CMS Health Technology Ecosystems RFI Comment Response

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Rising T1DE Alliance – Medical Device Data Interoperability

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Executive Summary

The Rising T1DE Alliance urges CMS and ASTP/ONC to extend patient access, interoperability, and certification requirements—currently applied to EHRs and certified health IT—to include medical device data platforms. These steps are essential to support data-driven, value-based care and empower Medicare beneficiaries with full control of their health information

Key Recommendation: Medical device data portals should be subject to the same regulatory framework as EHRs and certified health IT systems, including FHIR API requirements, patient access standards, and interoperability mandates under the 21st Century Cures Act. This framework is essential for supporting data-driven care models and ensuring the long-term sustainability of value-based care initiatives.

About the Rising T1DE Alliance

The Rising T1DE Alliance (RTA) is a multi-institution collaboration committed to revolutionizing diabetes care through data-driven, patient-centered, scalable innovation. Co-led by Children's Mercy Kansas City and Ann & Robert H. Lurie Children's Hospital of Chicago, RTA brings together clinicians, data scientists, implementation leaders, patient advocates, payors, and industry experts to develop, test, and disseminate cutting-edge tools and models for diabetes population health. In addition to its leaders, active participants in the Alliance include Cincinnati Children's, University of Kansas Medical Center, Montana HIE Big SKY Care Connect, and activities cover both pediatric and adult patient populations. The RTA also works closely with the Diabetes Technology Society, who created The Integration of Continuous Glucose Monitoring Data into the Electronic Health Record (iCoDE) Project. The 2022 iCoDE Report: CGM-EHR Integration Standards and Recommendations serves as a model for a collaborative, multi-stakeholder approach to advancing medical device data interoperability and integration.

Primary Recommendations by RFI Section

PC-2: Patient Data Access and Integration

Medical device data represents a critical gap in current patient health information access. While patients can access basic claims data through Blue Button 2.0, continuous glucose monitor readings, insulin pump data, and other medical device information remain siloed in proprietary platforms.

Specific Recommendations:

- Extend Patient Access API requirements to medical device manufacturer data platforms

- Extend USCDI compliance requirements to medical device data portals via new certification criteria analogous to ONC's Health IT Certification Program
- Ensure patients have full access rights, control, and portability over their device-generated health data
- Implement same-day electronic access requirements for all medical device-generated electronic health information (EHI), aligning with patient access provisions under the ONC Cures Act Final Rule

TD-7: USCDI Expansion for Medical Devices

Current USCDI standards do not adequately address medical device data elements, creating interoperability gaps.

Recommendations:

- Expand USCDI to include standardized medical device data classes
- Define data elements for continuous glucose monitors, insulin pumps, and other therapeutic devices
- Establish device interoperability requirements similar to EHR certification criteria

VB-3 & VB-4: Essential Health IT Capabilities for Value-Based Care

Medical device data represents a critical component for successful value-based care arrangements, particularly for chronic disease management programs like diabetes care.

Current Gap: Value-based care organizations lack access to real-time medical device data needed for risk stratification, care coordination, and outcome measurement.

Recommendations:

- Include medical device interoperability as essential health IT capability for Alternative Payment Methods
- Require medical device data integration for diabetes-focused value-based care programs
- Establish device data as core element for population health analytics and risk stratification

VB-11: Interoperability Challenges in Value-Based Care

The absence of standardized medical device data creates significant barriers to effective value-based care implementation.

Specific Challenges:

- Inability to track real-time glucose patterns for diabetes management programs
- Limited medication adherence monitoring through device data
- Fragmented care coordination due to missing device-generated insights

Proposed Solutions:

- Mandate FHIR- or HL7-based device data APIs for VBC participation
- Create device data reporting requirements for quality measurement
- Establish real-time data sharing protocols for care team coordination

Detailed Policy Framework

Patient Access and Transparency Requirements

Current Gap: Medical device data is often trapped in proprietary systems without standardized patient access mechanisms.

Proposed Solution:

1. **Data Ownership:** medical device data has legally ambiguous ownership status. Patients must have full access rights, control, and portability over their device-generated health data, and device manufacturers should not be able to use data ownership to limit data sharing so long as it is consistent with TPO activities.
2. **Consent Framework:** Require explicit patient consent for any data use beyond direct patient care (TPO activities excepted)
3. **Access Standards:** Implement same-day electronic access requirements for medical device data, matching EHR standards

Interoperability Standards

Current Challenge: Medical device data exists in proprietary formats, preventing integration with other health IT systems. The 2022 iCoDE Report: CGM-EHR Integration Standards and Recommendations serves as a model for a collaborative, multi-stakeholder approach to advancing medical device data interoperability and integration.

