AHRMM
Advancing Health Care through
Supply Chain Excellence

March 17, 2026

Dr. Michelle Tarver
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Tarver,

As stakeholders concerned with patient safety, we ask the Food and Drug Administration (FDA) to enhance the Recall Enterprise System (RES) to discretely store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields. This will improve machine-based interoperability between FDA and stakeholders.

The RES stores and publishes information regarding recalled devices, including the UDI.[1] The UDI includes the device model and production information. The RES displays the UDI in a free-text format that is not machine-readable. Without this information being machine-readable, software cannot perform automated information retrieval. This means that systems cannot be automatically updated to reflect which devices are recalled. As a result, the entry of UDI information into provider systems requires manual intervention, making the process less efficient, timely and complete as it could be.

Currently, health care providers review dozens of recall notices each week. In each instance, they must find the UDI in each notice, and visually match it with devices they have in stock or have used in caring for their patients. Recall notices also often include multiple UDIs, creating long blocks of text that are difficult to visually parse. Ultimately, patient safety is the highest priority for supply chain and all hospital leaders. They want to ensure that UDI information is as accessible and usable as possible to ensure that they can identify all affected devices, remove them from service and notify patients about device recalls as promptly as possible.

FDA can address this issue by creating a discrete field for the UDI in the RES. This would let software "know where to look" to find the UDI and help it communicate that information to healthcare providers. This would ensure information sent via the Medical Device Recalls API is legible for receiving systems.
This request also is consistent with 2021 recommendations by the FDA Patient Engagement Advisory Committee, which noted that it would help "communicate medical device recall information to patients and the public."[2]

[1] In this letter, UDI includes the device identifier and production information for each unique medical device. Together, this information identifies not only the manufacturer and type of device, but also the individual device being recalled.
[2] FDA, "October 6, 2021: Patient Engagement Advisory Committee Meeting Announcement," https://www.fda.gov/advisory-committees/advisory-committee-calendar/october-6-2021-patient-engagement-advisory-committee-meeting-announcement-10062021#event-information

Lastly, we believe this change is feasible and not unduly burdensome for This enhancement would not create significant burden for manufacturers. Notably, in 2025, over 96% of recall notices already incorporate this information, albeit in the free-text format. By directing stakeholders to enter this information into a discrete field, FDA can improve the interoperability of device recalls – this would save lives. Further, this enhancement would align with the structure of other databases, including the Manufacturer and User Facility Device Experience (MAUDE) database, used for adverse event reporting.

In summary, placing UDI information into discrete fields in the RES will improve the effectiveness, efficiency and safety of the recall process, and improve the interoperability of life-saving recall information. It would help fulfill our mutual commitment to protecting patients. Thank you for your consideration of this issue.

Sincerely,



Michael Schiller, FAHRMM, CMRP
Executive Director
AHRMM
American Hospital Association

March 20, 2026

Marty Makary, MD MPH
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

Michelle Tarver, MD PhD
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Makary and Tarver,

SMI and its members are writing in support of the letter sent by Mike Schiller Executive Director of AHRMM requesting the Recall Enterprise System (RES) be enhanced to discreetly store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields.

SMI is a non-profit supply chain organization consisting of healthcare providers, suppliers, and distributors to network and collaborate on innovations that drive meaningful improvements in supply chain agility, efficiency, and resilience. In addition, we have a physician advisory group that provides guidance and participates in our initiatives who are committed to improving patient safety.

Please see the list of SMI members below.

Thank you for your consideration.

