CMS Prospective Payment Rule

UDI Requirement for Implantable Medical Devices

Executive Summary

CMS has incorporated an attestation requirement for recording the Unique Device Identifier (UDI) for implantable devices as part of the Medicare prospective payment rule. Beginning with the CY 2027 EHR reporting period, **eligible hospitals and Critical Access Hospitals (CAHs) will be required to demonstrate that they can electronically capture and store the UDI information associated with applicable implantable medical devices in Certified Electronic Health Record Technology (CEHRT).** There is an exemption for hospitals that implant fewer than 5 devices in the calendar year. The initial measure is designed to establish a baseline and encourage hospitals to develop reliable UDI capture capabilities.

The requirement is focused on electronic health record data capture, not Medicare billing. At this time, CMS is not requiring UDI information to be reported on Medicare claims or cost reports

1. What Is a Unique Device Identifier

A Unique Device Identifier (UDI) is a standardized identifier assigned to a medical device. It is intended to identify a device accurately from manufacturing through distribution and use.

UDI-DI (Device Identifier): identifies the specific device, including the manufacturer and model/version.

UDI-PI (Production Identifier): provides production-specific information, such as a lot or batch number, serial number, expiration date, or manufacturing date, when applicable.

The FDA UDI system requires regulated industry to place the identifier on applicable device labels and packages in both human-readable and machine-readable form, allowing the information to be captured electronically.

2. Patient-Level Device Identification

Capturing UDI as structured data in the EHR allows a specific device to be associated with a specific patient. CMS identifies potential benefits including more accurate device identification, faster response to recalls, improved follow-up and care coordination, and stronger post-market surveillance and research.

3. What Is CMS Requiring

Beginning with the CY 2027 EHR reporting period, CMS is adding the Unique Device Identifiers for Implantable Medical Devices measure to the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program.

The measure focuses on the ability of eligible hospitals and CAH's to electronically capture and store the complete UDI for applicable implantable medical devices in discrete data fields within CEHRT. The complete UDI includes the UDI-DI and applicable UDI-PI. CMS clarified that non-CEHRT technologies such as inventory management systems or procedure documentation systems can be used to capture and transmit the UDI, but it ultimately must be stored in discrete data fields in CEHRT.

4. What Devices Are Covered

The measure applies to applicable implantable medical devices subject to the FDA's UDI requirements. CMS recognizes the exclusions for devices or circumstances covered by applicable FDA UDI exceptions. Therefore, any implantable device with a UDI on its label is covered by the CMS rule.

5. What Should Hospitals Do Now

Find where UDI data exists today: Map UDI capture across ERP/MMIS, inventory, operating room, cath-lab, procedural documentation, and other systems.

Confirm complete UDI capture: Determine whether both UDI-DI and applicable UDI-PI are captured, not merely a catalog number or model name.

Confirm EHR integration: Determine whether UDI information reaches CEHRT and is stored in the required structured, discrete form.

Assess point-of-care workflow: Define who captures the UDI, when it is captured, how it is associated with the patient/procedure, and how exceptions are handled.

Review AHRMM/SMI UDI Quick Start Guides: Identify which guides can support your organization's compliance efforts. Click here to access the Quick Start Guides.

Identify who is responsible for submitting Prospective Payment Attestations to CMS: This can vary across health systems. Departments that may be involved include IT, Compliance, Revenue Cycle or Legal.

Prepare for future evolution: Treat CY 2027 as a starting point; CMS has indicated that it will consider future modifications and broader uses of UDI data.

6. How Will Compliance Be Reported

The initial measure is an attestation measure. Eligible hospitals and CAH's will attest 'Yes,' 'No,' or claim an applicable exclusion. CMS is using the initial implementation to establish a baseline rather than immediately imposing a performance threshold. However, failure to attest could result in a downward adjustment to payments.

7. The Bottom Line for Health Care Providers

CMS is beginning to require hospitals to electronically capture and store the UDI of applicable implantable medical devices in the patient's EHR.

For clinicians, the practical change will be participation in an organizational workflow that captures the device identifier at or near the point of care and makes the information available as structured data in the patient's electronic record.

CMS Rule and Additional Information

The authoritative source is CMS's FY 2027 Hospital Inpatient Prospective Payment System (IPPS) Final Rule. CMS's official final-rule page provides the final rule and related materials.

CMS identifies the final rule as CMS-1849-F and notes that it was published August 4, 2026.