Congress of the United States
Washington, DC 20515

November 19, 2015

The Honorable Shaun Donovan
Director
Office of Management and Budget
725 17th Street NW
Washington, D.C. 20503

Dear Director Donovan,

We are writing to encourage you to include policies to improve patient care, strengthen safety and enhance transparency of the use of Medicare dollars for medical implants in the President's fiscal year 2017 budget request for the Department of Health and Human Services (HHS). Specifically, the new unique device identifier (UDI) system—developed by Food and Drug Administration (FDA) at the direction of Congress—can provide Medicare with better information on the types of artificial hips, cardiac stents and other implants used by patients if it is included on the claims form. Ultimately, this will provide higher quality care to Medicare beneficiaries and ensure the wise use of taxpayer dollars.

Currently, health insurance claims submitted to Medicare and private health plans can only indicate procedures, such as a knee replacement surgery, but not the specific type of implant used. The UDI system, which provides each medical device with a code indicating its manufacturer and model type, can provide claims with additional specificity on the product implanted in the patient.

Once incorporated in claims, these data can then be utilized in much the same way that other claims data on drugs and procedures are already leveraged by FDA, the Centers for Medicare & Medicaid Services (CMS), entrepreneurs, researchers and other stakeholders. For example, the FDA's post-market surveillance Sentinel Initiative relies primarily on claims data to analyze the safety of pharmaceuticals; Congress in 2012 required FDA to expand this system to devices. Similarly, CMS has recently released troves of claims data to the public, researchers and medical product manufacturers as part of efforts to "achieve better care, smarter spending, and healthier people".

However, missing from these data is any information on the specific models of devices implanted, thus hindering their use for medical devices and resulting in CMS' inability to know which devices it has paid for and those that Medicare beneficiaries receive. This omission exists even though joint replacement surgery—a procedure with an implant at its core—is the most common Medicare in-patient procedure, resulting in more than 440,000 discharges and approximately $6.6 billion in costs for fiscal year 2013 alone. Additionally, there are millions of Medicare patients with other implanted devices, such as cardiac stents and defibrillators.

Many in the Administration have already expressed support for UDI incorporation in claims. FDA, as part of its plans to improve the data available on the performance of medical devices, has indicated that UDI must be incorporated into claims and other electronic data sources. Similarly, HHS Secretary Burwell stated in her confirmation process that FDA's Sentinel system would benefit from UDI incorporation in claims. Last, the National Medical Device Post-market Surveillance Planning Board and the National Medical Device Registry Task Force—two groups of experts convened by FDA—have recommended the inclusion of UDI in claims data to enhance the information available on long-term outcomes associated with specific products.

Many private sector organizations—including health plans, hospitals systems, clinicians, patients and public health organizations—have also expressed their support for the incorporation of UDI in claims. Health systems and payers that have expressed the value of UDI in claims to their businesses include Aetna, Duke Medicine, Intermountain Healthcare, Mercy and Geisinger Health System. However, because the claims form is standard across all payers and hospitals via CMS regulations, these organizations cannot incorporate UDI in claims and accrue the benefits for their organizations until the agency acts.

Despite widespread support for UDI in claims, CMS has expressed concerns about the implementation costs, citing how much it costs to update a number of administrative transactions in 2012. The costs cited by CMS, though, include implementation of the International Classification of Diseases-10 codes and changes to a host of other administrative transactions beyond the claim, such as eligibility and prior authorization forms. Additionally, the budget requests—and subsequent congressional appropriations—for CMS include specific funding for the implementation of revisions to these administrative transactions, thus ensuring that the agency has the resources it needs to upgrade its forms.

Collecting UDI in claims could also benefit the Medicare program. Better data on medical device performance can help identify faulty products more quickly, thus saving Medicare resources needed to treat the negative side-effects or remove the failed implant. One study suggested that the costs to Medicare of the failure of a single type of cardiac defibrillator could have surpassed a billion dollars. Similarly, the Office of the Inspector General has found that hospitals do not adequately pass-on savings to CMS from manufacturer credits for recalled or faulty implants; UDI information could help the agency proactively ensure that hospitals report those credits, further saving Medicare resources.

The organizations responsible for administrative transaction standards—including the claim form—are currently making revisions, which CMS is expected to adopt through rulemaking for implementation in approximately 2020. Unless UDI is incorporated into this forthcoming update, UDI may not be included in claims—and Medicare or the private sector may not be able to exchange and utilize this information—until the end of the next decade.

Therefore, we strongly urge the Administration as part of the HHS budget request for fiscal year 2017 to indicate that it will devote funding for the incorporation of UDI in claims to improve care quality, generate better data on the long-term outcomes associated with devices and shed light into the specific products reimbursed through the Medicare program.

The Administration should now ensure UDI incorporation into claims so that patients, physicians and researchers can realize the quality improvement benefits envisioned by Congress.

Thank you for your consideration of this matter.

Sincerely,

Bill Pascrell, Jr.
Member of Congress

Sander M. Levin
Member of Congress

Frank Pallone, Jr.
Member of Congress

Jim McDermott
Member of Congress

Mike Fitzpatrick
Member of Congress