ASTP | Health IT Advisory Committee

September 19, 2024

Micky Tripathi, Ph.D. M.P.P.
Assistant Secretary of Technology Policy
National Coordinator for Health Information Technology
U.S. Department of Health & Human Services
330 C Street, SW
Washington, DC 20201

Dear Dr. Tripathi:

The Health Information Technology Advisory Committee (HITAC) asked the HTI-2 Proposed Rule Task Force 2024 to evaluate and provide recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

This transmittal letter offers these recommendations, which are informed by deliberations among the HTI-2 Proposed Rule Task Force 2024 and HITAC subject matter experts.

This transmittal letter offers the final report from the HITAC with recommendations for your consideration.

Respectfully submitted,

Medell Briggs-Malonson

/s/
Medell Briggs-Malonson
Co-Chair, Health Information Technology Advisory Committee

Sarah DeSilvey

/s/
Sarah DeSilvey
Co-Chair, Health Information Technology Advisory Committee

ASTP | Health IT Advisory Committee

HTI-2 Proposed Rule Task Force 2024

Recommendations on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule

REPORT TO THE HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

September 12, 2024

HHS

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Background

The Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule Task Force 2024 has developed these recommendations to the HITAC regarding implementing provisions of the 21st Century Cures Act and making updates to the Office of the National Coordinator (ONC) Health IT Certification Program (Program) with new and updated standards, certification criteria, and implementation specifications in 45 CFR part 170. The HTI-2 Proposed Rule Task Force 2024 has also provided recommendations to the HITAC regarding enhancements to support information sharing under the information blocking regulations in 45 CFR part 171 and implementing certain provisions related to the Trusted Exchange Framework and Common Agreement™ (TEFCA™) in new 45 CFR part 172.

On August 5, 2024, the Assistant Secretary for Technology Policy (ASTP) published its HTI-2 Proposed Rule. The HTI-2 Proposed Rule seeks to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information through proposals for: standards adoption; adoption of certification criteria to advance public health data exchange; expanded uses of certified application programming interfaces (APIs), such as for electronic prior authorization, patient access, care management, and care coordination; and information sharing under the information blocking regulations. It proposes to establish a new baseline version of the United States Core Data for Interoperability (USCDI). The proposed rule would update the Program to enhance interoperability and optimize certification processes to reduce burden and costs. The proposed rule would also implement certain provisions related to the TEFCA, which would support the reliability, privacy, security, and trust within TEFCA. As part of this public feedback process, ASTP charged the HITAC and the HIT-2 Proposed Rule Task Force 2024 to make specific recommendations on the HTI-2 Proposed Rule.

ASTP Charge To HITAC

Overarching Charge: The HTI-2 Proposed Rule Task Force will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

Specific Charge:

- **Review and provide recommendations on the HTI-2 proposals on public health, standards and certification, and information blocking and TEFCA.**
- **Recommendations are due prior to the end of the 60-day public comment period.**

Additional Background Information

The HTI-2 Proposed Rule Task Force 2024 (Task Force) includes an engaged group of subject matter experts representing various groups including direct patient care providers, public health, patients, health IT developers, standards development organizations, and others. The roster included in Appendix A of this document reflects the Task Force membership at the time these recommendations were finalized.

To assist in the development of these recommendations, the Task Force invited several external subject matter experts to give testimony regarding their areas of expertise, interest, and work. These presenters also responded to questions from Task Force members to inform their deliberations and recommendations. These included:

