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Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street SW
Washington, DC 20201

Regarding Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5 Draft Rule)

To the Assistant Secretary for Technology Policy:

The Joint Public Health Informatics Taskforce (JPHIT) appreciates the opportunity to comment on the HTI-5 Draft Rule released by the Assistant Secretary for Technology Policy (ASTP) in late December 2025. JPHIT represents a coalition of public health associations committed to advancing health information technology to support public health infrastructure and surveillance capabilities.

This response outlines our position on key aspects of the proposed rule and offers recommendations to ensure continued progress in public health interoperability while maintaining the efficiencies and cost-savings that standards-based approaches provide. While we appreciate ASTP's efforts to reduce regulatory burden, preserving the use of clearly defined standards to ensure interoperability between health care and public health systems is essential to safeguarding data integrity, consistency, and quality. Public health and the healthcare industry have made substantial investments in the current infrastructure, and being required to retool systems to accommodate less standardized data would impose significant new resource demands. Data discrepancies would also necessitate additional manual follow-up, increasing both the financial and administrative burden on providers and data recipients.

The Community Needs Time and Investment to Prepare for FHIR

JPHIT supports ASTP's vision of moving toward Fast Healthcare Interoperability Resources (FHIR) as a modern standard for health information exchange. However, we emphasize that State, Tribal, local, and territorial (STLT) public health authorities (PHAs) and developers require adequate time and sustained investment to successfully transition to FHIR-based

systems and it is premature to remove Clinical Document Architecture (CDA) and HL7 v2 as the referenced standards for data exchange.

Many Implementation Guides Are Still in Development

The FHIR community is still developing guides for public health reporting through initiatives such as the Helios project. In many cases, FHIR standards are not fully vetted and tested and cannot be implemented by the public or private sector. For example, the Cancer FHIR Implementation Guide (IG) is still early in development and will not be ready for HL7 balloting for some time. Therefore, it is premature to remove the CDA standard for cancer reporting because there is not a FHIR IG to replace it. ASTP should carefully assess the maturity of FHIR standards when considering these changes and work with PHAs in advancing FHIR so we can evolve from legacy reporting methods and transition without disrupting existing data flows that are critical to public health reporting.

Retain Legacy Standards During Transition

STLT PHAs need time and sufficient resources to transition to FHIR. During this period, it is critical to retain CDA and HL7 v2.5.1 standards. These legacy standards are well-established, widely implemented, and continue to serve public health surveillance needs effectively. Removing these standards prematurely would disrupt existing data flows and create gaps in public health reporting capabilities.

Investment Is Essential for FHIR Adoption

The emphasis on FHIR, at this time, is aspirational and represents an important step forward. However, to realize this vision, we need new, sustained investment in public health infrastructure. Many PHAs still lack the capability to implement FHIR-based systems and will not achieve this capability without dedicated resources. Investment in public health modernization is essential to support the development of FHIR servers, establish FHIR capabilities, and train staff in new technologies.

With few exceptions, PHAs cannot currently receive FHIR-based data exchanges and reporting facilities are not ready to make the transition for public health reporting. As one PHA testified: "*Our information exchange is not supporting FHIR, and it has not expressed any readiness. I don't have a single one of my reporting facilities in the state… who's expressed any willingness or desire to do anything with FHIR. I don't have any funding to support FHIR within our jurisdiction. And I don't have any manpower with any expertise to support FHIR*." Another added: "*We and our reporting partners are not ready to transition from CDA to FHIR. We know how the data could flow in our system but still need extensive funding and development before being able to receive and process our first FHIR message.*

PHA capability is unlikely to change in the next several years. Critical pandemic era funding was used to initiate the closing of longstanding gaps due to decades of underfunding; however, gaps still remain and pandemic era data modernization funding is expiring, leaving large unmet needs to bring PHAs to current. Introducing new data collection and workflows on top of reductions in budget and workforce will further exacerbate longstanding challenges without off-setting benefits. Additionally, existing federal funding mechanisms for public health surveillance have not prioritized FHIR capabilities, limiting PHAs' ability to invest in new infrastructure, like FHIR servers. CDC and ASTP must coordinate with PHAs to plan, fund, and implement FHIR-capable infrastructure before deregulating existing standards, like CDA.

FHIR Is Not a Universal Solution

FHIR is neither a panacea for all health information exchange challenges, nor necessary to support all existing data flows. If certain data exchange protocols are working effectively, they should not be forcefully replaced simply because newer technologies are available. For example, For example, two thirds of state PHAs receive 90% or more of their laboratory results via ELR electronic laboratory reporting (ELR), mostly using HL7 v2.5.1; this standard is largely meeting public health data needs (Pew Charitable Trusts, 2024). At this level of adoption, transitioning to another process would itself become a burden and should not be prioritized over addressing systems that genuinely need improvement.

