improves patient outcomes and reduces patient health risks and enhances tracking and reporting related to specific devices," while "also [saving] taxpayer funds."⁵

Medical device failures may be uncommon, but when they happen, they can lead to serious health problems and significant financial costs. A 2017 investigation by the HHS Office of Inspector General (OIG) 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.⁶ Without DI information, OIG had to rely on a "complex and labor-intensive audit" to calculate these costs, which it acknowledged

¹ X12, "X12 Member Announcement: Recommendations to NCVHS," June 8, 2022, <https://x12.org/index.php/news-and-events/news/x12-member-announcement-recommendations-ncvhs>.

² NCVHS, "Recommendation Letters," <https://ncvhs.hhs.gov/reports/recommendation-letters/>.

³ Letter from Senator Warren, Senator Grassley, Representative Pascarella, Representative Fitzpatrick, and Representative Doggett to HHS Secretary Becerra and CMS Administrator Brooks-LaSure, <https://www.warren.senate.gov/oversight/letters/bipartisan-group-of-lawmakers-urge-hhs-and-cms-to-include-unique-device-identifiers-in-medicare-claims-forms>.

⁴ 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>.

⁵ X12, "X12 Member Announcement: Recommendations to NCVHS," June 8, 2022, <https://x12.org/index.php/news-and-events/news/x12-member-announcement-recommendations-ncvhs>.


⁶ 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>.


yielded a conservative estimate.⁷ 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.⁸


The inclusion of 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. The data can then be used to establish population-level correlations between a particular treatment and a long-term outcome or side effect.⁹ We have extensively advocated for DI information to be collected in both electronic health records and on claims transactions¹⁰ to help reduce health risks and costs to the Medicare system.

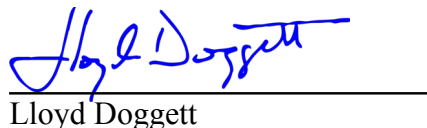
We urge NCVHS to expeditiously assess X12’s recommendations to include DI information on Medicare claim forms and to issue an official recommendation to HHS to adopt these standards. We also request more information on the process that NCVHS will use to evaluate X12’s recommendations, whether NCVHS intends to endorse such recommendations, and the expected timeline for NCVHS to issue its formal recommendation to HHS. We would appreciate a response, in writing, by July 6, 2022.

Sincerely,


Elizabeth Warren
United States Senator


Charles E. Grassley
United States Senator


Bill Pascrell, Jr.
Member of Congress


Lloyd Doggett
Member of Congress


Brian Fitzpatrick
Member of Congress

CC: Richard W. Landen, Co-Chair of the Subcommittee on Standards; Denise E. Love, Co-Chair of the Subcommittee on Standards

⁷ *Id.*, p.9

⁸ *Id.*, p. 10.

⁹ 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>.

¹⁰ 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>.