Sincerely,



Jane Pleasants
President
SMI
www.smisupplychain.com

Sent via email and U.S. mail

SMI HEALTH SYSTEM MEMBERS

AdventHealth (FL)
Adventist Health (CA)
Advocate Health (NC)
Akron Children's Hospital (OH)
Allegheny Health Network (PA) Allina Health (MN)
AtlantiCare (NJ)
Ascension/TRG (MO)
Avera Health (SD)
Banner Health (AZ)
Baptist Health South Florida (FL)
BayCare Health System (FL)
BJC HealthCare (MO)
Bon Secours Mercy Health (OH)
Boston Medical Center (MA) Cleveland Clinic (OH)
Community Health Network (IN) Cone Health (NC)
Corewell Health (MI)
Dartmouth-Hitchcock Health (NH)
Duke Health (NC)
ECU Health (NC)
Emory Health (GA)
Encompass Health (AL)
Endeavor Health (IL)
Froedtert Health (WI)
Geisinger Health System (PA)
Hartford Healthcare (CT)
HCA Healthcare (TN)
Henry Ford Health System (MI)
Indiana University Health (IN)
Intermountain Healthcare (UT) Johns Hopkins Health System (MD) Kaiser Permanente (CA)
Kettering Health Network (OH) LeeSar (FL)
Legacy Health (OR)
Lifepoint Health (TN)
Mass General Brigham (MA)
Mayo Clinic (MN)
McLeod Health (SC)
Memorial Hermann (TX)
Memorial Sloan Kettering Cancer Center (NY)
Mercy Health System (MO)
Mount Sinai Health System (NY)
MultiCare Health System (WA)
Northwell Health (NY)
Northwestern Medicine (IL)
Norton Healthcare (KY)
Novant Health (NC)
Ochsner Health System (LA)
OSU Wexner Medical Center (OH)
OU Health (OK)
Parkland Health & Hospital Health System (TX)
Prisma Health (SC)
PointCore (IL)
Renown Health (NV)
Rush University Medical Center (IL)
RWJ Barnabas Health (NY)
Saint Luke's Health System (MO)
Sarasota Memorial Health Care System (FL)
Sentara Healthcare (VA)
Sharp Healthcare (CA)
SSM Health (MO)
St. Luke's Health System (ID)
Stamford Health (CT)
Stanford HealthCare (CA)
Sutter Health (CA)
Texas Health Resources (TX) TriHealth (OH)
UC Davis Health (CA)
UC Health (CO)
UChicago Medicine (IL)
UNC Health System (NC)
Universal Health Services, Inc. (PA)
University of Miami Health System (FL)
UTMB Health (TX)
UT Southwestern Medical Center (TX)
UW Medicine (WA)
Vanderbilt University Medical Center (TN)
VCU Health System (VA)

SMI INDUSTRY PARTNER MEMBERS

Allergan Aesthetics (NJ)
Alliance Healthcare Partners (AZ) Amazon Business (WA)
Avanos Medical, Inc. (GA)
Baxter Healthcare Corporation (IL) B. Braun Medical, Inc. (PA)
BD (Becton, Dickinson and Company) (NJ)
BioTissue, Inc. (FL)
Breg, Inc. (CA)
Capsa Healthcare (OH)
Cardinal Health (OH)
CareLine Inc. (TN)
Casechek (IL)
Clarium (NY)
Concordance Healthcare Solutions (OH)
ConMed (NY)
Cook Medical (IN)
Deloitte (MA)
DeRoyal (TN)
Direct Supply (WI)
Fresenius Kabi (IL)
Front1 Health Partners (IL)
GCB Medical Supply (MA)
Genesis Automation USA (FL)
Global Healthcare Exchange (GHX)
GOJO Industries, Inc. (OH)
Grainger (IL)
Handle Global (KY)
Hanger (TX)
Henry Schein, Inc. (SC)
HWL Works (GA)
Infor (NY)
Innovative Health (AZ)
Johnson & Johnson Medical Device Companies (NJ)
KARLSTORZ Endoscopy-America (CA)
Kurin (CA)
LabCorp (SC)
L.E.K. Consulting LLC (MA)
LogicSource (CT)
McKesson Healthcare Corporation (TX)
Medline Inc. (IL)
MedSpeed (IL)
Olympus (PA)
Oracle (TX)
Owens & Minor, Inc. (VA)
PAR Excellence (CA)
PartsSource (TN)
Philips (MA)
Ryder System Inc. (OH)
Smith & Nephew (MA)
Sodexo (MD)
Solventum (MN)
SpendMend (MA)
Staples (MA)
STERIS Corporation (OH)
Stryker Corporation (MI)
SxanPro (MI)
Symmetric Health Solutions (PA)
Tecsys (IL)
Trimedx (IN)
WL Gore & Associates, Inc. (DE)
Workday (CA)
Zimmer Biomet (IN)

DATE: March 17, 2026

Dr. Marty Makary
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

Dr. Michelle Tarver
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Makary and Tarver,

Epic is writing in support of the letter sent by Mike Schiller Executive Director of AHRMM requesting the Recall Enterprise System (RES) be enhanced to discreetly store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields.

We strongly support the use of machine-based interoperability to reduce human error and thereby enhance patient safety and increase efficiency. Storing the UDI in distinct fields would be the first critical step in achieving this goal.

Thank you for your consideration.

Sincerely,

Devin Bobulski

Devin Bobulski | Subject Matter Expert, Medical Device Safety & UDI | Epic Systems Corporation | AHRMM UDI Workgroup

March 17, 2026

Dr. Marty Makary
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

Dr. Michelle Tarver
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Makary and Tarver,

Device Events is writing in support of the letter submitted by Mike Schiller, Executive Director of AHRMM, requesting that the Recall Enterprise System (RES) be enhanced to discretely store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields.