JPHIT also recommends ASTP hold listening sessions with public health to identify potential FHIR pilots. A careful piloting program would enable the industry to test the use of FHIR, or the feasibility of FHIR, for specific public health use cases to assess their benefits over existing CDA or v2.5.1 standards. For example, JPHIT sees potential for FHIR to augment existing reporting pathways in the immunization space through the use of decision support and query and response.

JPHIT Supports the Retention of Standards-Based Requirements

JPHIT advises that ASTP retain standards-based public health reporting criteria for health IT certification rather than transitioning to functional requirements.

Moving from standards-based to functional requirements creates variability and adds burden for both PHAs and the private sector. The benefits of standards significantly outweigh any burden on health IT developers and result in greater efficiencies, improved data quality, and cost-savings overall.

For Health IT Developers: For many years, HIT developers have been building standard implementation guides (IGs), which detail the context, vocabularies, and constraints on reported data. These IGs limit the need to independently interpret STLT reporting specifications and develop reporting functionality that satisfies each jurisdiction's requirements. Many of these standards are well-established with most Certified Electronic Health Record Technology (CEHRT) vendors today, so there is minimal burden in retaining them. Removing these standards would reverse years of progress and squander the substantial investments healthcare organizations (HCOs), health IT developers, and PHAs have made to build functional, interoperable systems. A shift to functional-only requirements would create fragmentation across the health IT ecosystem and compromise data quality, with each vendor implementing different data formats and structures, ultimately placing an untenable burden on and expense for PHAs to support this variability and limiting their ability to effectively respond to threats.

Further, existing data quality validation tools are based on messages received in a standard format using published IGs. If public health is not able to use these tools during onboarding, they will have limited resources to evaluate data quality, which will result in onboarding delays and ultimately, have a negative impact on our ability to respond to public health threats.

JPHIT welcomes the opportunity to provide specific examples of how standards support data quality and also how maintaining a variety of reporting mechanisms can compromise it.

For Providers and Healthcare Organizations: With increased variability, providers and HCOs may struggle to evaluate and select an HIT solution that meets public health reporting criteria. If their chosen system cannot natively meet the jurisdiction’s requirements, each HCO will still need to configure the system for the jurisdiction's requirements, plus conduct additional testing and evaluation by PHAs of each data feed. This fragmentation undermines the efficiencies gained through standardization and merely shifts the burden from the health IT developer to the HCO. If PHAs receive incomplete, non-standardized, or difficult to interpret reports from health care, they will need to manually follow up with providers to obtain missing information or to clarify unclear information, slowing public health action and increasing the reporting burden and manual steps for the HCO.

For Public Health Agencies: PHAs can develop and maintain systems to ingest standardized, predictable data, increasing certified HIT portability across STLT jurisdictional boundaries. ASTP certification criteria serve as a critical reference point that allows for consensus-based IGs that STLTs use to align requirements. These criteria reduce

the need for resource-intensive technical specifications and prevent a return to fragmented, jurisdiction-specific reporting rules that public health and health IT have been working for years to harmonize. Standard IGs improve data quality so that public health can spend less time correcting data inconsistencies and can make decisions regarding community health based on better data.

Recommended Standards Retention

JPHIT recommends retaining the standards as proposed in the original HTI-2 Draft Rule since these standards reflect the reality of how these data are currently shared with public health. In the case of electronic case reporting (eCR), newer standards than those referenced in the HTI-2 proposed rule now exist; JPHIT recommends ASTP adopt those newer standards in updated certification criteria as described in the table below.

Criteria	**Recommended Standard**
§ 170.315(f)(1) Immunization registries—Bi-directional exchange	HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update vocabulary standards (CVX and NDC)
§ 170.315(f)(2) Syndromic surveillance—Transmission to public health agencies	Update to 2019 version of HL7 v2.5.1 Implementation Guide: Syndromic Surveillance, Release 1
§ 170.315(f)(3) Reportable Laboratory Results and Laboratory Orders	Update to these ELR standards: HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Edition 5 - US Realm; HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Edition 5 - US Realm, specifically the Public Health Profile within the IG
§ 170.315(f)(5) Electronic case reporting	Update to these eCR standards: eICR R3.1.1 (HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1.1 - US Realm); and FHIR eCR R2.1.2 (HL7 FHIR®

	Implementation Guide: Electronic Case Reporting (eCR), Release 2.1.2 - US Realm)
§ 170.315(f)(6) Antimicrobial use and resistance reporting	Update from 2013 IG to 2020 IG (includes AUR, ARO, and AUP)
§ 170.315(f)(7) Health care surveys	Update HL7 CDA R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3.1
§ 170.315(f)(8) Birth reporting	Transmission according to the Birth and Fetal Death Reporting IG

