



One Prince Street
Alexandria, VA 22314-3318
☎ 703.838.0033
✉ 703.548.1890

July 14, 2016

Senator Lamar Alexander
Chairman, Committee on Health, Education,
Labor and Pensions
U.S. Senate

Senator Patty Murray
Ranking Member, Committee on Health,
Education, Labor and Pensions
U.S. Senate

Senator Orrin Hatch
Chairman, Committee on Finance
U.S. Senate

Senator Ron Wyden
Ranking Member, Committee on Finance
U.S. Senate

Congressman Fred Upton
Chairman, Committee on Energy and
Commerce
U.S. House of Representatives

Congressman Frank Pallone, Jr.
Ranking Member, Committee on Energy and
Commerce
U.S. House of Representatives

Congressman Kevin Brady
Chairman, Committee on Ways and Means
U.S. House of Representatives

Congressman Sander Levin
Ranking Member, Committee on Ways and
Means
U.S. House of Representatives

Dear Congressional Members:

On behalf of AMGA, an organization representing 450 multi-specialty medical groups and integrated delivery systems representing approximately 180,000 physicians caring for one-in-three Americans, I am writing to express our support for the passage of congressional legislation that would include a new field in the standard insurance billing claims forms that would note the Unique Device Identifier (UDI) for high-risk medical or Class III devices, including cardiac implants and joint replacement implants. We are greatly concerned if the Congress fails to pass UDI in claims legislation before the end of this year, the next opportunity to add the UDI data field to claims may not be until approximately 2030.

As you are aware, implantable medical devices—for example artificial hip and knee replacements—can unexpectedly malfunction, causing substantial harm to patients and even death. Causes of joint replacement failure include mechanical loosening, osteolysis or the destruction of bone tissue, infection, instability, peri-prosthetic fracture and implant failure. These can lead to, among other consequences, cerebral and nervous system impairment, bone deterioration, and amputation. If a hip or knee implant fails, a second replacement has a higher failure rate than a primary replacement.

These surgeries require more technical expertise, are significantly more expensive and fewer surgeons have the ability to perform second or "revision" replacement surgeries making access to these procedures limited in some regions. We also note there are other health risks associated with these procedures. For example, in research published online in Arthritis and Rheumatology in 2015 by Na Lu, et al., titled, "Total Joint Arthroplasty and the Risk of Myocardial Infarction - A General Population, Propensity Score-Matched Cohort Study," found that compared to a control population for knee arthroplasty, there was an eight-fold increase in heart attack risk in the month after surgery and for hip arthroplasty risk increased more than fourfold.

For these reasons and others the AMGA argued in its March 1 comment letter in response to the Center for Medicare and Medicaid Service's (CMS's) December 2015 draft "Measure Development Plan" white paper that the UDI be included as a quality measure in all CMS pay for value programs and demonstrations. Since CMS identified "safety" as one of MACRA's five quality domains and since the agency's first "National Quality Strategy" goal is "making care safer," we argued the MACRA Merit-Based Incentive Payment System (MIPS) should adopt a UDI-related measure. In our March 28 comment letter in response to the Health Care Plan Learning Action Network's (HCPLAN) "Elective Joint Replacement" draft white paper, we again argued for including UDI in all joint replacement episode payment arrangements. That the draft HCPLAN document did not make mention of the UDI we found disappointing because we know from the CMS Acute Care Episode (ACE) demonstration that providers used cheaper surgical implants, equipment and materials in both their orthopedic and cardiovascular procedures to produce cost savings. As bundled payments and alternative payment models continue to increase, providers must have the ability to demonstrate that they are using high quality products, and not simply reducing costs by selecting a cheaper—and potentially medically inferior—product.

As you are aware, Congress passed legislation in 2007 to require that FDA develop the UDI, and since 2014, all high risk devices must now have UDIs. Assigning UDIs to devices is not enough; to achieve the full benefit from UDI implementation, a field should be added to the insurance claims form that allows a hospital to include a UDI for high risk implants. Currently, the claims form only lists or names the implant procedure, and as a result, the form lacks any information about the specific manufacturer or implant model.

Including the UDI on the claims form would provide several benefits. Among others, the FDA, CMS and private payers would be able to evaluate the long-term effects of medical devices much in the same way that claims are already used to analyze drug safety. UDI claims data would enhance disease registries. It would improve care delivery and outcome transparency, enable care innovation and allow pay for performance providers—such as Accountable Care Organization providers—greater ability to improve care quality and outcomes and reduce spending growth. It would also improve inventory management, reduce waste, eliminate errors related to data transcription, and increase

billing accuracy. Failure to add the UDI to the claims form will also prevent private health plans from accruing the benefits of its use. All these points aside, most of its use would help to avoid or reduce patient suffering.

We recognize there are administrative costs associated with this reform. However, these transactional costs can be mitigated by phasing in this administrative change over a limited period of time, for example, over three years. Additionally, UDI should be added as part of the next update to the claims form, and not as a stand-alone or emergency update.

We are proud to lend our support to the further adoption and use of the UDI along with AARP, Aetna, the Altarum Institute, the American College of Cardiology, the American Joint Replacement Registry, Duke Medicine, Geisinger Health System, HL7 International, Intermountain Healthcare, Mercy, the National Health Council, the Pacific Business Group on Health, the Leapfrog Group, the Pew Charitable Trusts, Premier, the Society of Thoracic Surgeons, and others.

We would be remiss if we did not note, just yesterday, July 13, the CMS Acting Director Mr. Andy Slavitt and the FDA Commissioner, Dr. Robert Califf, forwarded a letter to Mr. Gary Beatty, Chair of the Accredited Standards Committee X 12 encouraging the committee to "complete its work on the next version of the claims form . . . to permit the DI [Device Identifier] for implantable devices to be included in the claims form." The letter stated further, "HHS . . . believes that monitoring medical device product safety and performance is critical for ensuring public health and safety."

Before time runs out on updating the claims form, we urge Congress to act. That is require CMS to add a field to the standard, electronic claims transaction for the UDIs of medical implants to equip providers with the evidence they need on the performance of devices and improve patient care and population health.

If you have any questions concerning our letter please do not hesitate to contact David Introcaso, Ph.D., Senior Director for Regulatory and Public Policy, at dintrocaso@amga.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald W. Fisher".

Donald W. Fisher, Ph.D, CAE
President and CEO