ASTP/ONC HTI-5 Proposed Rule Public Comments

Rising T1DE Alliance | www.risingT1DEalliance.org

Submitted to: Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC)

RE: Public Comment on HTI-5 Proposed Rule – Advancing Safe, Scalable API-Based Interoperability for Diabetes Care

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Dear ASTP/ONC Leadership,

The Rising T1DE Alliance (RTA) appreciates the opportunity to comment on the HTI-5 Proposed Rule. RTA is a multi-institution community focused on advancing data-driven diabetes care by improving the real-world usability of electronic health information (EHI) and enabling safe, scalable integration of diabetes-related data into clinical workflows. We submit this comment on behalf of the Alliance, separate from any single health system perspective.

Executive Summary

Rising T1DE Alliance (RTA) supports ONC's HTI-5 Proposed Rule and its forward-looking direction to strengthen API-based interoperability, which is essential for modern diabetes care. Diabetes device data (e.g., continuous glucose monitors, insulin pumps, smart insulin pens, and blood glucose meters) too often remain difficult to integrate into EHR workflows in ways that are reliable, timely, and clinically actionable. While we support reducing unnecessary burden, we are concerned that deregulatory changes that weaken baseline certification assurances could shift security and operational risk onto healthcare organizations as API-enabled exchange expands. We urge ONC to retain (or clearly replace) minimum baseline expectations for auditability, authentication/authorization, encryption, and API performance transparency to ensure interoperability scales safely and sustainably.

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.

I. Interoperability is Essential to Modern Diabetes Care

Diabetes care increasingly depends on patient-generated health data from a diverse and rapidly evolving ecosystem of devices and applications: continuous glucose monitors (CGMs), insulin pumps and automated insulin delivery systems, smart insulin pens, blood glucose monitors, and related software. Yet in many care settings, these data remain difficult to integrate into the electronic health record (EHR) in ways that are timely, reliable, and clinically actionable. When device data are fragmented across portals, apps, and stand-alone platforms, clinicians lack the full clinical context needed to interpret data, coordinate care, and respond to safety issues. Patients and families also face inconsistent experiences in accessing and sharing their data across providers and settings. For diabetes, where decisions are frequent, time-sensitive, and high-stakes, interoperability is not an abstract policy goal; it is a prerequisite for safe and effective care.

II. RTA Supports HTI-5's API-Forward Interoperability Direction

RTA strongly supports ONC's forward-looking emphasis on a FHIR-based API foundation and related efforts to promote more consistent access, exchange, and use of EHI in real-world conditions. We also appreciate ONC's continued focus on improving the practical implementation of interoperability policies, including modernizing concepts that affect how EHI is accessed and used through software applications and automated workflows. We believe diabetes care represents a "stress test" for interoperability: high-frequency physiologic data, a multi-vendor device ecosystem, care delivered across inpatient/outpatient/community settings, and increasing reliance on digital tools to support patient self-management and clinical decision-making. Policies that improve API-based interoperability have outsized potential to improve outcomes in diabetes.

III. Key Concern: Deregulatory Changes Could Shift Safety and Assurance Burden Onto Healthcare Organizations

While RTA supports reducing unnecessary burden, we are concerned that certain deregulatory actions—particularly those that reduce certification-related security and assurance expectations—could unintentionally shift risk and operational burden onto healthcare organizations (HCOs) at the very moment that API-enabled exchange is expanding.

As access to EHI becomes more API-mediated and more dependent on third-party applications, HCOs must be able to rely on consistent baseline expectations for security, auditability, and operational performance. If those assurances are weakened at the certification level without a clear replacement, HCOs may be forced to recreate assurance through bespoke contracting, local governance, additional reviews, and technical controls. This introduces variability across the market, increases cost, slows adoption, and can create friction for patients and innovators, while also increasing the likelihood of inconsistent security practices across implementations.