- On July 30, 2024, Lynn Gibbs-Scharf from CDC/NCIRD/ISD, Kafayat Adeniyi-Inniss from CDC/NCIRD/ISD, Jennifer Junkins from CDC/NCIRD/ISD, Laura Conn from CDC/IOD/OPHDST, Karl Soetebier from CDC/IOD/OPHDST, Daniel Kurowski from CDC/IOD/OPHDST, Andrea Benin from CDC/NCEZID/DHQP/SB, Hsiu Wu from CDC/DDID/NCEZID, Amy Webb from CDC/NCEZID/DHQP/SB, Prachi Mehta from CDC/CGH/DGHT, Jessica Diamond from CDC/NCCDPHP/DCPC, and Sean Porter from CDC/NCCDPHP/DCPC joined the discussion on existing public health certification criteria in § 170.315(f)(1)-(f)(7).
- On August 6, 2024, Lynn Gibbs-Scharf from CDC/NCIRD/ISD, Kafayat Adeniyi-Inniss from CDC/NCIRD/ISD, Jennifer Junkins from CDC/NCIRD/ISD, Chrissy Miner from CDC/NCIRD/ISD, Laura Conn from CDC/IOD/OPHDST, Jessica Diamond from CDC/NCCDPHP/DCPC, Sean Porter from CDC/NCCDPHP/DCPC, Rebecca McNall from CDC/IOD/OLSS/CLSR, Jason Hall from Deloitte, and Riki Merrick from APHL joined the discussion on new public health certification criteria in § 170.315 (f)(3),(f)(21)-(f)(25) + (a)(2) for computerized provider order entry (CPOE) labs.
- On August 13, 2024, Joyce. A Martin from CDC/IOD/OPHDST/NCHS, Karl Soetebier from CDC/IOD/OPHDST, Daniel Kurowski from CDC/IOD/OPHDST joined the discussion on new public health certification criteria in § 170.315(f)(8), (f)(28), (f)(22) and a new standardized API for public health data exchange in § 170.315(g)(20).
- On August 20, 2024, Pat Knue from Institute for Intergovernmental Research (IIR), Don Vogt from IIR, Kevin Borcher from IIR, and Laura Conn from CDC joined the discussion on continuation of new public health certification criteria in § 170.315(f) and g(20); (f)(9), (f)(29).

Recommendations

Introduction

The focus of the HTI-2 Proposed Rule Task Force 2024 was to make specific recommendations on the proposals contained in the HTI-2 Proposed Rule. The following recommendations represent the views of the Task Force regarding particular provisions of the HTI-2 Proposed Rule.

Task Force Recommendations

ONC Health IT Certification Program Updates

The United States Core Data for Interoperability Version 4 (USCDI v4)

- **HTI-2-PR-TF-2024_Recommendation 01 –** The Task Force is supportive of the adoption of the United States Core Data for Interoperability Version 4 (USCDI v4). However, the Task Force recommends that for future versions of USCDI, the Task Force would continue to advocate for the addition of data elements recommended in previous ASTP comment cycles (e.g., for immunization-related fields, Vaccine Administration Date, Vaccination Event Record Type, MRN (and other IDs), Mother's Maiden Name, multiple birth indicator and birth order (for minors), medication administration information, Laboratory results: date and timestamps, Laboratory Test Performed Date, Specimen collection date/time), and Lot Number is in USCDI v5.

SMART App Launch 2.2

- **HTI-2-PR-TF-2024_Recommendation 02 –** Recommend that ASTP specify the references to SMART Health Cards and HL7® Fast Healthcare Interoperability Resources-based (FHIR®) SMART Health Cards.

- **HTI-2-PR-TF-2024_Recommendation 03 –** Recommend that ASTP work with partners to reconcile conventions across implementations of SMART concepts.

- **HTI-2-PR-TF-2024_Recommendation 04 –** If both the SMART Health Cards Framework and SMART Health Cards Vaccination and Testing Implementation Guides (IGs) are published before the final rule is issued, recommend that the final rule reference the optional adoption of both SMART Health Cards and SMART Health Links functionality to offer flexibility for implementers to provide consumers with the most functional data (using SMART Health Cards for a subset of the full record (e.g., a record of immunizations received that day), and using SMART Health Links to provide the full consolidated patient immunization record). Additionally, the Task Force notes that both the SMART Health Cards Framework and SMART Health Cards Vaccination and Testing IGs are not yet published. If either of the guides is not yet published, the Task Force recommends that this certification criterion be postponed to a future version as a functional requirement without these guides would not yield sufficiently consistent implementations and we cannot recommend the use of an unpublished guide. The Task Force supports patients accessing their immunization information through Electronic Health Records (EHRs) that manage immunization data using the SMART Health Cards Framework but has concerns that this technology is not feasible for producing and sharing a consumer version of the full lifespan immunization record, given the limited space on a 2D/Quick-Response code (QR code).

- **HTI-2-PR-TF-2024_Recommendation 05 –** Recommend that ASTP work with the IG developers of the SMART Health Cards Vaccination and Testing IG, currently under development and not yet published, to include best practice guidance that Health IT Technology query the Immunization Information System (IIS) prior to providing the patient/consumer with their full immunization record, to ensure the consolidated record is as complete as possible. The Task Force sees the delivery of a consumer immunization record primarily as a public health function to provide access to the consolidated and possibly official record through the IIS, as these records are likely to be more complete.

