United States Senate

WASHINGTON, DC 20510

August 29, 2016

Gary Beatty
Chair
Accredited Standards Committee X12
8300 Greensboro Drive, Suite 800
McLean, VA 22102

Dear Mr. Beatty,

We are writing to express our support for the inclusion of the unique device identifier (UDI) of medical devices on health insurance claim forms and to request a briefing on the process that the Accredited Standards Committee X12 (ASC X12) - the body responsible for recommending any changes to the standard electronic claim forms - will follow in coming months as it develops new standards related to these forms.

Congress has long recognized that establishing an effective tracking system for medical devices is a fundamental component of a robust post market surveillance system, including detecting and responding to adverse events and assisting with product recalls. As part of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress required the Food and Drug Administration (FDA) to create a UDI system that would support these goals.[1] And in 2012, Congress required that medical devices be included in the FDA's Sentinel Initiative, which uses insurance claims data to monitor FDA-regulated products and ensure patient safety.[2]

These were important milestones in the effort to strengthen the nation's post market surveillance system. However, realizing the promise of the UDI system requires an additional step: UDI information must be incorporated into electronic health data sources, including insurance claims.

In March, we wrote to HHS Secretary Sylvia Burwell, CMS Acting Administrator Andy Slavitt and FDA Commissioner Robert Califf to inquire about progress that had been made in adding the UDI of medical devices to health insurance claim forms.[3] Last month, in a reply to our letter,

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[1] Section 226 of the Food and Drug Administration Amendments Act of 2007, PL 110-85 (online at: https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/html/PLAW-110publ85.htm).

[2] Section 615 of the Food and Drug Administration Safety and Innovation Act of 2012, PL 112-144 (online at: https://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf).

[3] Letter from Senator Elizabeth Warren and Senator Charles E. Grassley to Sylvia Matthews Burwell, Secretary, U.S. Department of Health and Human Services, Andy Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, and Robert Califf, Commissioner, Food and Drug Administration (March 8, 2016) (online at: http://www.grassley.senate.gov/sites/default/files/news/upload/2016_03_09%20CEG%20to%20HHS%20regarding%20UDI.PDF)

Secretary Burwell stated that "HHS affirmatively supports adding the device identifier (DI) portion of the UDI for claims for implantable devices."[4]

Furthermore, in a July 13 letter to you in your capacity as ASC X12 Chair, CMS Acting Administrator Slavitt and FDA Commissioner Califf outlined the significant benefits to collecting device identifiers on claims forms.[5] They also asked that "ASC X12 revisit the current business requirements to support capturing on the claim form the device identifier (DI) portion of the unique device identifier for implantable devices," and that ASC X12 "complete its work on the next version of the claims form ... to be released December 1, 2016."[6]

Collecting device identifiers on insurance claims forms would allow device performance and safety concerns to be tracked and evaluated at the model level, enable the collection and analysis of detailed device and patient data, facilitate outcome comparisons across device models, and protect the integrity of the Medicare program by allowing for faster identification of poorly performing and recalled devices and ensuring that proper reimbursements take place with regard to these devices.[7]

Daniel Levinson, of the non-partisan Department of Health and Human Services, Office of Inspector General, wrote September 1, 2015 "The establishment of a UDI system is a great first step to assist in identifying the total costs to Medicare for defective medical devices, ensure patient safety, and safeguard the Medicare trust funds."[7]

We understand that the ASC X12 is currently working to finalize the next version of standards associated with these claims forms, and is anticipating releasing them by the December 1, 2016 deadline.

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[4] Letter from Sylvia M. Burwell, Secretary, U.S. Department of Health and Human Services, to Senator Elizabeth Warren and Senator Charles E. Grassley (July 13, 2016).

[5] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, and Robert Califf, Commissioner, Food and Drug Administration, to Gary Beatty, Chair, Accredited Standards Committee X12 (July 13, 2016) (online at: https://pascrell.house.gov/sites/pascrell.house.gov/files/wysiwyg_uploaded/LETTER_FDA%20CMS%20Beatty%20Letter%20on%20UDI%20in%20Claims%207.13.16.pdf).

[6] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, and Robert Califf, Commissioner, Food and Drug Administration, to Gary Beatty, Chair, Accredited Standards Committee X12 (July 13, 2016) (online at: https://pascrell.house.gov/sites/pascrell.house.gov/files/wysiwyg_uploaded/LETTER_FDA%20CMS%20Beatty%20Letter%20on%20UDI%20in%20Claims%207.13.16.pdf).

[7] Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, and Robert Califf, Commissioner, Food and Drug Administration, to Gary Beatty, Chair, Accredited Standards Committee X12 (July 13, 2016) (online at: https://pascrell.house.gov/sites/pascrell.house.gov/files/wysiwyg_uploaded/LETTER_FDA%20CMS%20Beatty%20Letter%20on%20UDI%20in%20Claims%207.13.16.pdf).

[7]Letter from Daniel Levinson, Inspector General, HHS to Senators Chuck Grassley and Elizabeth Warren (Sept. 1, 2015)(online at http://www.grassley.senate.gov/sites/default/files/news/upload/IG%20Levinson%20Response%20to%20Senator%20Grassley%20and%20Senator%20Warren%20re%20UDI%20-%209.01.2015.pdf

In order for our offices to better understand the process that ASC X12 is following in developing these standards, and the status of the discussion of including DI information for implantable devices, we request that you provide our staff with a briefing on the steps the Committee will take to finalize its recommendations. We ask that this briefing take place no later than September 9, 2016, and that it address:

1. The Committee's process, both before and after the December 1 deadline, for developing recommended changes to claims forms.

2. The timeline associated with each stage of this process.

3. The process for incorporating feedback from members – including HHS's request that ASC X12 revisit current requirements to support capturing DI information on the claims form – into final consensus recommendations of the Committee.

4. The status of discussions related to inclusion of DI information in claims for implantable devices.

5. The status of discussion related to inclusion of DI information into claims for reimbursable supplies, such as pre-filled syringes.

If you have any questions about this letter, please do not hesitate to contact Brian Cohen in Senator Warren's office and Karen Summar in Senator Grassley's office. Thank you.

Sincerely,

Chuck Grassley
U.S. Senator

Elizabeth Warren
U.S. Senator