In diabetes, where device data are increasingly used to guide treatment decisions and population health efforts, inconsistent assurance and traceability can also reduce clinician trust in integrated data and slow the adoption of interoperable workflows.

IV. Specific Recommendations: Preserve Baseline Security & Assurance for API Ecosystems

RTA urges ONC to either (a) retain key baseline security/audit capabilities within certification (preferred), or (b) if ONC removes these certification requirements, publish a clearly defined "minimum assurance set" that HCOs and developers can rely on as a consistent baseline for API-enabled exchange.

We recommend ONC focus that baseline on the following four areas:

1) Audit logs and traceability for API access (minimum baseline)
ONC should ensure there is a consistent baseline for audit logging and traceability for API-mediated access to EHI, including:

- Who accessed data (user/app identity)
- What data was accessed (resource/data category)
- When access occurred (timestamp)
- Which patient record(s) were accessed
- Which authorization scope(s)/permissions were used

Why this matters: without standardized auditability, health systems must recreate assurance through bespoke contracting and local controls, slowing adoption and increasing operational burden while also limiting incident response and patient trust.

2) Authentication and authorization expectations for app ecosystems
ONC should retain or specify baseline expectations for API ecosystem authentication and authorization, including:

- A consistent baseline approach to app identification, user identity, and authorization scope management
- Clear expectations for how authorization is granted, reviewed, and revoked
- Practical expectations that support safe and scalable third-party access enablement without increasing information blocking risk

Why this matters: HCOs need predictable controls to safely support patient- and provider-authorized apps without inventing unique governance frameworks for each integration.

3) Encryption expectations
ONC should preserve or define minimum expectations for encryption that align with the realities of API-enabled exchange, including:

- Encryption in transit for API traffic as a baseline
- Clear minimum expectations for protecting EHI as it moves across systems, intermediaries, and authorized applications

Why this matters: unclear or inconsistent encryption expectations can lead HCOs to impose additional screening and contracting requirements, increasing variability, delays, and cost.

4) API performance and availability transparency

If ONC is advancing a FHIR-first interoperability direction, ONC should also ensure that API-based access is operationally real by promoting transparency around performance, including:

- Basic uptime/availability reporting or transparency
- Reasonable disclosure around latency, rate limiting, and planned downtime
- Practical mechanisms for HCOs and app developers to assess whether API performance supports real-world clinical and patient-facing use cases

Why this matters: "FHIR-first" will only scale if organizations can trust that APIs function reliably enough for care workflows, patient access, and responsible downstream use (including analytics and decision support).

V. Why This Matters for Diabetes Device Data Integration

RTA's experience across sites is that integrating diabetes device data into the EHR is rarely blocked by a single technical barrier; rather, it is constrained by inconsistent interfaces, variable assurance practices, incomplete traceability, and operational fragility when systems move from pilot deployments to durable, scalable implementation. These are precisely the areas where clear, consistent baseline expectations can reduce burden for HCOs and developers alike. In practice, healthcare teams need device data in clinical context (medications, labs, diagnoses, encounters, and care plans) to make the data actionable. When interoperability and assurance are inconsistent, organizations may limit integration or keep workflows outside the EHR, undermining the very outcomes the Proposed Rule seeks to advance.

VI. Closing

RTA supports ONC's direction toward API-based interoperability and appreciates ONC's efforts to modernize the framework to better reflect real-world access and use of EHI. At the same time, we urge ONC to reconsider deregulatory changes that reduce baseline security and assurance expectations without replacement, because doing so may shift burden onto healthcare organizations and slow safe adoption—particularly for high-impact domains like diabetes device data integration.

We respectfully recommend that ONC retain baseline security and assurance capabilities within certification where possible, and where not feasible, publish a clear minimum assurance set that reduces variability, limits burden-shifting, and supports safe, scalable API-enabled interoperability. Thank you for your consideration.

Respectfully submitted,
Juan Espinoza, MD, on behalf of the Rising T1DE Alliance