User-Access Brands and Endpoints

- **HTI-2-PR-TF-2024_Recommendation 06 –** Recommend that publication of the trust community details with endpoints is unnecessary and should be removed as it is already a requirement of Unified Data Access Profiles (UDAP™) IG to published as part of the well-known endpoint: https://build.fhir.org/ig/HL7/fhir-udap-security-ig/discovery.html#multiple-trust-communities.

New Imaging Requirements for Health IT Modules

- **HTI-2-PR-TF-2024_Recommendation 07 –** Recommend that ASTP address security concerns related to utilization of imaging links, especially when image links are shared with patients through an API and not in a provider portal.

- **HTI-2-PR-TF-2024_Recommendation 08 –** Recommend that providing access through an API be mandatory, enabling the patient to use the tool of their choice when accessing their information.

- **HTI-2-PR-TF-2024_Recommendation 09 –** Recommend that ASTP adopt a process for testing Heath IT Modules' capabilities to produce imaging links that function as intended in both laboratory and real-world scenarios. The test certification criteria should be developed in conjunction with interested parties, including Digital Imaging and Communications in Medicine (DICOM), providers, and patients. Recommend that ASTP consult the Argonaut Project to specify a standard that specifies a baseline file format and resolution. The scope of the reference in § 170.315(g)(9) to 'all data' requires additional description, clarifying precisely what is included in "all data."

- **HTI-2-PR-TF-2024_Recommendation 10 –** Recommend that ASTP clarify the circumstances regarding the transmission of image links including, but not limited to, the persistency of the link.

Revised Clinical Information Reconciliation and Incorporation Criterion

- **HTI-2-PR-TF-2024_Recommendation 11 –** Recommend that automated reconciliation not be required.

- **HTI-2-PR-TF-2024_Recommendation 12 –** Recommend developing best practices or IGs for how to conduct automatic reconciliation for USCDI data elements.

- **HTI-2-PR-TF-2024_Recommendation 13 –** Recommend going to six USCDI data elements for certification.

- **HTI-2-PR-TF-2024_Recommendation 14 –** Recommend that ASTP align with recommendation on dynamic client registration protocol.

Revised Electronic Prescribing Certification Criterion

- **HTI-2-PR-TF-2024_Recommendation 15 –** Recommend splitting the certification criteria between the provider and payer to account for responsibilities on both sides for the provider and payer.

New Real-Time Prescription Benefit Criterion

- **HTI-2-PR-TF-2024_Recommendation 16 –** Recommend aligning target dates and requirements on both sides, the payers and providers, and possibly pharmacy depending on the role. The Task Force is concerned that the payer/pharmacy side of electronic prior authorization (ePA) is addressed as well.

- **HTI-2-PR-TF-2024_Recommendation 17 –** Recommend splitting the certification criteria between the provider and payer to account for responsibilities on both sides for the provider and payer.

- **HTI-2-PR-TF-2024_Recommendation 18 –** Recommend that ASTP clarify that CMS Medicare Part D requires real time prescription benefit tools.

Revised End-User Device Encryption Criterion

- **HTI-2-PR-TF-2024_Recommendation 19 –** Recommend that ASTP, instead of using the term 'server-side', replace with 'health IT storage.'

Revised Criterion for Encrypt Authentication Credentials

The Task Force reviewed this proposal and had no comments or recommendations in this area.

Health IT Modules Supporting Public Health Data Exchange

- General Comment
    - **HTI-2-PR-TF-2024_Recommendation 20 –** Recommend that ASTP provide consistent certification criterion naming convention, focusing on the role of the actor for the certification criterion's capability being defined. We suggest that the provider and payer certification criteria for (g)(34) and (g)(35) are the best example and should be followed. For (f)(1) – (f)(9) these would then be generally renamed to "[Capability] – Provider" and (f)(21) – (f)(29) would be renamed to [Capability] – PHA. Specific capabilities may benefit from a more specific role name and/or may need an additional role. For example, electronic laboratory reporting can benefit from separating an ordering provider vs. laboratory role as not all ordering providers have laboratory requirements based on jurisdiction while a laboratory would, or in the case of immunization reporting the State, Tribal, Local, and Territorial (STLT) public health agencies may be more specifically identified as an immunization registry.