USCDI V6 and Public Health Data Elements

The United States Core Data for Interoperability (USCDI) Version 6 includes numerous data elements not available in previous versions that support public health functions. These elements reflect the maturation of standards to better serve public health needs and include:

- Social determinants of health (SDOH) data elements including housing stability, food insecurity, transportation access, and social connection (note that in the draft Version 7 of USCDI that ASTP recently released, the SDOH data elements would be incorporated into broader data elements, such as Patient Goal, Problem, and Procedure).
- Expanded immunization data including vaccine lot numbers and administration details
- Laboratory observation data supporting syndromic surveillance
- Additional lab data elements related to specimen (Specimen Condition Acceptability, Specimen Identifier, Specimen Source Site) and related to results (Result Units of Measure, Result Reference Range and Result Interpretation)
- Vital signs and clinical observations relevant to chronic disease monitoring
- Encounter and diagnosis information critical for case reporting
- Medication administration data supporting antimicrobial stewardship

These USCDI V6 data elements demonstrate the alignment between clinical data exchange standards and public health surveillance needs. As FHIR implementation advances, these standardized data elements will facilitate more comprehensive and timely public health

reporting. However, their successful implementation depends on maintaining certification requirements that incentivize adoption of these standards.

JPHIT therefore encourages ASTP to adopt USCDI V6 rather than retaining USCDI V3, or a new V3.1.

JPHIT Supports the Retention of Standards-Based Requirements for Cancer Registry Reporting, eCR, Antimicrobial Use and Resistance Reporting, and Healthcare Surveys

JPHIT urges ASTP to retain standards-based certification requirements for cancer registry reporting, eCR, antimicrobial use and resistance reporting, and healthcare surveys. These specialized reporting areas have made significant progress through standardization, and removing certification requirements would jeopardize this progress.

The Cost of Manual Reporting

Removing certification requirements for these reporting areas could force a return to manual reporting methods, creating substantial unfunded costs for both healthcare providers and PHAs. Consider this illustrative example: if a healthcare system reporting approximately 100,000 cancer event records electronically were forced to return to fax-based reporting, the costs would be significant.

At an estimated cost of $2.50 per fax, faxing these records would cost approximately $250,000. Manual data entry, estimated at $3.75 per form (15 minutes per form at $15/hour), would cost approximately $375,000. Assuming a conservative 2% error rate with correction costs of $50 per error, error correction would add approximately $100,000. This example illustrates a total cost exceeding $700,000 to have providers fax records and PHAs manually enter and correct errors—approximately $7.25 per health record.[1]

When extrapolated across all providers and extended to state, local, tribal, and territorial health departments, the costs accumulate rapidly. This example represents only one data source among many impacted by the proposed rule. Many jurisdictions collect hundreds of millions of records electronically using standards-based exchange. We ask ASTP to carefully consider these potential costs and their impact on the healthcare system and

[1] This example is based on estimates provided by the Washington State Department of Health in 2026.

public health infrastructure. Any cost-savings for health IT developers with deregulation are offset by these downstream impacts.

JPHIT Supports the Retention of Artificial Intelligence (AI) Guidelines

JPHIT urges ASTP to retain AI guidelines in health IT certification and not remove the AI transparency rules finalized as part of HTI-1. As AI technologies continue to evolve and are increasingly integrated into clinical workflows and health information systems, it is essential to maintain appropriate oversight and transparency requirements. These guidelines help ensure that AI-enabled health IT products meet safety and effectiveness standards while providing clinicians and patients with necessary information about how AI is being used in their care.

As AI technologies are quickly evolving, understanding when and how AI can access public health data is an area that JPHIT believes would benefit from guidance on the national level. Currently, there are many open questions. For example, given information blocking rules, would immunization information systems (IIS) be expected to scale limitlessly to respond to queries, even from autonomous AI requests? We encourage ASTP to continue developing transparent guidelines and expectations as this industry sector matures.

JPHIT Supports Real-World Testing

JPHIT strongly supports the continuation of real-world testing requirements for CEHRT vendors. Real-world testing is important and saves time for all parties involved in health information exchange. There are fewer problems that need to be addressed during provider onboarding when vendors have conducted thorough real-world testing, and less time and resources are needed for validation. In-house testing alone does not solve real-world problems, and it is difficult to assess what products can actually accomplish based solely on vendor attestations.

PHAs and their partners benefit significantly from knowing what is happening in real-world implementations. PHAs often discover data structure and data quality issues during the onboarding of providers using CEHRT. These issues frequently occur because a CEHRT vendor has attested to meeting criteria for public health exchange but has not conducted real-world testing to ensure it works properly in practice. These issues lead to delays in onboarding that could be avoided through adequate real-world testing.

