

June 11, 2015

The Honorable Kevin Brady  
Chairman, Subcommittee on Health  
Committee on Ways and Means  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Brady:

We are writing to thank you for your statement at the June 2 Ways and Means Committee legislative mark-up that you intend to work with Congressman Pascrell on improving health care quality and patient safety through the use of a new medical device identification system to generate better data on the artificial hips, cardiac stents and other implants utilized by millions of Medicare beneficiaries.

The Ways and Means Committee oversees the Medicare program to ensure that it is providing high quality care to our nation's seniors. As newly released Medicare data has indicated, joint replacement surgeries are the most common inpatient procedure for Medicare beneficiaries;<sup>1</sup> improving quality of these and other implant procedures requires better data on the products used in care. While this committee has endorsed legislation that expands availability of Medicare data for research purposes,<sup>2</sup> that data lacks information on the specific brands or models of medical devices disproportionately used by seniors. The Subcommittee on Health has an opportunity to help fill that gap in claims data.

In 2007, Congress instructed the Food and Drug Administration (FDA) to develop a unique device identifier (UDI) system to provide each medical device with a code corresponding to its manufacturer and model. This new UDI system—which took effect last year—has the potential to significantly improve healthcare by allowing providers and regulators to more easily identify safety problems and help track down recalled products. In order for this system to fully achieve its potential to protect patients, it must be included in electronic data sources, particularly insurance claims utilized by Medicare and private health plans.

Currently, the claims form used by both private and public health plans only lists the procedure—for example a knee replacement surgery—but lacks any information on the specific manufacturer or model of implant. Claims do contain this kind of information about the specific prescription drugs a patient receives.

The UDI system can provide claims with needed specificity to allow Medicare and other health plans, researchers and the FDA to conduct the same types of analyses for devices that are currently conducted on drugs and procedures. Specifically, adding UDI data to claims would support:

- *FDA evaluations of device safety*: FDA, as it does with drugs, could utilize claims data for analyses on the long-term effects of medical devices. For example, FDA's postmarket surveillance Sentinel system relies primarily on claims data to evaluate drug safety. FDA

cannot efficiently expand this system to medical devices—as instructed by Congress in 2012—until claims contain UDI data.

- *Analyses and care management by health plans:* Health plans often conduct research on their own data to better understand drug utilization, patient outcomes and cost. These types of analyses are not possible for medical devices until claims contain UDI. Similarly, health plans utilize their data to help patients’ manage their health; UDI data would help them contact patients with recalled devices and help ensure appropriate follow-up care.
- *Enhancements to registries:* Registries often link with multiple databases to conduct robust assessments of patient outcomes. Including UDI in claims would support registries’ ability to conduct longitudinal analyses of device performance.
- *Support for alternative payment models:* As Congress and the administration continue to emphasize the use of new care delivery models, such as accountable care organizations, better data on product performance and quality is essential to support alternative approaches that improve outcomes while reducing costs.
- *Transparency in Medicare spending:* The Centers for Medicare & Medicaid Services (CMS) and Congress have both recently supported policies to ensure public and researcher access to claims data, yet this information lacks a key component of care—the device implanted in patients. Incorporating the UDI in claims would infuse additional transparency into the data to enhance the value of these efforts for patients that rely on implanted medical devices.

The incorporation of UDI in claims is supported across the health care delivery continuum, including by hospitals, health plans, accountable care organizations, FDA, clinicians and patients.<sup>3-14</sup>

CMS issues regulations to adopt new standards for the claims form used by private and public payers. Given that CMS approves the claim form used throughout the country, failure of Medicare to support adding UDI to claims would prevent private health plans and hospitals from seeking better data on medical devices.

We applaud you for your interest in this important issue. The addition of this device information would ensure that patients, providers and the health care system writ large can utilize claims to improve patient care for implants much in the same way that this information is already used for drugs and procedures.

We thank for your statement that you intend to work with Congressman Pascrell on this important patient safety and quality improvement initiative. Should you have any questions or if we can be of assistance, please contact Josh Rising, director of healthcare programs at The Pew Charitable Trusts, at 202-540-6761 or [jrising@pewtrusts.org](mailto:jrising@pewtrusts.org).

Sincerely,

Aetna  
American Joint Replacement Registry  
Duke Medicine

Geisinger Health System  
HL7 International  
Intermountain Healthcare  
Mercy  
National Health Council  
Pacific Business Group on Health  
The Leapfrog Group  
The Pew Charitable Trusts  
The Society of Thoracic Surgeons  
Trust for America's Health

cc: The Honorable Jim McDermott, Ranking Member, Subcommittee on Health, Committee  
on Ways and Means  
The Honorable Bill Pascrell

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<sup>1</sup> “Vast Trove of Medicare Data Details How Billions are Spent.” *New York Times*. June 1, 2015.

<http://www.nytimes.com/aponline/2015/06/01/us/politics/ap-us-medicare-data-trove.html>.

<sup>2</sup> Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, April 16, 2015.

<sup>3</sup> C. Gaus, letter to Stacey Barber at Accredited Standards Committee X12, March 2, 2015.

<sup>4</sup> American College of Cardiology, First Databank, et al, letter to FDA, ONC and CMS, May 29, 2014,

<http://www.pewtrusts.org/en/about/news-room/letters/letters/2013/05/29/groups-urge-onc-fda-and-cms-to-support-new-field-in-health-insurance-claims-for-udi>.

<sup>5</sup> National Postmarket Surveillance Planning Board, “Strengthening Patient Care: Building an Effective National Medical Device Surveillance System,” Feb. 2015,

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM435112.pdf>.

<sup>6</sup> Food and Drug Administration, Center for Devices and Radiological Health, “Strengthening our National System for Medical Device Postmarket Surveillance: Update and Next Steps,” April 2013,

<http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf>.

<sup>7</sup> M. Boutin, letter to Stacey Barber at Accredited Standards Committee X12, April 23, 2015.

<sup>8</sup> The Brookings Institution, “Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation,” Dec. 2014,

<http://www.brookings.edu/~media/research/files/papers/2014/12/05%20medical%20device%20tracking%20system/udi%20final%2012052014.pdf>.

<sup>9</sup> S. Kilpinen, Executive Director of National Contracting, Aetna, Inc., Hearing on Administrative Simplification: Use of UDI in Administrative Transactions, National Committee on Vital and Health Statistics, June 10, 2014.

<sup>10</sup> D. Templeton, letter to Accredited Standards Committee X12, June 3, 2014.

<sup>11</sup> V. Moore, and J. Drozda, letter to Accredited Standards Committee X12, April 3, 2014.

<sup>12</sup> D.J. Berry, letter to Margaret Weiker at Accredited Standards Committee X12, Jan. 8, 2015.

<sup>13</sup> B. Childs, letter to Margaret Weiker at Accredited Standards Committee X12, April 9, 2014.

<sup>14</sup> C. Bocchino, Comment on Docket No. FDA-2011-N-0090, Nov. 7, 2012.