- Revised Certification Criteria
    - "Immunization registries—bi-directional exchange" – (f)(1)

- **HTI-2-PR-TF-2024_Recommendation 21 –** Recommend the (f)(1) certification criteria focus on the 2018 update to the 2.5.1 Implementation Guide, as the IG under development will likely not be published until late 2025/early 2026.

- **HTI-2-PR-TF-2024_Recommendation 22 –** Recommend the term “Bi-Directional” be replaced, and that the “actors” in each use case (e.g., EHRs and Immunization Information System (IIS)) be better identified in each individual requirement). Specifically, the Task Force recommends replacing the title of “Immunization Registries – Bi-Directional Exchange” with “Immunization Information Systems: Submission and/or Query.” The (f)(1) section is highlighting the certification expectations for certified Health IT Modules, so it is helpful to center them as the “actor” in this portion of exchange. For additional clarity, since both the terms immunization registry and immunization information system are used interchangeably throughout the document, the Task Force recommends using only immunization information system as this term is more representative of the dynamic exchange capabilities of today’s systems.

- **HTI-2-PR-TF-2024_Recommendation 23 –** Recommend that the ability for a provider to respond to an immunization query be supported by § 170.315(g)(10) and § 170.315(g)(20) using a common FHIR based approach rather than requiring implementation of an HL7 v2 based query, as the Task Force is not aware of any parties interested in such queries, and alignment with already available FHIR based queries should be our go-forward approach. If this recommendation is accepted, the following sections would no longer be necessary: Bullet (iii) on page 79“: "(C) Receive incoming patient-level immunization-specific query or request from external systems and respond in accordance with paragraph (f)(1)(ii)(A) of this section. (iii) Receive incoming patient-level immunization-specific query or request from external systems and respond.”

- **HTI-2-PR-TF-2024_Recommendation 24 –** Recommend that ASTP rephrase the language that includes the term "immunization-specific queries." This is not a term IIS are familiar with, as our queries focus on patient information, which includes the patient's consolidated immunization information in the returned message.

- **HTI-2-PR-TF-2024_Recommendation 25 –** Recommend that ASTP clarify the target dates for (f)(1). The fact sheet indicates Jan 1, 2028, while the proposed rule text indicates Jan 1, 2027.

- **HTI-2-PR-TF-2024_Recommendation 26 –** The Task Force supports patients accessing their immunization information through health IT that manages immunization data using the SMART Health Cards Framework. However, the Task Force has concerns that this technology is not feasible for producing and sharing a consumer version of the full lifespan immunization record given the limited space on a 2D/QR barcode. The Task Force also notes that the HL7 FHIR SMART Health Cards: Vaccination and Testing IG referenced is not yet published, while the HL7 FHIR SMART Health Cards and Links Framework is going through HL7 ballot and may be

published in time to replace the SMART Health Cards Framework guide. Recommends the following to ASTP:

- If both guides are published before the final rule is issued, the Task Force recommends that the final rule reference the optional adoption of SMART Health Cards and SMART Health Link functionality using the HL7 FHIR SMART Health Cards and Links Framework plus the HL7 FHIR SMART Health Cards: Vaccination and Testing guides, providing flexibility for implementers to provide consumers with the most functional data for a subset of the full record (e.g., a record of immunizations received that day) on a SMART Health Card, and using SMART Health Links to provide the full consolidated patient immunization record.

- If the HL7 FHIR SMART Health Cards: Vaccinations and Testing guide is not yet published, the Task Force suggests that this certification criterion be postponed to a future version as availability of that guide would provide the ability to move adoption and consistent implementations to the next level.

- Recommend that ASTP work with the IG developers of the HL7 FHIR SMART Health Cards Vaccination and Testing IG to include best practice guidance that health IT technology query the IIS prior to providing the patient/consumer with their full immunization record, to ensure the consolidated record is as complete as possible. The Task Force notes that the delivery of a consumer immunization record is primarily a public health function to provide access to the consolidated and possibly official record through the IIS, as these records are likely to be more complete.

  - **HTI-2-PR-TF-2024_Recommendation 27 –** Recommend modifying the wording to ensure that both submission and query persist as expectations for certified health IT after January 1, 2027. The references to what functionality sunsets and what functionality persist for EHR exchange with IIS is ambiguous.

