Trinity Health

February 26, 2026

Thomas Keane, Assistant Secretary and National Coordinator HIT
Assistant Secretary for Technology Policy
Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

Re: RIN 0955-AA09; Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity

Submitted electronically via http://www.regulations.gov

Dear Assistant Secretary Keane,

Trinity Health appreciates the opportunity to comment on policies set forth in RIN 0955-AA09. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 127,000 colleagues and more than 29,000 physicians and clinicians caring for diverse communities across 25 states. Nationally recognized for care and experience, the Trinity Health system includes 92 hospitals, 101continuing care locations, the second largest PACE program in the country (a total cost of care program), 121 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 8,200 medical group physicians and providers. Based in Livonia, Michigan, its annual operating revenue is $25.4 billion with $1.4 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 12 Clinically Integrated Networks (CINs) that are accountable for 1.4 million lives across the country through alternative payment models. Our health care system participates in 12 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes 10 markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participated in the “enhanced track”, which qualifies as an advanced alternative payment model (AAPM). Two of the 12 markets also participate in the Comprehensive Primary Care Plus Model. In addition, we participated for many years in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Trinity Health is committed to interoperability and is on target to be the largest single-instance Epic user with a finalized roll out our entire 25 state footprint expected by the Spring of 2026.

Trinity Health appreciates efforts by HHS to reduce regulatory burden. However, it is premature to implement some of the changes proposed in the rule, as several provisions are inconsistent with existing federal requirements, including privacy regulations and may re-fragment the EHR marketplace. In addition, the rule would impact hospitals' ability to meet requirements for interoperability programs. We urge ASTP/ONC to propose regulatory changes to prevent these negative impacts prior to finalizing the provisions proposed in HTI-5. Many of the changes are proposed with the hope that the market will move toward Fast Healthcare Interoperability Resources (FHIR). We recommend HHS offer incentives to encourage faster adoption of FHIR. Once the industry implementation of FHIR is at 95%, ASTP/ONC can revisit the provisions proposed in this rule. Our key comments include the following, with more detail outlined below:

- Do not finalize the proposed changes to Patient Demographics criteria.
- Maintain Care Coordination criteria to support patient safety and quality of care.
- Keep the Privacy and Security Framework certification criteria in place until a comprehensive evaluation focused on the risks associated with the proposed removal is complete and until the future changes to the planned HTI-6 regulation are finalized.
- Maintain Patient Engagement Certification criteria as health systems rely on this data to meet requirements of reporting programs, including the Promoting Interoperability Program.
- For the safety of public health and alignment with existing HHS requirements, maintain criteria focused on the Transmission to Cancer Registries, Transmission of Antimicrobial Use and Resistance Reporting, and eCR Reporting.
- Do not finalize removal of the Design and Performance Certification criteria so that health systems can continue to use certified technology to meet requirements under the Promoting Interoperability Program.
- Prior to finalizing the provision that would codify that the terms "access" and "use" include access via automated means, we urge ONC/ASTP to codify in regulation requirements that balance innovation with the protection of the patients we serve.
- Identify and stop misuse in lieu of finalizing changes to the Infeasibility Exception in information blocking.
- Do not finalize changes proposed for the Manner Exception in information blocking until more of the market has moved to FHIR.
- Maintain the TEFCA Manner Exception until all TEFCA governance structures are established and mature and all Qualified Health Information Networks are able to support FHIR exchanges.

<u>Certification Criteria Changes</u>

The agencies propose significant changes that would alter nearly 70% of existing requirements under the certification program by removing 34 and revising 7 of the current 60 certification criteria.

*Patient Demographics*

The proposed rule would require HIT modules record sex in accordance with either the 248152002 Female (finding) or 248153007 Male (finding) SNOMED CT® U.S and remove patient observation data elements that focus on sexual orientation, gender identify, sex parameter for clinical use, name to use, and pronouns. The rule would also remove the Clinical Decision Support, Family Health History, and Implantable Device List criteria.

**Trinity Health does not recommend these provisions be finalized at this time.** The proposal to remove demographic gender identity classifications is not consistent with the Federal Section 1557 non-discrimination regulations and CMS 42 CFR § 482.13 - Condition of participation: Patients' Rights state that patients must be treated with respect, dignity and courtesy. Removing demographic indicators for only one specific population of patients may be perceived as disrespectful and could undermine our patients' trust —trust is a key element of patient safety. At Trinity Health, we have a core value of Reverence and honor the sacredness and dignity of every person.

