Symmetric Health Solutions

WHITE PAPER

UDI: The Data Standard Healthcare Executives Cannot Afford to Overlook

> Operationalizing Unique Device Identification for Patient Safety, CMS Compliance, and Financial Protection

A Symmetric Health Solutions White Paper

Prepared for Health System Executive Leadership: CSCO · CFO · CIO · CMO · CNO

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Thesis: Why Readiness is Critical for Healthcare

Unique Device Identification (UDI) is no longer just an FDA medical device regulatory requirement - it is rapidly becoming a hospital operating and compliance requirement. CMS is collaborating with the FDA to integrate UDI regulations with CY 2027 CMS Inpatient Prospective Payment rules impacting hospital billing and future readiness for tracking implants in Certified Electronic Health Records (CEHRT), leaving the door open for potential future expansion of UDI reporting into Medicare claims and cost reports. This is a policy shift that turns UDI into a shared operating standard for End to End Medical Device Traceability (E2EMDT), connecting supply chain data, clinical documentation, revenue integrity, and patient safety. The question for health systems is no longer whether UDI will touch their operations, but whether their device data will be ready when it does. In many organizations, item master data was never built to carry reliable device-level identifiers from the receiving dock to the patient record to the claim, and closing that gap takes time. **Executive teams that treat UDI as infrastructure will be better positioned to create reliable device-level data across the enterprise. Those that wait risk scrambling to comply on a regulator's timeline instead of their own.**

Executive Summary

- **The Policy Shift (What It Changes Operationally):** For the first time, CMS is asking healthcare systems to attest to whether they are electronically scanning the complete UDI both the static Device Identifier (UDI-DI) and the dynamic Production Identifier (UDI-PI) for implantable devices into discrete EHR fields at the point of care. The answers collected in CY 2027 establish the baseline for future requirements, and CMS has left the door open.
- **The Stakes (Clinical and Financial):** In the short term (CY 2027) failure to attest to whether you electronically capture and transmit UDI data risks a reduction in CMS reimbursement levels. In future iterations of CMS IPPS rules failure to capture the UDI could result in audit triggers, missed recall tracing, and lost reimbursement under the Medicare Promoting Interoperability Program. Regardless of regulations, not capturing UDI, especially for implants, risks delayed identification of at-risk patients when a device is recalled.
- **Strategic Blueprint:** Moving health systems from manual entry in OR/procedural area documentation to electronic point-of-care UDI capture that is linked directly to patient safety attributes and stored consistently across Supply Chain (MMIS-ERP), EHRs, POU's and Billing systems.
- **The Patient Care Thesis:** UDI is the connective tissue between what was implanted, who it was implanted in, and how quickly the system can act in case of an adverse event or recall. Every recommendation in this paper is framed through that lens.

- **The Goal: End-to-End Medical Device Traceability (E2EMDT):** a digital UDI-enabled framework that connects device information across ordering, receiving, inventory, point-of-care use, patient documentation, outcomes monitoring, postmarket surveillance, and recall response. By scanning and recording UDI across systems that feed the patient chart, E2EMDT helps confirm that the right device was used on the right patient and supports tracking of device performance over time.

What This Ruling Means to You

The CMS IPPS rule that includes UDI attestation requirements touches every corner of the health system: clinical documentation, IT infrastructure, the revenue cycle, and supply chain operations. The table below sets out what the ruling means for each executive stakeholder and the priority action to take now.

ROLE	WHAT IT MEANS	PRIORITY ACTION
Chief Supply Chain Officer	Item catalog master accuracy, barcode standardization (GS1, HIBCC, ICCBBA), scanner readiness, and dock-to-disposition visibility to ensure that the ERP is the single point where clinical, financial, and regulatory data converge.	Complete a GUDID/master data audit targeting >95% valid UDI-DI mapping, and validate full functioning scanner deployment across OR, Cath Lab, and Interventional Radiology workflows.
CIO	CEHRT certification requires your EHR to parse UDI-DI and UDI-PI into discrete, queryable fields and exchange them via HL7 FHIR Device resources, not store them as free text.	Audit EHR implant-log configuration against CEHRT parsing requirements and establish real-time GUDID API integration.
CFO	UDI requirement moves implantable devices from a supply chain detail onto the balance sheet: by electronically capturing and automating UDIs under the Medicare Promoting Interoperability Program can, improve audit support for NTAP, pass-through payments, and manufacturer recall credits, and improve cash flow as claim edits drive down Discharged not final bill (DNFB) days.	Form an executive task force that unites Supply Chain, IT, Revenue Cycle, and Perioperative Operations around a single workflow that sends point-of-care UDI scans directly into the EHR, replacing the manual entry and disconnected inventory systems that cause most non-compliance.
CMO/CNO	Improved active surveillance, recall response, and patient communication creates patient-safety infrastructure, not documentation overhead.	Support and advocate for inclusion of UDI-DI and scanning capability across the enterprise. Set the strategy of clinical decision-making based on data.