  - **HTI-2-PR-TF-2024_Recommendation 28 –** Recommend that ASTP clarify whether "query" and "request" mean the same thing. If so, it would be good to choose a single term. However, if they are different, please distinguish between them.

- "Syndromic surveillance—Transmission to public health agencies" – (f)(2)

  - **HTI-2-PR-TF-2024_Recommendation 29 –** Recommend that use of the newly recommended standard begins in alignment with reporting for Morbidity and Mortality Weekly Report and other schedules.

  - **HTI-2-PR-TF-2024_Recommendation 30 –** Recommend that ASTP consider the aggregate effort required by health IT developers and implementers and the proposed adoption schedule. For a usage date of 1-1-2027, the software modifications need to be available no later than 9-1-2026 for development and testing. In addition to the work

required on the "sender" systems, receiving systems must also be modified. There is insufficient time for many public health agencies to modify receiving systems.

- **HTI-2-PR-TF-2024_Recommendation 31 –** Recommend, for future advancement of this standard, that ASTP, the Centers for Disease Control and Prevention (CDC), Public Health Authorities (PHAs), and associations that operate the National Syndromic Surveillance Program Community of Practice (Council for State and Territorial Epidemiologists/National Syndromic Surveillance Program Community of Practice (CSTE/NSSP COP)), and other associations and partners to explore the future opportunity to align methods of reporting across multiple use cases, in particular considering alignment of syndromic surveillance with case reporting. This would enable a more appropriate and robust method of reporting on clinical data beyond the demographic data and observational data that a syndromic HL7 v2 admit, discharge, and transfer (ADT) and Observational Report – Unsolicited (ORU) is primarily focused on conveying.

- "Reportable laboratory results—Transmission to public health agencies—and Laboratory Orders—Receive and validate" – (f)(3)

  - **HTI-2-PR-TF-2024_Recommendation 32 –** Recommend that ASTP remove the laboratory ordering capabilities from § 170.315(f)(3) and include the ordering capabilities in § 170.315(a)(2) Computerized Provider Order Entry - Laboratory in support of Electronic Laboratory Reporting by laboratories.

  - **HTI-2-PR-TF-2024_Recommendation 33 –** Recommend that ASTP work closely with the federal agencies and states that would establish target dates, e.g., Centers for Medicare & Medicaid Services (CMS), CDC, and states, to set realistic time frames that both providers and PHAs, and their respective health IT suppliers can address once such dates are proposed and set.

  - **HTI-2-PR-TF-2024_Recommendation 34** – Recommend that ASTP references the most current published version of the Laboratory Results Interface guide, specifically the HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Edition 5, US Realm, May 2024. Recommend that ASTP references the overall Laboratory Results Interface guide in support of Electronic Laboratory Reporting, and specifically references the LRI_PH_COMPONENT, within the aforementioned IG.

  - **HTI-2-PR-TF-2024_Recommendation 35 –** Recommend that ASTP address the reporting module's ability to include all relevant data to better ensure conformance with the specified IG, whether the reporting module is part of an integrated solution that has access to that data, or can otherwise obtain it from the source that manages that data, ensuring completeness of the data that the reporting organization manages in one or more health IT systems.

  - **HTI-2-PR-TF-2024_Recommendation 36 –** Recommend that ASTP separate the responsibilities of the ordering provider who may report on laboratory results to public health, and a laboratory that has responsibilities to report laboratory results to public

health. The laboratory is required to report to public health and must have the ability to receive laboratory orders that include data relevant to public health and report to public health. While the ordering provider only needs to report to public health, they should not be responsible for also reporting lab orders separate from the case report. A case report should also include any ask on order entry questions, critical demographics and clinical information from the lab orders as one of the required elements of Electronic Initial Case Reporting (f)(5) (see recommendation 42 below). The lab, especially if an outsider provider was not able to pass that information on in the recent pandemic, their LIMS systems did not have the fields to store. Provider organizations that may have both roles would have a need to support both, but that still may involve different systems.

- **HTI-2-PR-TF-2024_Recommendation 37 –** Recommend that the laboratory (including hospital and clinical laboratories) report reportable laboratory results to PHAs. Health care providers should report case reports, which can include details about the order. However, laboratory order messages themselves should not be reported to public health (unless they are critical reportable on suspicion).