**ASTP/ONC should conduct a reconciliation of the proposed changes and all other HHS regulatory requirements to ensure that there are no compliance gaps between federal regulations.**

*Care Coordination Criteria*
The proposed rule offers several changes to Care Coordination Criteria, including removing the Care Plan criteria to reduce burden to HIT developers and modifying/removing provisions under the Decision Support Interventions criteria.

**These proposed changes risk re-fragmenting the marketplace by removing standards and causing issues with communication between providers.** Removing the Care Plan criteria undermines patient care and may cause continuum of care issues. In addition, the complexity of medical records and patient care is such that slimming down these requirements could adversely affect quality of care. For example, removing Decision Support Intervention criteria would remove requirements for interventions when there are issues with allergies, intolerances or contraindications. **For these reasons, we urge ASTP/ONC not to finalize these proposals.**

*Privacy and Security Certification Criteria*
ASTP/ONC propose removing all of the privacy and security certification criteria under §170.315(d) and the associated privacy and security certification framework under §170.550(h) to reduce burden and encourage innovation.

**This proposal should not be finalized as it is inconsistent with the HHS OCR Security Regulations that require both audit logs and the regular review of audit logs (45 C.F.R. §164.312(b) 45 C.F.R. §164.308(a)(1)(ii)(D) 45 C.F.R. §164.316(b)(2)). We request that ASTP/ONC conduct a reconciliation of the proposed changes and all other HHS regulatory agency requirements to ensure that there are no compliance gaps between federal regulations.** During this time of increasing risk, the removal of any of the privacy and security framework criteria weakens our ability to assess threats to our electronic medical records. Data encryption, multi-factor authentication, encryption of credentials, date/time stamps, etc. are all critical elements of a secure electronic record. The goal of updating standards to support new technologies should not be obtained at the risk of patient medical records. The medical record serves as a source of truth, and the documentation is used for care decisions across the continuum of care. **The proposal to remove these criteria is premature, creates risk to the integrity of the medical record and ultimately erodes patient and provider trust.**

**In addition, should this proposal be finalized, there is the potential impact for patient data to be disseminated in an unexpected/unanticipated manner. The Privacy and Security Framework certification criteria should remain in place until a comprehensive evaluation focused on the risks**

**associated with the proposed removal is complete and until the future changes to the planned HTI-6 regulation are finalized.**

*Patient Engagement Certification Criteria*
The rule would remove the web content accessibility guidelines requirement to enable HIT developers to use other ways to provide viewing functionality as well as other provisions for the View, Download, and Transmit to a 3rd Party Criteria. This rule would also remove patient health information capture criterion that allows health care providers to incorporate unstructured patient generated health data or data from a non-clinical setting into a patient record.

Health systems rely on ONC-certified EHR and HIT modules to meet the requirements of numerous federal programs, including Promoting Interoperability Programs, CMS quality programs, and CMS alternate (at-risk) payment models. **If standards are weakened at the certification level, providers will be left with systems that impede our ability to meet mandatory program measures. We urge ASTP/ONC to maintain this criteria.**

*Public Health Certification Criteria*
ASTP/ONC propose revisions that would remove and revise requirements related to transmission to cancer registries, electronic care reporting (eCR), and antimicrobial use and resistance reporting to public health agencies.

**It is premature to remove these reporting criteria.** Transmission to cancer registries is critical for understanding prevalence and public health investigations into cancers and for those entities who don't move to FHIR, we will lose critical public health information. Similarly important, the antimicrobial use and resistance reporting criteria is critical for identifying significant risks to public health, including use of reported data to inform benchmarking, reduce antimicrobial resistant infections through antimicrobial stewardship, and interrupt transmission of resistant pathogens at individual facilities or facility networks. This reporting also supports CMS § 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

In addition, providers need the transmission to public health agencies eCR and the antimicrobial use and resistance reporting criteria to meet ongoing CMS Promoting Interoperability requirements. If these criteria are removed, we will not have certified technology to meet the standard. **For the safety of public health and alignment with existing HHS requirements, we urge ASTP/ONC to maintain the transmission to cancer registries, transmission of certified technology resistance reporting, and eCR reporting. Additionally, as recommended above, ASTP/ONC should offer incentives for faster adoption of FHIR and the proposed policies can be revisited once the industry implementation of FHIR is at 95%. We're not aware if FHIR has been applied to antimicrobial use and resistance reporting and therefore feel it premature to transition to this platform until it has been thoroughly tested and validated.**

*Design and Performance Certification Criteria*
The rule would remove the automated numerator recording and the automated measure calculation.