What is more, JPHIT supports the expanded use of real-world testing data. We encourage ASTP to maintain the Insight reporting program, which aligns with recommendations previously recommended by the HTI-2 Proposed Rule Taskforce 2024. This real-world testing program promises the ability to provide transparency regarding real-world data from EHR products, demonstrating how much information they successfully share with IIS at the product level and offering valuable insights into what is actually happening in operational environments. The Insight model of transparency could be extended to other public health systems to improve overall data quality and system performance. JPHIT recommends that ASTP certify use and implementation in real world environments with thresholds for completeness and data quality.

JPHIT Supports Maintaining Current Language for Contracting with Government Entities

ASTP proposes to revise § 171.301(a) to add explicit contractual limitations requiring that any agreement governing access, exchange, or use of electronic health information must be at "market rate," must not be a "contract of adhesion," and must not contain "unconscionable terms." JPHIT is concerned that this language may be interpreted as banning standardized contract language and require all contracts between data exchange partners to be individually negotiated. This approach creates unnecessary administrative burden and disadvantages non-profit entities, smaller HCOs, and PHAs.

Public health reporting fundamentally differs from commercial healthcare markets. Health information exchanges (HIEs) and the AIMS Platform provide consistent, equitable services to all data exchange partners at standard rates. This arrangement is key to the success of AIMS as a public health intermediary. Additionally, we see TEFCA as an important foundation for achieving national interoperability, and the contractual limitations may disincentivize or at least confuse participation in the network.

Applying market-based contracting principles to public health reporting risks increasing costs to taxpayers and misunderstands its nature and purpose, which is to safeguard the health of the American public, not to turn a profit. Vendor contracts with government entities typically follow state procurement policies, and vendors are provided with the standard contract language they must agree to prior to submitting a bid. JPHIT recommends that the rule should explicitly allow for this arrangement.

More specifically, JPHIT recommends that agreements supporting public health reporting be exempt from these contractual limitations when their terms are developed or approved through a governance process that provides meaningful input from participants. Such

structured governance represents collective bargaining that protects all parties' interests. Therefore, data use agreements signed with PHAs, HIEs, or the AIMS Platform should be permitted under the Manner Exception.

We note that Qualified Health Information Networks (QHINs), HIEs, and other entities have raised similar concerns in their comments and encourage ASTP to review these submissions for additional perspective.

Conclusion

JPHIT strongly supports continued certification requirements for public health reporting. Standards-based certification requirements have driven significant progress in public health informatics, and this progress must be preserved and expanded with increasing needs for interoperability thereby reducing burden on health care systems. Timely, accurate, and complete reporting of public health data ensures that all jurisdictions can protect their community's health both on a routine basis and during emergencies and disasters.

Federal support for jurisdictional public health reporting must remain strong, including the provision of sustained investment to ensure public health systems can become and remain interoperable. As we move toward FHIR-based systems, it is essential to maintain current standards during the transition period so as to not disrupt existing data flows, and to provide adequate resources for PHAs to modernize their infrastructure. Public health must remain poised for emergency response throughout this transition. FHIR standards should be leveraged when and where it will have the most return on investment and improve data quality. JPHIT invites ASTP to hold listening sessions with public health to identify specific use cases that might benefit from FHIR pilots.

The proposed shift from standards-based to functional requirements risks creating fragmentation in health information exchange, increasing costs for all stakeholders, and reversing years of progress toward harmonized, interoperable systems. We urge ASTP to retain standards-based certification requirements and to work collaboratively with public health to ensure that regulatory changes support rather than undermine public health infrastructure.

We note that the Unfunded Mandates Reform Act of 1995 requires federal agencies to assess the impacts of regulations on state, local, and tribal governments. ASTP should consider that the potential variability in data formats under HTI-5 may impose significant unfunded mandates for both the public and private sectors that conflict with this Act, as detailed throughout this response.

JPHIT looks forward to partnering with ASTP and the other agencies within HHS to further the important work of improving the nation's health IT ecosystem. JPHIT intends to engage with ASTP in the months ahead to cogently articulate the policy and rules that will continue to modernize the public health system, with benefits to local, state, and federal public health organizations, healthcare providers, health IT, and the nation's health. Thank you for the opportunity to provide comments on the HTI-5 Draft Rule. Should you have any questions about JPHIT's feedback, please do not hesitate to contact us; inquiries can be directed to jphit@astho.org.

JPHIT Members include:

American Immunization Registry Association (AIRA)

American Medical Informatics Association (AMIA)

Association of Public Health Laboratories (APHL)

Association of State & Territorial Health Officials (ASTHO)

Big Cities Health Coalition (BCHC)

Council of State and Territorial Epidemiologists (CSTE)

Healthcare Informatics and Management Systems Society (HIMSS)

National Association of County and City Health Officials (NACCHO)

Network for Public Health Law (NPHL)

Public Health Informatics Institute (PHII)