- "Cancer registry reporting—transmission to public health agencies" – (f)(4)

  - **HTI-2-PR-TF-2024_Recommendation 38 –** Recommend that ASTP modify the name to "Cancer registry reporting – Transmission to public health agencies" to change the name to "Cancer registry reporting and Cancer pathology reporting– Transmission to public health cancer registries."

  - **HTI-2-PR-TF-2024_Recommendation 39 –** Recommend that ASTP does not require the use of the FHIR-based IG for Public Health Cancer Registries for cancer case reporting at this time, and instead focus on the efforts to adopt the CDA based reporting. The Task Force is concerned that shifting this at this time will increase resource requirements on providers, vendors, and public health in light of many other priorities where continued focus on CDA based reporting has increased and improved reporting. Alignment on FHIR for cancer case reporting can be addressed at a later date.

  - **HTI-2-PR-TF-2024_Recommendation 40 –** The Task Force recommends that there is clear distinction between cancer case reporting and cancer pathology reporting. Both may be required by PHAs as separate transactions. It might be worth specifically addressing both the Cancer Case Report and the Cancer Pathology Report in the recommendation as a phase A and B. The Task Force would recommend the focus for case reporting to be in the CDA based report, and for pathology reporting the FHIR IG would be preferred but the Task Force is unclear on its adoption nationally.

- "Electronic case reporting—transmission to public health agencies" – (f)(5)

  - **HTI-2-PR-TF-2024_Recommendation 41 –** Recommend that ASTP update (f)(5) to use all profiles (the electronic initial case report (eICR), reportability response (RR), and electronic reporting and surveillance distribution (eRSD)) in the HL7 FHIR eCR IG or

the HL7 CDA eICR and HL7 CDA RR IG, along with the eRSD FHIR profile in the HL7 FHIR eCR IG.

- **HTI-2-PR-TF-2024_Recommendation 42 –** Recommend that the HTI-2 final rule indicate that however the Health IT Module sends the eICR, it must be able to receive the RR in the same format and process it. This would be consistent with what was finalized in HTI-1.

- **HTI-2-PR-TF-2024_Recommendation 43 –** Recommend that certification should address all functions and data needed to do business, including incorporating data sourced from systems outside of an EHR (e.g., laboratories' information management systems) that contain data required to produce a complete eICR report and satisfy all certification criteria needed for a successful exchange, including meeting content validation requirements. In this example, the certification should evaluate that the laboratory information and results are populated using standardized code sets (e.g., LOINC and SNOMED) and that Ask at Order Entry (AOE) data is properly included.

- **HTI-2-PR-TF-2024_Recommendation 44 –** Recommend that (f)(5) should transition from self-attestation to demonstrated testing to show the capabilities required for electronic case reporting, meeting expected completeness and data quality thresholds. Future work could include future insight measures for other public health-related performance measures. These should align with the data quality metrics developed by the eCR Quality Assurance (QA) Workgroup, which includes over 31 State, Tribal, Local, and Territorial (STLTs) public health agencies. These metrics define the rules for ensuring the validity and completeness of eICR content and are utilized by CDC, the Association of Public Health Laboratories (APHL), and STLTs for onboarding and validating eCR data for public health purposes.

- **HTI-2-PR-TF-2024_Recommendation 45 –** Recommend that ASTP work with respective federal agencies (HHS: CMS, CDC, Indian Health Service (IHS); the U.S. Department of Justice (DOJ); U.S. Department of Defense (DoD); Veterans Health Administration (VHA); the U.S. Department of Homeland Security (DHS); and others) to ensure that all parties affected including designated intermediaries and STLTs by these enhanced standards are resourced to make the necessary improvements.

- **HTI-2-PR-TF-2024_Recommendation 46 –** Recommend that (f)(5) should persist the choice of HL7 FHIR eCR IG or HL7 CDA eCR IG by EHR vendors. The proposed expiration date for existing eCR public health standards is January 1, 2028, just two years after the introduction of the updated CDA eICR R3.1 standard for this use case. Currently, most EHRs are transitioning to CDA eICR R3.1 rather than the FHIR eICR 2.1.1. The accelerated shift to FHIR will require EHRs to prioritize the adoption of the new standard, which may limit their ability to allocate sufficient resources for maintaining and enhancing the quality of existing interfaces. Additionally, this transition will necessitate re-onboarding and validation of both existing and new partners, requiring considerable effort from EHRs, healthcare organizations, and public health. This retesting will slow the ability of public health to transition to only electronic

reporting (in other words, delaying the reduction in the burden of manual reporting that electronic reporting can allow).

