Congress of the United States
Washington, DC 20510

July 21, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services (HHS)
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

We write today to ask you to commit to including the device identifier portion of a medical device's unique device identifier (UDI) in Medicare claims forms. Doing so will improve safety and quality of care for millions of patients that rely on medical devices. It will also enable more efficient tracking of medical device outcomes, saving lives and money throughout our nation's healthcare system. We were encouraged by Secretary Becerra's recent comments to Congress on the importance of tracking device outcomes in Medicare claims, as well as President Biden's support for UDIs in his FY2022 budget and hope you will expeditiously push this important policy forward.

When medical device failures occur, they can create serious health problems and pose significant financial costs. In 2017, the Office of the Inspector General (OIG) at the Department of Health and Human Services (HHS) sought to analyze "the costs that Medicare and its beneficiaries incur to replace recalled or prematurely failed medical devices."[1] The OIG struggled to capture the full cost of faulty medical devices, noting that "Medicare claim forms…do not contain a field for reporting medical device-specific information."[2] However, after a "complex and labor intensive auditing procedure," the office found that premature failures and recalls from just seven cardiac devices resulted in $140 million in out-of-pocket costs to beneficiaries and $1.5 billion in taxpayer-funded Medicare payments.[3] OIG ultimately concluded that "including the DI [device identifier] on claims forms" would help policymakers "more effectively identify and track Medicare's aggregate costs related to recalled or prematurely failed devices" and "provide

[1] 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, pg. 1.
[2] Id., 7.
[3] Id.

additional patient safety benefits."[4] It recommended that the Centers for Medicare and Medicaid (CMS) "work…to ensure that the DI is included on the next version of claims forms."[5]

For UDIs to be included in Medicare claims, X12, which sets standards for claims transactions, must first submit a formal recommendation to the National Committee on Health and Vital Statistics (NCHVS)—an HHS advisory body—urging CMS to do so. NCHVS must then, after assessing the recommendation, officially recommend to CMS that they include UDIs in claims. Finally, CMS must add UDIs to Medicare claims through the rulemaking process.

For years, bipartisan groups of lawmakers have advocated for the inclusion of UDIs in Medicare claims,[6] and health officials in Democratic and Republican Administrations have expressed support for doing so.[7] Since 2020, X12 has included requirements regarding the inclusion of the device identifier portion of UDIs in its published implementation guides, and we were happy to learn from X12 in April that the Committee is "finalizing its recommendation related to the adoption of new versions of the health care claim transactions…and expects to present that recommendation of [NCVHS] this summer."[8]

We believe that HHS and CMS should expeditiously take steps to add the device identifier portion of UDIs in Medicare claims, and we ask you to commit to finalizing this change as soon as possible. We have been encouraged by the Administration's comments in recent months regarding the policy. Specifically, we were pleased by Secretary Becerra's recent acknowledgment to the House Ways and Means Committee that "we've got to make sure that through…Medicare claims…we can track" device outcomes, and his commitment to stay engaged with Congress and other stakeholders as the X12 process proceeds.[9] Meanwhile, Administrator Brooks-LaSure committed during her confirmation process to "look into this issue

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[4] Id., 9-10.
[5] Id., 10.
[6] See, for example, 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.
[7] Fierce Healthcare, "CMS joins FDA in backing unique device identifiers on claims forms," Katie Dvorak, July 15, 2016, https://www.fiercehealthcare.com/it/cms-joins-fda-backing-udi-claims-forms; U.S. Food and Drug Administration, "FDA Fiscal Year 2020 Justification of Estimates for Appropriations Committees," https://www.fda.gov/media/121408/download, pg. 174.
[8] X12, "New X12 Publications Support Inclusion of Device Identifiers," Cathy Sheppard, June 15, 2021, https://x12.org/news-and-events/news/new-x12-publications-support-inclusion-device-identifiers.
[9] U.S. House of Representatives Ways and Means Committee, "Ways and Means Hearing on The President's Proposed Fiscal Year 2022 Budget with the Department of Health and Human Services Secretary Becerra," June 8, 2021, https://waysandmeans.house.gov/legislation/hearings/ways-and-means-committee-hearing-presidents-proposed-fiscal-year-2022-budget.

further" and stay in touch with lawmakers throughout the process.[10] President Biden also expressed support for UDIs in the U.S. Food and Drug Administration's FY22 budget, noting that the "establishment of the UDI system has been a tremendous milestone in building a stronger, more modernized medical device safety net."[11]

We look forward to working with you and your staff on a bipartisan basis to ensure that the device identifier portions of UDIs are included in Medicare claims forms. Please do not hesitate to reach out to us or our staff as the process continues.

Sincerely,

Elizabeth Warren
United States Senator

Charles E. Grassley
United States Senator

Bill Pascrell, Jr.
Member of Congress

Brian Fitzpatrick, Jr.
Member of Congress

Lloyd Doggett
Member of Congress

[10] Response to Questions for the Record from U.S. Senator Elizabeth Warren.
[11] U.S. Department of Health and Human Services, U.S. Food and Drug Administration, "Fiscal Year 2022: Justification of Estimates for Appropriations Committees," May 2021, https://www.fda.gov/media/149616/download, pg. 181.