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August 31, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW, Washington, DC 20201

Re: Docket ID: CMS-2015-0075, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; etc.

Thank you for the opportunity to comment on efforts by the Centers for Medicare & Medicaid Services (CMS) to reduce costs associated with failed or recalled medical implants—such as implanted cardiac defibrillators or iliac artery stents—as part of proposed changes to payment policies for hospital outpatient procedures.

The Pew Charitable Trusts is an independent, non-profit research and public policy organization. Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

Much in the same way that customers can obtain refunds if they purchase defective consumer goods, hospitals receive credits for faulty or recalled medical devices from the manufacturers of those products if they need to replace the device. Since 2007, CMS has required hospitals to report to the agency any manufacturer credits they have received for certain costly medical implants. In turn, Medicare reduces the hospital's reimbursement for a set of specified procedures because the manufacturer already covered the cost of the device. Under this Hospital Outpatient Prospective Payment System (HOPPS) proposed rule, CMS would expand existing policy to all implants used in procedures where the cost of the product is at least 40 percent of the total cost of the procedure, not just those devices on a list specified in the regulations.

As CMS changes this policy to recoup costs associated with recalled or faulty products, a recent analysis described challenges that the agency has experienced in enforcing and overseeing this program. An investigation last year by the Office of Inspector General (OIG) of the Department of Health and Human Services found that hospitals regularly did not report manufacturer credits to CMS and often neglected to request those credits from manufacturers in the first place. OIG found in its review of a set of 600 claims filed in one region in 2011 for mechanical complications associated with implanted cardiac devices that in 86 cases hospitals did not request a credit from the manufacturer or report credits they obtained, totaling approximately $550,000 in overpayments from CMS for those claims alone.[1] As these findings are only for one geographic area, a single set of products, and represent a small sample of claims data, nation-wide savings for all costly medical implants is likely far greater. To help better understand those potential savings, OIG is investigating the total costs to Medicare of defective devices.[2]

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Enforcement of this policy relies on hospitals requesting credits from manufacturers and reporting those credits to CMS. Given that claims data only indicate that a particular procedure occurred and not which brand or model of a device the hospital implanted, CMS and Medicare contractors lack the information they need to proactively identify claims associated with recalled or failed devices. As a Medicare Administrative Contractor indicated to OIG, the company "would not know, unless a provider reported it on the claim…that a device was subject to recall/warranty and therefore warranted no payment or reduced payment."

Until recently, inclusion of standard device identifying information in claims was not possible. However, in 2013, the Food and Drug Administration (FDA) finalized regulations establishing a unique device identifier (UDI) system to assign each medical device a code corresponding to its manufacturer and model. The UDI system can provide claims with needed specificity on the brand of device used and would enhance enforcement of CMS' efforts to reduce costs associated with failed or recalled devices.

- **Ensuring hospitals obtain device credits**: In the event of a recall, CMS could proactively search their claims database using the UDI to identify hospitals that billed for the particular device and remind them to obtain—and then report—a credit from the manufacturer if a patient needs revision surgery.
- **Identifying claims for reporting device credits**: Should hospitals report UDIs to CMS, the agency could know—based on the device model—whether a particular beneficiary underwent revision surgery before the expected lifespan of the product. CMS could then proactively query the hospital on whether they received or are owed credits from the manufacturer.
- **Detecting patterns of problems with specific devices**: One of the original goals of this policy identified in the 2007 final rule was to "advise [CMS] of the extent to which devices are being replaced due to device failures so that, if patterns are identified [CMS] could explore them to see if there are systemic problems with certain devices." Collecting UDI in claims would help CMS better evaluate the performance of specific devices in ways that are currently not possible without brand and model information.

To achieve these benefits and better enforce this policy, the claims form must have new capabilities to transmit the UDIs of implanted device from providers to CMS. However, the claims forms are only updated periodically, with revisions under discussion for implementation within the next few years. Failure to include a field for UDI on this update to the claims form would prevent the exchange of this information until the next update—at the earliest—in the mid-late 2020s. Given the challenges that CMS already faces in recouping costs related to faulty and recalled devices, waiting a decade or more is simply too long to increase knowledge of device failure patterns and save Medicare resources. The agency has an opportunity to support this addition to the claims form on the next update as it moves through the administrative process.

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Along with the utility of UDI in claims to enforce CMS' manufacturer credit policies and ability to identify device performance patterns, these data would also greatly improve transparency in how Medicare dollars are spent; enhance analyses by researchers, FDA and registries in the performance of products; and support the development of innovative coverage and benefits designs. Given the many business uses of UDI in claims, many stakeholders—including large health plans,[3] accountable care organizations,[4] clinical specialty societies,[5] patient advocates and public health groups[6]—have supported the exchange of this information to health plans.

As CMS weighs expanding this payment adjustment policy for medical devices, the new UDI system has potential to enhance the agency's implementation and enforcement of this program to proactively ensure that Medicare—and taxpayers—receive the savings due to them and help improve patient care. Thank you for considering our comments. Should you have any questions or if we can be of assistance, please contact me at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

Josh Rising, MD
Director, Healthcare Programs
The Pew Charitable Trusts

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[1] Department of Health and Human Services, Office of Inspector General, "Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits," Oct. 2014, http://oig.hhs.gov/oas/reports/region5/51300029.pdf.
[2] Department of Health and Human Services, Office of Inspector General, "Work Plan Fiscal Year 2015," Oct. 2014, http://oig.hhs.gov/reports-and-publications/archives/workplan/2015/FY15-Work-Plan.pdf.
[3] Hearing on Administrative Simplification: Use of UDI in Administrative Transactions, (June 10, 2014), (statement of Stuart Kilpinen, Executive Director of National Contracting, Aetna, Inc.), accessed May 4, 2015, http://www.ncvhs.hhs.gov/wp-content/uploads/2014/06/140610p26.pdf
[4] C. Gaus, letter to Stacey Barber at Accredited Standards Committee X12, March 2, 2015.
[5] American College of Cardiology, et al., Letter to National Coordinator DeSalvo, Commissioner Hamburg and Administrator Tavenner, May 29, 2014.
[6] Patient, Consumer, Public Health Coalition, Letter to Margaret Weiker at Accredited Standards Committee X12, March 28, 2014.