- "Antimicrobial use and resistance reporting—transmission to public health agencies" – (f)(6)
    - **HTI-2-PR-TF-2024_Recommendation 47 –** Recommend that ATSP align to a similar cadence as used with CMS to introduce new versions for certification and the version used in actual annual reporting. The current proposed timeline for R3 is January 1, 2027, while NHSN currently requires R3 for ARO numerator and denominator and R1 for AUP. At the same time NHSN is indicating that it wants to start to use R4 in CY 2025. The Task Force asks ASTP to work with CDC to consider requiring R3 for January 1, 2026, for all three ARO and AUP components, given the current adoption for first arrive at using a single version, and introduce R4 in SVP 2026 for use in CY 2027.
- "Health care surveys—transmission to public health agencies" – (f)(7)
    - **HTI-2-PR-TF-2024_Recommendation 48 –** Recommend that the final rule include both a) the latest The HL7 CDA R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3.1 - US Realm *or* b) The HL7 FHIR Health Care Surveys Content IG 1.0.1 https://build.fhir.org/ig/HL7/fhir-health-care-surveys-reporting-ig.
- "Birth reporting—Transmission to public health agencies" – (f)(8)
    - **HTI-2-PR-TF-2024_Recommendation 49 –** Recommend that ASTP does not yet include this certification criterion given the limited use and no real-world production implementation of the specified FHIR-based IG. The Task Force suggests that more utilization occur before inclusion into the certification program. Additionally, we want to raise a concern that any data in the IG that is not in USCDI in particular, but USCDI+ Public Health as well, should be considered for and included in either USCDI or USCDI+ Public Health. We suggest that USCDI+ may require a vital statistics focused domain to best support the intent, while USCDI cannot be expanded with data that not all health IT, including specialty EHR, would have to support.
- "Prescription Drug Monitoring Program (PDMP) databases—query, receive, validate, parse, and filter: Functional requirement" – (f)(9)
    - **HTI-2-PR-TF-2024_Recommendation 50 –** Recommend that ASTP adopt functional certification criteria only for Pharmacies to PDMP reporting, EHR to PDMP query and PDMP to PDMP state exchange. The standard(s) for these are in need of investment and coordination between the parties with oversight of this work. The Task Force agrees with the NPRM's position that opioid use is a critical public health crisis. A flight path to get states to an open health standard such as HL7 FHIR is needed (https://build.fhir.org/ig/HL7/fhir-pdmp/). Pre-pandemic, some efforts from the PDMP community were making progress in this area. Pharmacies are now providers under HTI-2 so there is an opportunity to move them away from proprietary standards. ASTP should work with the Substance Abuse and Mental Health Services Administration (SAMHSA), CDC, Health Resources and Services Administration (HRSA), Agency for

Healthcare Research and Quality (AHRQ), CMS, IHS, FDA, and other federal agencies like DOJ that have a role in the opioid space to determine the functional goals and work towards a set of standards. The Task Force recommends separating the reporting into the PDMP "Opioid registries", the bi-directional interstate data exchange between PDMPs, and the PDMP/EHR integration where a provider can query for a patient's medication history prior to prescribing new medications. All three should have the same specific standard referenced, whether SMART on FHIR, NCPDP Script 2017071, ASAP 4.2 or whichever is the most recently adopted and appropriate open standard. Transport methods are similarly heterogeneous, and many are PMIX, which is not a health IT standard. This may benefit from approaches to harmonize such as Qualified Health Information Network™ (QHIN™) and IHE standard implementations.

