United States Senate
WASHINGTON, DC 20510

October 24, 2023

The Honorable Robert M. Califf, M.D.
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

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. On June 14, 2023, the National Committee on Vital and Health Statistics (NCVHS) encouraged[1] your agency to review stakeholder comment letters and testimony submitted to NCVHS to identify concerns submitted to NCVHS regarding the collection of UDI codes. Given the decades-long effort to include DI information on Medicare claims forms, we urge your agency to fairly and expeditiously review the stakeholder comments and testimony and to give full consideration to the interests of patients and taxpayers in your evaluation.

Since 2014, we have called for DI information to be collected on claims transactions[2] to help reduce health risks and costs to the Medicare system. In October 2021, Department of Health and Human Services (HHS) Secretary Xavier Becerra noted in response to our letter[3] that, before HHS can take steps to add the DI portion of UDI in Medicare claims, the American National Standards Institute's Accreditation Standards Committee (X12) and NCVHS must formally recommend this policy change to the Department.[4] The following year, X12 issued such a recommendation to NCVHS,[5] stressing 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 policy "improves patient

[1] Letter from NCVHS to HHS Secretary Becerra, June 14, 2023, https://ncvhs.hhs.gov/wp-content/uploads/2023/06/Recommendation-Letter-Updated-Version-of-X12-Standard-June-14-2023.pdf.
[2] 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.
[3] *Id*.
[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] Letter from X12 to NCVHS, June 8, 2022, https://x12.org/news-and-events/letter-to-ncvhs.
[6] *Id*.

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

Following this announcement, we urged NCVHS Chair Jacki Monson in a June 2022 letter[8] to promptly evaluate X12's recommendation and support the inclusion of DI information on Medicare claims forms in NCVHS's recommendations to HHS for the next version of standard transactions.[9] In June 2023, NCVHS released a letter stating that NCVHS would issue "no specific recommendation" on the X12 proposal to include DI information on the Medicare claims forms, but encouraged FDA to conduct a "review of stakeholder comment letters and testimony" regarding this policy.

The inclusion of DIs on claims transactions would greatly improve our health care system's ability to identify risks and reach patients who may be affected by device failures, which contribute to serious health problems and impose significant financial costs. In 2017, a 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.[10] 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.[11] 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.[12] Including DI on the Medicare claims form remains a top unimplemented recommendation by the HHS OIG to reduce fraud, waste, and abuse in HHS Programs.[13]

It is therefore critical for the Food and Drug Administration (FDA) to promptly clarify its strong support for the inclusion of DI information in the Medicare claims, a policy that FDA endorsed as recently as last year. In 2016, you joined the Centers for Medicare and Medicaid Services' (CMS) Acting Administrator Andrew Slavitt in a letter to X12 in support of including DI on the Medicare claims forms for implantable devices.[14] FDA recognized the numerous benefits of collecting DI, such as evaluating product performance, identifying safety concerns,

[7] *Id*.

[8] 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.

[9] NCVHS, "Recommendation Letters," https://ncvhs.hhs.gov/reports/recommendation-letters/.

[10] 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.

[11] *Id.,* p. 9.

[12] *Id*., p. 10.

[13] Department of Health and Human Services (HHS) Office of Inspector General (OIG), "OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs," 2022, https://oig.hhs.gov/documents/top-unimplemented-recommendations/1102/compendium2022.pdf.

[14] Letter from CMS Acting Administrator Slavitt and FDA Commissioner Califf to X12 Chair Betty, July 13, 2016, https://pascrell.house.gov/sites/pascrell.house.gov/files/wysiwyg_uploaded/letter_fda%20cms%20beatty%20letter%20on%20udi%20in%20claims%207.13.16.pdf.

aiding providers and payers in calculating and comparing total costs and outcomes, and supporting program integrity.[15] Last year, the FDA Center for Device and Radiological Health (CDRH) wrote in a letter to NCVHS that it "fully supports the inclusion of the UDI-DI in the updated electronic claim transaction standard."[16] CDRH stated that the policy would improve analysis of devices on the market, reduce medical errors, enable more accurate reporting, and enable the evaluation of device performance, patient outcomes, and quality of care.[17]

In an effort to be responsive to NCVHS and advance this sensible, life-saving policy, we urge the FDA to expeditiously assess X12's recommendations and NCVHS stakeholder comments and testimony to include DI information on Medicare claim forms. We further request that, following this review, the FDA issue an official recommendation to HHS to adopt these standards to ensure patient safety and taxpayer dollars are protected. We request an update on the FDA's review no later than November 22, 2023. We appreciate your timely attention to this matter.

Sincerely,

Charles E. Grassley
United States Senator

Elizabeth Warren
United States Senator

[15] *Id*.
[16] Letter from FDA UDI Team to NCVHS, December 15, 2022, https://ncvhs.hhs.gov/wp-content/uploads/2023/05/0%20Public%20Comments-Standards%20Subcommittee%20Meeting-January%2018-19,%202023_amended.pdf, p.100-101.
[17] *Id.*