**Both of these criteria are requirements for the CMS Promoting Interoperability Program and as such, removing them will impact our ability to comply with the program. We urge ASTP/ONC to maintain these criteria.**

Interoperability

The rule proposes to adopt USCDI v3.1, which removes or updates from USCDI v3 the data elements for Sex, Sexual Orientation, and Gender Identity in the Patient Demographics/Information Data Class.

**The proposal to remove demographic gender identity classifications through the adoption of USCDI v3.1 is inconsistent with the Federal Section 1557 non-discrimination regulations and CMS 42 CFR § 482.13 - Condition of participation: Patients' Rights state that patients must be treated with respect, dignity and courtesy.** Removing demographic indicators for only one specific population of patients may be perceived as disrespectful and could undermine our patients' trust in our care and trust is a key element of patient safety. At Trinity Health we have a core value of Reverence and honor the sacredness and dignity of every person.

**We urge ASTP/ONC not to finalize this provision and instead conduct a reconciliation of the proposed changes and all other HHS regulatory requirements to ensure that there are no compliance gaps between federal regulations.**

Information Blocking

*"Access" and "Use" Definitions*

The rule would codify that the terms "access" and "use" through various technological means includes access via automated means, such as robotic process automation (i.e., "bots") and AI.

Trinity Health is concerned that the inclusion of bots—without corresponding safeguards, technical standards, and clear accountability requirements—could unintentionally increase cybersecurity risks and expose patients to new privacy vulnerabilities. The inclusion of bots in the definitions of "access" and "use" must be accompanied by safeguards that preserve cybersecurity, patient privacy, clinical system integrity, and responsible data management. **Prior to finalizing this provision, we urge ONC/ASTP to codify in regulation requirements that balance innovation with the protection of the patients we serve. This includes:**

- **Requiring that bots be tied to a verifiable individual or organization that assumes responsibility for the bot's actions and data use.**
- **Requiring that bots comply with all HIPAA requirements applicable to the user/entity for whom they act.**
- **Provide guidance on liability and accountability if a bot misuses data or causes harm.**
- **Clarify that health systems are not liable for misuse of data by bots.**
- **Include an exception for state law/regulation compliance.**
- **Permit security safeguards to restrict unusual or excessive automated access and inappropriate disclosures.**

*Infeasibility Exception*

ASTP/ONC propose to revise or, in the alternative, remove the "manner exception exhausted condition" from the Infeasibility Exception because it believes this condition as currently codified is susceptible to misuse by actors, such as by holding EHI to unnecessarily inhibit access, exchange, and use of EHI.

Providers rely on this exception because information blocking requirements cannot always be met with what is in the marketplace. Removal of this criterion should not occur until ASTP/ONC can confirm that at least 95% of

certified EHRs are capable of making this data electronically available to a requestor, including through methods defined under the provider to patient exchange objective of the Promoting Interoperability Programs. In addition, ASTP/ONC should consider the potential for misuse when a patient requests that their data be made available to a third party technology platform that is not subject to any restrictions. **ASTP/ONC should maintain this criteria and instead, identify and stop misuse.**

*Manner Exception*
Under the Manner Exception, it is not considered information blocking for an actor to limit the manner in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met. ASTP/ONC proposes changes to ensure that the Manner Exception cannot be satisfied by any contract, agreement, or license that (i) is not at "market" rate; (ii) is a contract of adhesion; or (iii) contains unconscionable terms.

**Users of the software are not relying on the Manner Exception because they want to, but because of their inability to obtain functionality. We agree that this exception should not be misused to result in patient harm; however, we urge ASTP/ONC to hold finalization of this provision until more of the market has moved to FHIR.**

TEFCA
The proposed rule would remove the TEFCA Manner Exception and associated definitions as ASTP/ONC believes the exception is no longer necessary and may be negatively impacting participants in the health information ecosystem.

Trinity Health has significant concerns with the removal of the TEFCA Manner Exception. **The removal of the condition that the actor and requestor are both part of TEFCA would open the data exchange to actors that are not vetted in the same manner and create undue risk to protected health information on a wide scale across the country.** TEFCA is still developing many of their governance structures and the removal of this requirement without established exchange guardrails creates significant risk to the personal health information of millions of patients. We are also concerned with the removal of the condition that the requestor is capable of such access, exchange, or use of the requested EHI from the actor through TEFCA. **The exchange parameters need to be consistent across Qualified Health Information Networks (QHINs) for stable and secure transmission. We recommend maintaining the TEFCA Manner Exception until all TEFCA governance structures are established and mature and all QHINs are able to support FHIR exchanges.**

Conclusion
Trinity Health is committed to protecting patient privacy, maintaining data integrity, and supporting responsible interoperability and we welcome partnering with ASTP/ONC to improve HIT. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health