We strongly support the use of machine-based interoperability to reduce human error, enhance patient safety, and improve operational efficiency. Storing the UDI in discrete, machine-readable fields would be a critical first step toward enabling automated workflows across healthcare delivery systems, supply chain platforms, regulatory analytics tools, and electronic health records.

As a former member of the MAUDE and UDI Teams, I review correction notices with an eye toward how devices are labeled, communicated, and reported. A recent manufacturer-issued correction notice for the Omnipod® 5 system illustrates the challenge. Public-facing safety communications may include a single UDI for the primary device, while the same product is distributed across multiple packaging configurations with additional UDIs at the package level.

These identifiers are essential for accurate traceability across health systems, supply chain platforms, patient records, and for CDRH staff when evaluating MAUDE reports and classifying recalls. When all applicable UDIs—including both primary and package-level identifiers—are not captured in structured fields, stakeholders must rely on manual reconciliation across multiple data sources, increasing the risk of incomplete identification of affected devices at the point of care and within inventory systems. Notably, many MAUDE reports for these devices reference the package-level DI rather than the primary DI cited in the correction notice, further underscoring the importance of capturing the full UDI hierarchy.

Illustrative Example (Omnipod® 5 Pod):
Safety Notice (as issued):
• UDI listed: 10385083000527 (Primary Device)

UDI Database (AccessGUDID) – Complete Device Identifier Set:
• 10385083000527 (Primary Device)
• 20385083000531 (Package)
• 20385083000579 (Package)
• 20385083000753 (Package)
• 20385083000548 (Package)

This example demonstrates that a single UDI included in a safety communication (https://www.omnipod.com/mdc-3-26) may not represent all distributed configurations of an affected device. Capturing the full UDI hierarchy in discrete RES fields would help ensure complete traceability across clinical, supply chain, and patient-facing systems.

Because the majority of recall notices already include UDI information, this enhancement would represent a low-burden, high-impact improvement. Establishing discrete UDI fields within RES would strengthen interoperability across FDA systems and external stakeholders while supporting safer and more effective recall execution.

Thank you for your consideration and for your continued leadership in advancing patient safety.

Sincerely,

Madris Kinard

Madris Kinard, MBA
Founder & CEO
Device Events

Docusign Envelope ID: AA0F7FA8-8EBC-8F3A-832B-5F12252C0CCA

Symmetric Health Solutions

1500 Chestnut St. Suite 2 #1354
Philadelphia, PA 19102

www.symmetrichealthsolutions.com

March 23, 2026
Dr. Marty Makary
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

Dr. Michelle Tarver
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Makary and Tarver,

Symmetric Health Solutions is writing in support of the letter sent by Mike Schiller, Executive Director of AHRMM, requesting the Recall Enterprise System (RES) be enhanced to discreetly store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields.

We strongly support the use of machine-based interoperability to reduce human error and thereby enhance patient safety and increase efficiency. Storing UDI in distinct fields would be the first critical step in achieving this goal.

Thank you for your consideration.

Sincerely,

DocuSigned by:
Richard Kucera
F1EA9781D15949C...

Richard Kucera
CEO & President
March 23rd, 2026

PAR EXCELLENCE

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March 12, 2026

Dr. Marty Makary
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993

Dr. Michelle Tarver
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Makary and Tarver,

PAR Excellence Systems, Inc. is writing in support of the letter sent by Mike Schiller Executive Director of AHRMM requesting the Recall Enterprise System (RES) be enhanced to discreetly store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields.

We strongly support the use of machine-based interoperability to reduce human error and thereby enhance patient safety and increase efficiency. Storing the UDI in distinct fields would be the first critical step in achieving this goal.

Thank you for your consideration.

Sincerely,

Thaddeus MacKrell, CEO
PAR Excellence Systems, Inc.

Dr. Marty Makary
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, MD 20993
Dr. Michelle Tarver
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Makary and Tarver,

National Recall Alert Center is writing in support of the letter sent by Mike Schiller Executive Director of
AHRMM requesting the Recall Enterprise System (RES) be enhanced to discreetly store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields.

While the vast majority of medical devices now carry a UDI, the current push from organizations like the **National Recall Alert Center** is to ensure this data is placed into **discrete fields** within the RES. This would allow hospital systems to automatically match a recalled UDI against their inventory, rather than having staff manually read through recall descriptions.

We strongly support the use of machine-based interoperability to reduce human error and thereby enhance patient safety and increase efficiency. Storing the UDI in distinct fields would
be the first critical step in achieving this goal.

Thank you for your consideration.
Sincerely,

--

Dr. Mark Cohen

President & Founder, Trustee

National **R**ecall **A**lert **C**enter

uest

A Federally-Approved, Non-Profit Organization

The Nation's Premier Recall Alerting Center