May 17, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, DC 20201

Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Administrator Verma and Commissioner Gottlieb:

As you evaluate how to improve the costs and quality of patient care in your new roles, we write to urge you to maintain and advance your agencies' support for the addition of medical device identifiers to health insurance claims forms—a policy change that would equip patients, clinicians and researchers with better data to prevent harm and reduce cost.

At the direction of Congress to improve patient safety, the Food and Drug Administration (FDA) established a unique device identifiers (UDI) system to provide each medical implant—such as artificial joints and cardiac stents—with a code indicating its manufacturer and model number. The UDI system can only achieve its potential to improve patient care once it is included in health data sources, including health insurance claims forms.

Claims, unlike many other health data sources, provide information on patient outcomes across providers and over time. Researchers—including at FDA—have used claims to study drug safety and other aspects of the healthcare system. Claims, however, currently indicate that a particular procedure occurred (such as a hip replacement surgery) but lack information on the brand or model of device used. The incorporation of device identifiers to claims would fill that gap and allow researchers to better understand the long-term safety and performance of different devices.

Additionally, the Inspector General of the Department of Health and Human Services found that the failures of just seven cardiac implants cost $1.5 billion to the Medicare program and $140 million in out-of-pocket costs to beneficiaries. To more quickly detect these problems as well as prevent patient harm and avoid those costs, the Inspector General recommended the addition of device identifiers to claims.

The inclusion of device identifiers in claims has also garnered support across the healthcare system—including from clinical societies, hospitals, health plans, registries, patient groups and public health organizations—as well as from members of both parties in Congress. Last year, FDA and the Centers for Medicare & Medicaid Services also jointly endorsed the addition of device identifiers to claims given its patient safety, quality improvement and cost savings potential.

However, the claims form is not updated regularly. X12, the private committee responsible for claims, recently issued draft recommendations to incorporate device identifiers as part of many changes that would occur to standards for claims and other administrative and billing transactions. For device identifiers to appear on claims, X12 must finalize its recommendation following input from FDA, CMS and other stakeholders; other advisory committees must review the proposed changes; CMS would then

issue regulations adopting all of the recommended changes to claims; and hospitals and health plans would have approximately two years to make the associated changes. Given this lengthy process, these revisions will likely take effect in approximately 2021; missing this window of opportunity could delay the addition of device identifiers—and better data to prevent patient harm—for a decade or more.

As this process continues—including through eventual rulemaking by CMS—your agencies have a critical role in advancing patient safety and reducing costs through the addition of device identifiers to claims. We urge you to continue advancing this critical policy that has support across the healthcare system.

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.

Sincerely,
Aetna
Altarum Institute
American Association of Orthopaedic Surgeons
American College of Cardiology
American College Health Association
American Joint Replacement Registry
American Medical Group Association
Cook Group Inc.
DeRoyal Industries
Duke Health
Geisinger Health System
Intermountain Healthcare
Mercy
Oregon Health & Science University
Pacific Business Group on Health
Premier Inc. healthcare alliance
The Alliance of Community Health Plans
The Pew Charitable Trusts
The Society of Thoracic Surgeons