THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700 215.575.9050 Phone
Philadelphia, PA 19103-7077 215.575.4939 Fax

901 E Street NW, 10th Floor 202.552.2000 Phone
Washington, DC 20004 202.552.2299 Fax
www.pewtrusts.org

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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

Submitted electronically via regulations.gov

Re: Docket No: CMS-2016-0008: Medicare Program: Expanding Uses of Medicare Data by Qualified Entities CMS-5061-P.

Thank you for the opportunity to comment on proposed regulations that expand the ability of approved organizations—called qualified entities—to obtain, analyze, provide and use Medicare claims data to improve care quality as required by the Medicare Access and CHIP Reauthorization Act. Although the qualified entity program delivers claims information to researchers so they can improve health care quality and costs, this program lacks key data on an important facet of care: medical devices—such as cardiac stents and artificial joints—that are used disproportionately among Medicare beneficiaries. The Centers for Medicare & Medicaid Services (CMS) should act to remedy this key deficiency to improve the utility of claims data for qualified entities and other research organizations.

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.

The proposed regulations expand the qualified entity program to allow certain registries, all-payer claims databases, state health departments and other organizations to analyze and provide Medicare claims data to individual providers or employers to make informed decisions about care delivery. Previously, qualified entities were only allowed to conduct analyses for public use, not private organizations. While expansion of the qualified entity program can enable more organizations to make data-driven healthcare decisions, these stakeholders will still lack information on medical device performance until the underlying data—Medicare claims—contain information on specific implants.

Claims data enable qualified entities to provide unique information about health care

Qualified entities, registries, the Food and Drug Administration (FDA), health plans and medical product manufacturers already use claims data to evaluate the healthcare system. Because claims are standardized across providers and health plans, these data are easily aggregated for large numbers of patients across different care settings to better understand outcomes over time.

This aggregation allows for analyses that would not be possible with data from other sources, such as electronic health records that are formatted differently from hospital to hospital, thus preventing the same types of cross-provider analyses. Describing how these proposed regulations would leverage Medicare claims to improve care, CMS Acting Administrator Andy Slavitt said, "Increasing access to analyses and data that include Medicare data will make it easier for stakeholders throughout the healthcare system to make smarter and more informed healthcare decisions."[1]

Qualified entities have used claims data for many purposes, including:

- **Benchmarking of provider performance**: The Oregon Health Care Quality Organization and many other qualified entities have released reports that compare provider performance on key quality measures with statewide or nationwide averages.[2]
- **Demonstrating value**: The Wisconsin Health Information Organization's online tool rates providers in the state based on whether they give the right care at the right time, and whether they make good use of healthcare dollars.[3]
- **Analysis of healthcare spending**: The Health Care Cost Institute found that much of the increase in prescription drug spending in 2014 can be attributed to the rise in use of high-priced drugs that treat hepatitis C.[4]

Opportunity to enhance claims and the qualified entity program with device identifiers

Despite the proven value of claims to shed light on the complex health care system, including through the qualified entity program, they remain opaque on data related to medical devices implanted in patients. Currently, claims indicate that a particular procedure occurred—such as a knee replacement surgery—but not the specific product used. This omission is especially problematic for the Medicare program, where the most common in-patient procedure involves hip and knee replacements, affecting 400,000 patients at a cost of $7 billion annually for the initial hospitalization alone.[5]

However, a new tool developed by FDA can fill this gap in claims data to list the devices implanted in patients. The FDA's new unique device identifier (UDI) system provides each medical device with a code corresponding to its make and model to unambiguously identify products used in patient care. Starting last year, medical implants were required to have this identifier.

The addition of a field to claims for the UDIs of medical implants would enable FDA, researchers, clinicians, health plans and qualified entities to analyze devices much in the same way that they use Medicare data to assess other aspects of healthcare—including drugs. The proposed expansion of the qualified entity program could allow approved organizations to further study medical devices for private organizations using Medicare claims data, including by:

- **Analyzing patient safety**: Researchers could use claims to evaluate product performance and identify safety concerns, as is already done for drugs through FDA's Sentinel Initiative.
- **Comparing device outcomes**: Access to UDI data from claims can support comparisons on the safety or effectiveness of different devices, surgeries, drugs, lifestyle changes and other interventions.

- **Modeling and cost estimation**: By knowing which products are most frequently used, organizations can improve modeling of expected expenditures based on all factors that influence the cost of care, including device selection, and whether specific products result in more physical therapy or hospital readmissions, for example.

These types of analyses would support CMS' stated goals of expanding the qualified entity program in the hopes of "leading to more transparency regarding provider and supplier performance and innovative uses of data that will result in improvements to the healthcare delivery system."[6] Until that can occur, though, CMS must adopt a new version of the claims form that includes a field for the UDIs of implants. As discussions are already underway to incorporate UDI in the next version of the claims form, which would take effect in approximately 2021, CMS should publicly express support for the addition of this critical information on medical devices used in the Medicare population. Missing this critical window could delay the addition of UDI until the subsequent update, which may not be finalized for another decade or more.

Conclusion

Over the past few years, CMS has released Medicare claims data and enhanced access to this information in an effort to improve healthcare quality, increase transparency and realize cost savings. With these proposed regulations to further leverage claims by qualified entities, CMS further demonstrates that the agency recognizes the utility of this information to enhance understanding of the healthcare system. However, all these efforts—including the use of claims data by qualified entities—rely on the quality and completeness of information submitted to Medicare.

Until these data contain information on the devices used in care, the qualified entity program and other CMS initiatives to harness claims data will fall short for the millions of patients who rely on life-saving and life-changing medical implants. Therefore, CMS should help advance the addition of UDI in claims as part of the next update so that qualified entities, FDA, health plans, registries and researchers at other organizations can harness Medicare data to help patients that rely on medical implants make more informed decisions about their care.

Should you have any questions, please contact me at jrising@pewtrusts.org or 202-540-6761.

Sincerely,

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

[1] Centers for Medicare & Medicaid Services, "New Proposal to Give Providers and Employers Access to Information to Drive Quality and Patient Care Improvement," Jan. 29, 2016, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-01-29.html.
[2] Oregon Health Care Quality Corporation, "2014 Statewide Report," http://q-corp.org/2014-statewide-report.
[3] MyHealth Wisconsin. http://myhealthwi.org.
[4] Health Care Cost Institute, "New Report: Health Care Spending Grew 3.4 Percent in 2014, With More Dollars Going to Brand Drugs," Oct. 29, 2015, http://www.healthcostinstitute.org/news-and-events/new-report-health-care-spending-grew-34-percent-2014-more-dollars-going-brand-drugs.
[5] Centers for Medicare & Medicaid Services, "Comprehensive Care for Joint Replacement," July 9, 2015, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-07-09.html.
[6] Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 5397 (Feb. 2, 2016).