



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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November 29, 2017

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

Dear Administrator Verma,

On behalf of over 18,000 board-certified orthopaedic surgeons represented by the American Association of Orthopaedic Surgeons (AAOS), we are writing to reiterate our longstanding support for the inclusion of device identifiers in Medicare, Medicaid, and private insurance claims data. In late September the Office of the Inspector General (OIG) of the Department of Health and Human Services issued a report on “shortcomings of device claims data.” We fully support the OIG’s recommendation to ensure that the device identifier (DI) is included on the next version of the claim forms, and we encourage the Centers for Medicare & Medicaid Services (CMS) to continue with the implementation of this critical device surveillance mechanism. Although we have in the past supported the inclusion of the full unique device identifier (UDI) on claims forms, we believe the OIG’s recommendation to move forward with the inclusion of only the DI portion represents movement in the right direction.

The OIG’s report examined Medicare claims from 2005 through 2014 for all services provided to Medicare beneficiaries for seven recalled and failed cardiac medical devices. Replacement of these seven devices were estimated to cost taxpayers \$1.5 billion for the time period examined, with an additional \$140 million in beneficiary copayment and deductible liabilities. The costs to taxpayers and patients would certainly be even higher if orthopaedic and other medical devices were factored into these estimates. By adding the DI to claims forms, CMS could more effectively identify, track, and manage the costs to Medicare associated with recalled and failed medical devices.

AAOS has regularly expressed support for the collection of these data on claims forms. In June, we wrote to the Accredited Standards Committee X12 regarding its draft revisions, “Inclusion of these UDI in claims data would fill an important gap and play a critical role in evaluating the long-term safety and performance of orthopaedic medical devices.” We remain committed to ensuring that this tool for device surveillance and tracking be implemented. The failure to collect device identifiers has consequences beyond even the increased Medicare costs. By adding UDI

to claims, clinical data registries can provide even greater evaluations of device, clinician, and hospital quality to inform patient care decisions. These kind of longitudinal data are important to the success of clinical data registries, which are another invaluable tool for monitoring device performance and protecting patient safety.

In your letter to the Inspector General regarding his report, you expressed concern regarding “the potential that this policy would impose burden on physicians unnecessarily.” While we appreciate and share your desire to relieve unnecessary burdens on physicians, AAOS believes implementation of the OIG’s recommendation would protect patient safety, significantly reduce the costs to taxpayers and patients, and permit patients and their doctors to make more informed choices.

We look forward to continuing to work with CMS on this issue.

Thank you for your time and for the opportunity to share our views on this issue. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Wilford K. Gibson". The signature is written in a cursive, somewhat stylized font.

Wilford K. Gibson, MD
Chair, Council on Advocacy, American Association of Orthopaedic Surgeons

cc: Thomas E. Arend, Jr., Esq., CAE, AAOS Chief Executive Officer
William O. Shaffer, MD, AAOS Medical Director
Graham Newson, AAOS Director of the Office of Government Relations