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June 12, 2018

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

We are writing in response to the Food and Drug Administration's (FDA) recently-released Medical Device Safety Action Plan and to reiterate our view that, in order to meet the action plan's goals, device identifier information must be included on the Medicare claim form.

The FDA's action plan outlines the agency's efforts to ensure that medical devices meet the agency's gold standard, which includes maintaining a "vigilant postmarket surveillance system" that can quickly identify any safety issues that emerge in medical devices being used by patients and clinicians. As the FDA's action plan notes, the establishment and implementation of the unique device identifier (UDI) system – first directed by Congress in 2007 – "provides a standard and clear way to document device use, including in electronic health records, clinical information systems, *claims data sources*, and registries" and "has been a tremendous milestone in building a stronger, more modernized medical device safety net."[1]

The action plan also states that "[r]eal-world evidence – derived from multiple sources outside typical clinical research settings (e.g., electronic health records, *claims and billing activities*, product and disease registries, or health-monitoring devices) – provides an immense new set of information about medical devices, and it plays an increasing role in health care decisions."[2]

In order to "realize the promise of the UDI and real-world evidence" to enhance oversight of medical device safety, "FDA must optimize postmarket data collection, quality, completeness, and analysis."[3] FDA's efforts to establish the National Evaluation System for health Technology

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[1] Food and Drug Administration, "Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health," April 17, 2018, p. 5, https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf (emphasis added).

[2] Food and Drug Administration, "Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health," April 17, 2018, p. 5, https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf (emphasis added).

[3] Food and Drug Administration, "Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health," April 17, 2018, p. 6, https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf.

(NEST) aim to "link and synthesize data from different electronic health information sources, including device registries, electronic health records, *medical billing claims*, patient-generated data, and other sources."[4]

We agree with FDA's assertions regarding the importance of a robust postmarket surveillance system and support the agency's work to establish the NEST. As we have repeatedly contended, a critical aspect of ensuring the quality and completeness of postmarket data is incorporating device identifier information into the Medicare claim form.[5]

In addition to reducing risks to patient safety, including device identifier information on the Medicare claim form would improve the integrity of the Medicare program by helping the Centers for Medicare and Medicaid Services (CMS) track manufacturer credits owed on recalled devices and collect them from hospitals. A September 2017 analysis from the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) found that Medicare spent $1.5 billion on the medical services incurred in order to replace just seven types of poorly performing devices between 2005 and 2014, and Medicare beneficiaries whose devices were recalled or failed also paid an additional $140 million in out-of-pocket costs. [6]

We are not alone in calling for inclusion of device identifier information on the Medicare claim form. The Medicare Payment Advisory Commission stated in a June 2017 report: "requiring device identifiers on administrative claims for certain devices could improve the information available to conduct post market surveillance, which is critical to ensure device quality."[7]

Similarly, the OIG concluded that the current inability to track medical-device specific information through the Medicare claim form "impedes the ability of FDA and CMS to identify poorly performing devices as early as possible," which in turn "diminishes device recipients'

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[4] Food and Drug Administration, "Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health," April 17, 2018, p. 10, https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf (emphasis added).

[5] Letter from Senators Elizabeth Warren and Chuck Grassley to CMS Administrator Marilyn Tavenner, December 22, 2014; Letter from Senators Elizabeth Warren and Chuck Grassley to HHS Inspector General Daniel Levinson, August 12, 2015, https://www.grassley.senate.gov/sites/default/files/news/upload/2015.08.06%20UDI%20Letter%20to%20OIG.pdf; Letter from Senators Elizabeth Warren and Chuck Grassley to HHS Secretary Sylvia Matthews Burwell, March 8, 2016, https://www.grassley.senate.gov/sites/default/files/news/upload/2016_03_09%20CEG%20to%20HHS%20regarding%20UDI.PDF); Letter from Senators Elizabeth Warren and Chuck Grassley to Accredited Standards Committee X12 Chair Gary Beatty, August 29, 2016, https://www.warren.senate.gov/files/documents/2016-8-29_UDI_letter_to_ASC_X12.pdf; Letter from Senators Elizabeth Warren and Chuck 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.

[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, https://oig.hhs.gov/oas/reports/region1/11500504.pdf.

[7] Medicare Payment Advisory Commission, "Report to the Congress: Medicare and the Health Care Delivery System," June 2017, p. 234, http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.

chances of receiving timely followup care."[8] The OIG recommended that CMS continue to work with the standards committee charged with developing updates to the Medicare claim form to ensure that device identifier information is captured on the next version of the claim form.

The FDA has also previously expressed its support for such a step. In a July 2016 joint letter with CMS, sent to the same standards committee, the agency enumerated "several benefits to collecting the DI on claims forms for implantable devices," including the identification of safety concerns, evaluation of product performance, and the collection and analysis of patient data for medical devices at the model level.[9]

The FDA's Medical Device Safety Action Plan notes that real world evidence that can support postmarket surveillance can be "derived from multiple sources," including electronic health records as well as claims activities. While recording device identifier information in electronic health records (EHRs) is important, it is no substitute for capturing this information on the Medicare claim form. Electronic health records have a limited ability to track patients across provider, and researchers face barriers to combining EHR data to conduct analyses, constraining the usefulness of EHRs in enabling population-level surveillance of medical device safety.

The standards committee charged with updates to the Medicare claim form has already recommended including a field to collecting device identifier information in the institutional health care claim transaction released last year. The National Committee on Vital and Health Statistics will collect input on the claim form proposed by the standards committee before making a recommendation to CMS, which will then need to complete notice and comment rulemaking in order to fully adopt the standards.

Incorporating device identifier information into the Medicare claim form would greatly enhance the FDA's capacity to carry out key priorities in its Medical Device Safety Action Plan. We urge the agency to consider the importance of this pending update to the claim form to its postmarket surveillance activities and to maintain its active support for this change.

Sincerely,

Elizabeth Warren
United States Senator

Chuck Grassley
United States Senator

[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 28, 2017, https://oig.hhs.gov/oas/reports/region1/11500504.pdf.

[9] Letter from CMS Acting Administrator Andrew M. Slavitt and FDA Commissioner Robert Califf to Accredited Standards Committee X12 Chair Gary Beatty, 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.