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September 8, 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-5516-P, Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

Thank you for the opportunity to comment on the new program by the Centers for Medicare & Medicaid Services (CMS) to improve care and reduce costs through alternative payment models for hip and knee replacement surgeries. While several factors—including the patient's condition, hospital and implant—can affect the quality and costs of procedures, hospitals and CMS often lack key information on one of these elements—the artificial joint used.

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.

As part of the proposed Comprehensive Care for Joint Replacement model, hospitals within certain geographic areas will receive standard, bundled payments for all care associated with a knee or hip replacement surgery within 90 days of the implant procedure as a single episode of care. This model differs from current standard billing practices where follow-up care for the patient is reimbursed separately from the initial implant procedure.

This program is part of an effort to move the healthcare system away from fee-for-service policies, where providers receive more payments when delivering higher volumes of care, and may not have incentives to improve quality, reduce costs and better coordinate the patient's treatments with other clinicians. To test alternatives to the typical fee-for-service approach, CMS launched this pilot project in an effort to encourage higher value in hip and knee replacement procedures by improving—or at least maintaining—the quality of care while reducing costs.

Device selection can influence quality and cost

Since joint replacement is the most common inpatient procedure reimbursed by Medicare,[1] improving care and addressing costs for these surgeries is critical to enhancing care for the nation's seniors. For these procedures, there is well documented evidence that device brand and model selection can influence both quality and costs:

- *Device selection influences quality*: Several recent device failures underscore differences in the quality, safety and long-term performance of medical devices. For example, metal-on-metal hips, implanted in hundreds of thousands of patients, failed at much higher rates than prostheses made of other materials.[2] Similarly, various models of implantable

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cardiac defibrillator leads failed in different ways, unnecessarily shocking and even potentially killing some patients.[3] These medical device failures demonstrate that product brands and models can dramatically influence the quality of care, likelihood of revision surgeries and type of follow-up care required.

- *Device selection influences cost*: The specific brand of device can also dramatically influence the total cost of procedures and associated care. A 2012 study found that the ratio of hip and knee device costs contributed to as much as 87 percent of the total procedure cost.[4] Further, when devices fail or are recalled, the additional associated costs incurred can be high.

Quality measures lack consideration for device selection

To ensure that providers do not sacrifice the quality of care, CMS is proposing to use three hospital-level measures that assess complications, readmissions and the patient experience. As mentioned above, the quality of the device selection can dramatically affect these factors, such as when devices fail—resulting in complications—or if patients are not satisfied with their joint replacement because of poor range of motion, pain or other issues.

To help better evaluate quality scores according to these metrics, CMS is also proposing to share raw claims data to participating hospitals. However, as mentioned, the lack of device-specific information in claims hinders the ability for CMS or participants to incorporate device selection into comparisons of quality among hospitals.

An opportunity to incorporate device-specific information in claims

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 incorporation of the UDIs of hip and knee replacements in claims would benefit this program in several ways:

- **Better information to hospitals on device quality and costs:** Through these types of bundled care programs and the shift to alternative payment models—like accountable care organizations, providers are increasingly at risk for the long-term quality and costs of care. Given that device selection is an integral component of both those factors, providers require better information to make informed clinical decisions. While claims are regularly used by researchers, FDA and registries to provide clinicians and hospitals with better information to inform patient care decisions, these data cannot inform device selection.

  Should claims contain more specific device information, FDA, as it does with drugs, could utilize these data for analyses on the long-term effects of medical devices. For

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example, FDA's postmarket surveillance Sentinel system relies primarily on claims data to evaluate drug safety. FDA cannot efficiently expand this system to medical devices—as instructed by Congress in 2012—until claims contain UDI data.

Additionally, registries often link with multiple databases to conduct robust assessments of patient outcomes. Incorporating UDI in claims would support registries' ability to conduct longitudinal analyses of device performance, thus further providing data on quality to hospitals participating in this bundled payment program.

- **Enhanced data to CMS to ensure quality:** As mentioned, CMS will evaluate quality and release claims data to participants as part of this program. The incorporation of UDI in claims would also help CMS assess whether the implant used was associated with higher or lower scores on the quality measures that the agency will use to ensure that cost reductions do not have negative effects on care.

  In addition, the incorporation of UDI in claims can help participants demonstrate that they are using high quality products with good long-term outcomes—not just the lowest cost implants that will not fail during the 90-day window of care used in the proposed knee and hip replacement pilot project.

Given the need for better device-specific information, many stakeholders—including large health plans,[5] accountable care organizations,[6] clinical specialty societies,[7] patient advocates and public health groups[8]—have supported the inclusion of UDI in claims.

To achieve these benefits and enhance bundled payment initiatives, claims transactions should have new capabilities to transmit the UDIs of implanted device from providers to CMS. However, claims transactions 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 claims transactions would prevent the exchange of this information until the next update—at the earliest—in the mid-late 2020s.

Conclusion

The administration has launched an unprecedented effort to base 90 percent of Medicare payments on quality or value by 2018.[9] As joint replacement is the most common Medicare inpatient procedure, this proposed hip and knee bundled payment policy could shift a significant portion of payments toward that national goal. However, this policy, along with other bundled payment initiatives that involve implanted medical devices, omit a key factor that can influence both the cost and quality of procedures—the specific product utilized. To enhance this and other bundled payment initiatives, CMS should ensure that UDIs are incorporated in claims to develop better data on the influence of specific device brands on costs and quality.

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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] "Vast Trove of Medicare Data Details How Billions are Spent." New York Times. June 1, 2015. http://www.nytimes.com/aponline/2015/06/01/us/politics/ap-us-medicare-data-trove.html.
[2] Joshua P. Rising, Ian S. Reynolds, and Art Sedrakyan, "Delays and Difficulties in Assessing Metal-on-Metal Hip Implants," *New England Journal of Medicine* 367 (2012), doi:10.1056/NEJMp1206794.
[3] Robert G. Hauser, "Here we go Again—Another Failure of Postmarketing Device Surveillance," *New England Journal of Medicine* 366 (2012): 873-875, doi:10.1056/NEJMp1114695; and Robert G. Hauser et al., "Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads," *Heart Rhythm Journal* 9, no.8 (2012): 1227-35, doi:10.1016/j.hrthm.2012.03.048.
[4] James C. Robinson et al., "Variability in Costs Associated with Total Hip and Knee Replacement Implants," *Journal of Bone and Joint Surgery* 94, no. 18 (2012): 1693-8.
[5] 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.
[6] Cliff Gaus, letter to Stacey Barber at Accredited Standards Committee X12, March 2, 2015.
[7] American College of Cardiology, et al., Letter to National Coordinator DeSalvo, Commissioner Hamburg and Administrator Tavenner, May 29, 2014.
[8] Patient, Consumer, Public Health Coalition, Letter to Margaret Weiker at Accredited Standards Committee X12, March 28, 2014.
[9] Department of Health and Human Services, "Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value," Jan. 26, 2015, http://www.hhs.gov/news/press/2015pres/01/20150126a.html.