Section 1: The Directive & the Architecture

1.1 Collaboration on UDI Basics, Education

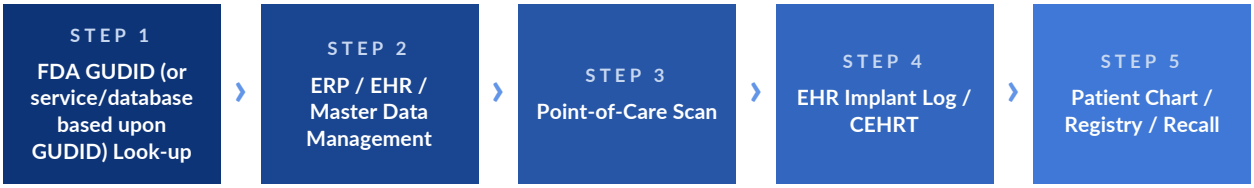
For over 15 years the AHRMM Learning UDI Community (LUC) has engaged "a coordinated, action-oriented, and early adopter unique device identifier (UDI) community. The LUC is a broad-based coalition of healthcare leaders including those from the association, clinical, distribution, financial, health IT, physician, provider, regulatory, standards organizations, and supplier/manufacturing sectors." Symmetric believes in the value of the LUC, has led multiple workgroups, and has edited every document produced by this group.

Recently, AHRMM has worked collaboratively with the Strategic Marketplace Initiative (SMI) on a set of Quick Start Guides UDI Quick Start Guides - Introduction - SMI aimed at level setting knowledge of UDI basics. The guides include details on UDI fundamentals, standards for data exchange, the benefits of data capture at the point of use, and the role of data management principles in achieving regulatory and business benefits of UDI.

1.2 Scope & Regulatory Convergence

- **Scope:** Prioritizing implantable devices directly addresses the greatest risk to patient safety. Policy efforts across three Federal Agencies are aligned to address this risk.
- **FDA:** GUDID data synchronization and barcode labeling compliance, the backbone of national active and recall surveillance.
- **ONC:** Health Tech Interoperability rules requiring EHRs to parse UDI elements into discrete database fields.
- **CMS:** Beginning with the CY 2027 EHR reporting period, eligible hospitals and Critical Access Hospitals (CAHs) will be required to attest to whether they can electronically capture and store the complete UDI (both UDI-DI and UDI-PI) associated with applicable implantable medical devices in discrete fields within Certified Electronic Health Record Technology (CEHRT). These initial attestation responses will form CMS's baseline for expanding future requirements.
- **Why Convergence Matters Clinically:** Health systems that address as one integrated workflow improvement rather than create three separate compliance projects will achieve patient benefits from a complete, accurate implant record instead of a partial one built only to satisfy billing. The hospital benefits by having the information needed to make more informed decisions about purchasing, inventory, receiving and evaluation of devices that will improve patient safety and outcomes.

1.3 Architecture at a Glance



- ERP and EHR master data alignment: item catalog masters mapped to UDI-DIs sourced from AccessGUDID.
- Clean master data and discrete UDI fields in clinical systems are what allow a faster more efficient process to support the recall management, active surveillance, and expiration date alerts.
- Point-of-care capture: fully functioning barcode scanners in ORs, Cath Labs, Interventional Radiology suites, and other implant procedure areas that are configured to parse GS1, HIBCC, and ICCBBA standards dynamically, eliminating manual keystrokes and reducing documentation time during active procedures.
- EHR / CEHRT integration: discrete UDI fields populated in the EHR implant record (Epic, Oracle Health, MEDITECH and many others) so structured device data is easily accessible and usable across the care continuum.

Section 2: Financial, Supply Chain Operations & Patient Care Impact

Implementing UDI capture establishes a continuous flow of structured device data across revenue cycle, supply chain, and clinical operations, safeguarding health system financial and operational performance regarding safe and available supplies while elevating patient safety.