Proposed Requirements:

1. **Message Exchange Standards:** All medical device manufacturers should enable EHR data integration using a FHIR-first strategy, with HL7 as an acceptable alternative.
2. **Terminology Standards:** As medical device manufacturers make their data available for ingestion in EHRs, they should work with professional societies and other stakeholders to add these new data concepts to relevant healthcare terminologies like LOINC.
3. **USCDI Alignment:** Device data must conform to expanded USCDI standards
4. **Bulk Export Capability:** Enable bulk export for population health management through REST APIs using industry standard formats like JSON, CSV, and Parquet.

Information Blocking Prevention

Current Issue: Some medical device manufacturers restrict data access or charge fees for patient data export.

Proposed Enforcement:

1. **Anti-Blocking Rules:** Extend 21st Century Cures Act information blocking prohibitions to medical device manufacturers whose platforms contain electronic health information (EHI) as defined by ONC, including data used in clinical decision-making or patient management.
2. **No-Cost Access:** Mandate free patient access to device-generated health data.
3. **Standardized APIs:** Require public, standards-based APIs without proprietary restrictions.

Implementation Recommendations

Phase 1: Policy Development (0-12 months)

- Expand USCDI to include medical device data elements
- Draft regulations extending USCDI requirements to medical device data portals
- Establish certification criteria for medical device data platforms

Phase 2: Industry Engagement (12-24 months)

- Collaborate with device manufacturers and relevant professional societies on implementation standards
- Develop guidance documents for FHIR-based device APIs
- Create patient education resources on data rights Phase 3: Enforcement (24-36 months)
- Implement certification requirements for device data platforms
- Begin enforcement of patient access and anti-blocking rules
- Monitor compliance and adjust standards as needed

Supporting Evidence

Patient Impact

- Improved diabetes management through integrated data access
- Enhanced care coordination between endocrinologists and primary care providers
- Better informed treatment decisions through comprehensive health data

Market Benefits

- Increased innovation in digital health applications through standardized device data access
- Reduced vendor lock-in for patients and providers, promoting market competition
- Enhanced competition among medical device manufacturers driving quality improvements
- **Sustainable value-based care programs through comprehensive data integration**
- **Economic efficiencies from automated data collection and standardized reporting**

Alignment with CMS Goals

- Supports value-based care through comprehensive patient data enabling risk stratification and outcome measurement
- Reduces administrative burden through standardized data formats and automated reporting
- Enhances patient engagement and self-management capabilities through better data access
- **Enables sustainable chronic disease management programs with measurable outcomes**
- **Supports Medicare Shared Savings Programs through accurate risk adjustment and care coordination**
- **Facilitates transition to data-driven care models that improve quality while reducing costs**

Conclusion

The Rising T1DE Alliance urges CMS and ASTP/ONC to extend comprehensive data access, ownership, and interoperability requirements to medical device data and its related platforms. This action would close a significant gap in the current digital health ecosystem, provide Medicare beneficiaries with complete control over their health information, and enable sustainable value-based care programs that improve outcomes while reducing costs.

Medical device data, including continuous glucose monitoring and insulin delivery data, falls within the definition of electronic health information (EHI) as outlined in the ONC Cures Act Final Rule. EHI encompasses not only the USCDI but all electronic protected health information (ePHI) maintained in a designated record set and used to inform care. As such, medical device platforms that hold, transmit, or display this information should be subject to the same access, interoperability, and anti-information blocking requirements applied to EHRs and other certified health IT.

Medical device data represents some of the most actionable health information available to patients and providers. The continuous, real-time nature of this data makes it particularly valuable for preventive care, chronic disease management, and population health initiatives. Ensuring this data is accessible, interoperable, and patient-controlled aligns perfectly with the goals outlined in this RFI and supports the transition to a truly patient-centric digital health ecosystem.

The sustainability of innovative care models depends on comprehensive data integration. The Rising T1DE Alliance's data-driven care programs demonstrate that when medical device data is properly integrated with clinical and claims data, the result is measurably better patient outcomes, reduced healthcare costs, and economically viable value-based care arrangements. Without standardized access to medical device data, these promising care models cannot achieve the scale necessary for broad Medicare beneficiary impact.

CMS has the opportunity to accelerate the adoption of evidence-based, data-driven care models by establishing the regulatory framework that makes comprehensive health data integration both possible and sustainable. The extension of EHR-level requirements to medical device data and its platforms represents a critical step toward this goal.

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This comment is submitted in response to CMS RFI CMS-0042-NC on the Health Technology Ecosystem, with specific focus on extending EHR-level data standards to medical device platforms.