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Why Insurance Claims Should Include Medical Device Identification

Overview

Insurance claims are a critical health care data resource. They facilitate payment to providers for services that patients receive. Researchers, government regulators, and health plans also use claims to analyze the quality of care, identify potential problems, and evaluate health care delivery. Unlike other data sources, claims provide information over long periods of time and across the many hospitals and doctors that a patient may visit.

Claims already include information about the drugs prescribed to patients. But when patients receive a medical implant, claims currently list only the procedure—such as hip replacement surgery or cardiac stent insertion—and lack any specific information about the product itself.

Congress can help address this gap in claims data with the addition of information on the manufacturer and model of device implanted, particularly for products that are more likely to cause harm. In 2007, Congress took the first step by requiring the Food and Drug Administration (FDA) to establish a unique device identification (UDI) system, which provides each device with a distinctive number, much like a bar code.

How researchers and hospitals can use UDI data from claims

- **Data-driven analysis:** Researchers use large databases that collect information from multiple health plans to evaluate costs and quality. If claims contained UDI information, researchers could also use these databases to evaluate product performance and identify safety concerns, as is already done for drugs.
- **Sentinel surveillance:** FDA's Sentinel Initiative postmarket surveillance program relies predominantly on claims data to assess drug and vaccine safety. Adding UDI data to claims would allow FDA to use Sentinel to conduct large, longitudinal analyses on device safety, as Congress required it to do in 2012.
- **Demonstrating value:** As Medicare, private health plans, and hospitals increasingly prioritize value, better information about devices can help health systems demonstrate that they are providing cost-effective care to patients without sacrificing quality. This information can help identify when lower- or higher-cost products may be clinically appropriate.
- **Improving registries:** Registries, which collect data on a group of patients treated with a particular device, often gather information on outcomes for a set period—for example, from the time a patient is admitted to a hospital until he or she is discharged. UDI information can help link registries with claims data sets to analyze longer-term safety and quality.

How health plans can use UDI data from claims

- **Comparative effectiveness research:** The lack of data on specific devices prevents health plans from comparing the safety or effectiveness of implants with that of different devices, surgery, drugs, lifestyle changes, and other interventions. Access to UDI data can support these types of comparisons and help identify problems with the safety or effectiveness of particular devices.
- **Follow-up care and recalls:** Health plans could use UDI information to ensure that their members obtain appropriate follow-up care, such as rehabilitation, which may be required for patients with specific implanted devices. In the event of a recall, UDI data could allow a health plan to notify affected members.
- **Modeling and cost estimation:** By knowing which devices their members use, health plans can improve modeling of expected expenditures based on all factors that influence the cost of care, including device selection.
- **Fraud and abuse detection:** Health plans could use UDI data to detect fraud and recoup payments owed to them when products fail.

As the standard insurance claims form undergoes revisions, Congress should act now to incorporate UDI information into claims, unlocking the data's many benefits.

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