2.1 Revenue Cycle

- UDI bridges clinical documentation and financial reimbursement in high-cost procedural care.
- Point-of-care scanning into the EHR eliminates manual errors to reduce charge capture leakage.
- Mapping product codes directly to the charge master increases clean claim rates and builds immutable audit trails.
- Automated item validation resolves pricing gaps and enables precise supply cost forecasting for patient financial estimates.
- Operationalizing UDI capture now also future-proofs the health system to meet any future expansions of UDI reporting

2.2 Supply Chain

- Item catalog master accuracy is the single point of convergence for clinical, financial, and regulatory data; every downstream use of UDI begins with this strong data foundation.
- Barcode standardization (GS1, HIBCC, ICCBBA) and fully functioning barcode scanner deployment across OR, Cath Lab, Interventional Radiology, etc., with defined scan failure exception workflows.
- Ensuring tracking of a device from point of receipt through point of use, enabling visibility at both the inventory and patient level.
- Appropriate capture also improves the Bill Only patient ordering process.

2.3 Clinical & Patient Impact

- Accelerated recall response as a result of discrete UDI-PI information in the EHR transforms the recall process, enabling automated information to prevent recalled devices from reaching patients and supporting outreach to affected individuals.
- Capturing UDI data supports national registries, strengthens device-performance tracking and informs future device selection.
- Patients and their care providers gain visibility into exactly which device was implanted and enable patient-carried device cards or digital records populated directly from UDI data.

Section 3: UDI Benefits & Key Advantages — Going Beyond the Regulatory Requirements

BENEFIT	WHY IT MATTERS
Faster, more precise implant documentation in the EHR	Scanning UDI in the OR reduces manual entry, automatically captures lot, serial number, expiration date, and device identifier, and links the product to standardized manufacturer, brand, device description, and safety attributes. Non-sterile implants still require workflow re-design, because the device may not move through a packaged sterile scan point before use.
Accelerated recall and adverse event response	A scanned UDI stored across health IT systems, including ERP and EHR platforms, enables teams to identify every patient who received a specific lot or serial number in hours rather than weeks, reducing manual record and inventory review, liability exposure, and regulatory risk.
Cleaner charge capture	Connecting UDI to accurate classification systems such as HCPCS and GMDN can populate cleaner device data into charges, reduce denials tied to incomplete documentation, and speed reimbursement for device-related payments.
Supply chain and inventory cost savings	UDI-enabled inventory systems that scan and use the full UDI, including UDI-DI and UDI-PI elements such as lot, serial number, and expiration date, reduce manual counting, expired or obsolete stock write-offs, and overstock.
Regulatory and interoperability compliance	FDA UDI requirements, CMS conditions of participation, and emerging interoperability expectations, including UDI in FHIR resources and national device registries, are moving health systems toward mandatory UDI capture in clinical documentation.
End-to-End Medical Device Traceability (E2EMDT)	When the full health care team supports lifecycle traceability across ordering, receiving, point of use, long-term use, outcomes analysis, and recall readiness, UDI becomes an infrastructure asset that confirms the right device was used on the right patient and enables tracking of short- and long-term device performance.

Section 4: Source Support

The evidentiary foundation for UDI integration rests on the regulatory convergence detailed in Section 1.2:

- **CMS Promoting Interoperability Program:** Establishes the CY 2027 attestation measure for capturing full UDI data in CEHRT for implantable devices as a baseline for potential future measures.
- **ONC CEHRT Criteria:** Mandates structured parsing of UDI-DI and UDI-PI elements into discrete EHR fields via standardized HL7 FHIR device resources.
- **FDA GUDID Standard:** Serves as the authoritative master reference database for device attributes, labeling, and safety specifications.

Section 5: Implementation Roadmap & Governance Checklist

PHASE 1
Data & Integration Readiness Audit
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PHASE 2
Data Capture Design
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PHASE 3
EHR ERP and Revenue Cycle Alignment
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PHASE 4
Go-Live, Monitoring, and Executive Governance

PHASE	KEY DELIVERABLE	PATIENT SAFETY & GOVERNANCE CHECKPOINT
PHASE 1 **Data & Integration Readiness Audit**	Master data audit of item catalog, GUDID, and EHR integration readiness targeting >95% valid UDI-DI mapping	Establishes executive governance baseline across Supply Chain, IT, and Finance to ensure data completeness before go-live
PHASE 2 **Data Capture Design**	Fully-functioning barcode scanners deployed; discrete UDI parsing enabled in EHR for point-of-care capture	Validates discrete implant data reaches the patient record to support active surveillance and safety tracking
PHASE 3 **EHR/ERP & Revenue Cycle Alignment**	Audit and alignment of item catalog master, charge-description master (CDM), and EHR implant record data for accurate UDI-DI mapping	Ensures seamless data flow between clinical and financial systems without care-related claim delays or charge errors
PHASE 4 **Go-Live, Monitoring & Executive Governance**	Fully-functioning barcode scanning live in high-volume procedural areas; ongoing data-quality monitoring and audit readiness	Active recall response workflows operationalized; ongoing cross-functional executive governance actively maintained

Section 6: Strategic Conclusion & Executive Action Plan

- **The CFO Agenda:** Safeguarding revenue integrity, reducing claim edits, mitigating audit risks, and preparing for future UDI-linked CMS report requirements.
- **The CIO Agenda:** Ensuring vendor readiness for CEHRT specifications, FHIR device data models, and GUDID API synchronization.
- **The Chief Supply Chain Officer Agenda:** Achieving end-to-end visibility from dock-to-disposition.
- **The CMO/CNO Agenda:** Ensuring UDI capture accuracy directly supports faster recall response, safer implant selection, and more complete patient records at the point of care.

Immediate Call to Action for Leadership

Executive leadership is urged to authorize a comprehensive, cross-functional UDI readiness audit. Initiating this assessment now will benchmark item master clean-up needs, audit EHR/ERP data parsing readiness, and establish the governance infrastructure required ahead of upcoming CMS reporting timelines.

UDI compliance should be positioned as a patient-safety infrastructure investment that also protects product identification, reimbursement readiness, recall response, and revenue integrity. Health systems that frame it this way secure stronger clinical buy-in and build an End-to-End Medical Device Traceability capability that outlasts any single regulatory deadline.

How Symmetric Health Solutions Can Help Advance End-to-End Medical Device Traceability

Symmetric is a champion of E2EMDT, a digital UDI-enabled framework that connects device information across ordering, receiving, inventory, point-of-care use, patient documentation, outcomes monitoring, postmarket surveillance, and recall response. By scanning and recording UDI across systems that feed the patient chart, E2EMDT helps confirm that the right device was used on the right patient and supports tracking of device performance over time.

Symmetric Health Solutions is advancing this framework, modeled on Closed Loop Medication Administration, as the foundation for a shared operating standard for device data.

Your Data Partner Through Every Phase

Symmetric Health Solutions specializes in helping health systems operationalize complex mandates, turning regulatory requirements like UDI into durable clinical and financial infrastructure, not one-time compliance projects. The following services represent the comprehensive, enterprise-wide offerings provided by Symmetric Health Solutions, extending beyond the specific themes and scope addressed in this white paper:

19M+
enriched records in our item master database

1,600+
clinical and regulatory attributes per product record

>95%
valid UDI-DI mapping targeted against FDA GUDID

- **Catalog Audit, Deduplication & Clean Baseline:** We audit and rationalize legacy item masters against our database of 19M+ enriched records, normalizing manufacturer names, eliminating redundant duplicate line items, and correcting multi-UOM packaging hierarchies.
- **ERP & EHR, GUDID Cross-System Synchronization:** We match catalog records against the FDA GUDID database targeting >95% valid UDI-DI mapping, creating a clean, unified data layer seamlessly integrated across your ERP (Workday, Infor, Oracle), EHR (Epic, Cerner), and contracting systems.
- **Barcode & Scanner Workflow Readiness:** We assess scanner coverage and parsing across high-volume procedural areas (OR, Cath Lab, Interventional Radiology) and design structured “scan failure” exception workflows, including non-sterile implant paths that bypass standard packaged scan points.
- **Value Analysis & Clinical Standardization:** We enrich product records with over 1,600 clinical and regulatory attributes (e.g., UNSPSC, GMDN, latex/sterile flags, functional substitutes) to

empower Value Analysis Committees with clean data for spend optimization and product rationalization.

- **Revenue Cycle Enablement & Governance:** We eliminate revenue leakage and ensure compliance by continuously mapping supply chain item catalog master data directly to ERP/EHR, charge masters, HCPCS/CPT codes, and Unique Device Identifiers enabling accurate point-of-use charge capture, preventing supply-driven claim denials, and maintaining an audit-ready bridge between procurement and reimbursement.
- **Ongoing Data Stewardship & Resiliency Monitoring:** Beyond go-live, our continuous monitoring layer automatically captures supplier catalog updates, product discontinuations, regulatory shifts, and price updates, keeping your data current and preventing catalog degradation as device portfolios evolve

About Symmetric Health Solutions

This white paper was developed by Symmetric Health Solutions as an educational resource for health system executive leadership. The content reflects Symmetric Health Solutions' regulatory and operational experience guiding health systems through FDA, ONC, and CMS data-interoperability requirements.

For questions or to discuss a UDI readiness assessment for your organization, contact your Symmetric Health Solutions representative. or learn more at **symmetrichealthsolutions.com**.

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