- New Certification Criteria
    - "Immunization information—receive, validate, parse, filter, and exchange—response" – (f)(21)
        - **HTI-2-PR-TF-2024_Recommendation 51 –** Recommend that ASTP clarify how the certification criterion for health IT for public health will be implemented, and how entities will conduct the testing and report on results, although the Task Force fully supports the strong promotion of adoption of standards across public health. In addition, the Task Force would welcome further information on how IIS may be funded to participate both in the initial testing and in making enhancements or modifications to their systems to meet standards. Recognizing that limited funding and competing priorities may be barriers, the Task Force recommends a long onramp for testing.
        - **HTI-2-PR-TF-2024_Recommendation 52 –** Recommend that ASTP clarify what vendor products within the IIS community would be the focus for certification. Specifically, the Task Force recommends that ASTP clarify how jurisdictions that support their own IIS system internally will be able to certify their products, given the definition of health IT for public health appears to have inadvertently left them out.
        - **HTI-2-PR-TF-2024_Recommendation 53 –** Recommend that ASTP clarify whether IIS are required to certify to § 170.315(g)(20) [(g)(20) is the ability to support FHIR access to EHR data for public health purposes and include bulk]. Because this is within the (f)(21) section for IIS certification, the Task Force assumes this means IIS will also have to certify to § 170.315(g)(20). If this reasoning holds, the Task Force believes this means IIS would be required to be a client to query for EHR data in bulk, which would be a significant and costly lift for IIS development. The Task Force does not believe there is currently a strong use case for this functionality, nor is there funding available to enhance IIS to perform this function. The Task Force also recommends that ASTP clarify if there are any other requirements of a public health system (e.g., MFA, Encryption, CDS, etc.) which are broader IT requirements that could apply to both health IT and health IT for public health.
        - **HTI-2-PR-TF-2024_Recommendation 54 –** Recommend that bulk FHIR query for IIS be suggested, but not required, at this time. The Task Force is in support of IIS

implementing the standard for Bulk FHIR query, but it is unsure IIS can reasonably implement this in the timeframe allotted and with the current funding limitations to build, maintain, and support operations. The Task Force also believes that the IIS community would benefit from an IIS specific IG for bulk FHIR.

- **HTI-2-PR-TF-2024_Recommendation 55 –** Recommend that ASTP modify the wording regarding immunization-specific queries. The standard in § 170.205(e) is not sufficient for the proposed functional requirement to respond to incoming patient-level and immunization-specific queries. The current standard only supports patient-level queries. There is no functional requirement in the standard for immunization-specific queries. When a provider queries for a patient, the receiving system returns the entire consolidated immunization history for the patient. That said, there has not been a need or desire for immunization-specific queries. The Task Force recommends removal of the phrase “immunization specific queries” throughout HTI-2 as it relates to this standard.

- **HTI-2-PR-TF-2024_Recommendation 56 –** Recommend that support of the SMART Health Card Framework be suggested, but not required, at this time, for the following reasons:

    - The QR code does not have enough space for a full lifespan immunization record, which is what is typically queried from an IIS, so the Task Force suggests focusing on SMART Health Links instead (noting that this methodology is earlier in its development, and likely not yet ready for regulation); however, see comments under (f)(1) regarding timing of balloted IGs and standards maturity.

    - Like the comments above regarding Bulk FHIR Query, this has a funding aspect to build, maintain, and support operations.

    - Similarly, there is also a local policy aspect for consideration. Some jurisdictions may need more lead time to work through policy and law to offer this in their jurisdiction. Requiring all vendors to support this would put undo cost onto a jurisdiction that may have to pay for something they can’t use.

- **HTI-2-PR-TF-2024_Recommendation 57 –** Regarding transport options, recommend that the first sentence should include a “Must,” or the second and additional sentences could say “additionally” rather than “Optionally.”

- **HTI-2-PR-TF-2024_Recommendation 58 –** Recommend, on page 798 of the NPRM, that ASTP consider removing (i)(B)(2), as Simple Mail Transfer Protocol (SMTP) is not used in this space and is unlikely to be adopted at this late stage for this use case.

- **HTI-2-PR-TF-2024_Recommendation 59 –** Recommend that ASTP define “parse” and “filter," as these terms vary and the definitions used are likely to change with each workflow and/or use case. For example, “filter” may mean something different to ELR

than it means to immunization. It would be helpful to have clear definitions to better understand the implications and expectations of these requirements, to ensure not only uniform implementation, but also to support clear testing methods for certification. Since the terms are not currently clear, they would be impossible to test. The Task Force also cautions against over-filtering and validation that could yield to declined submissions that still have very appropriate and relevant data, albeit not complete, i.e., a need to distinguish between data analytics to identify opportunities for improvements vs. filtering/validating the data flow restricting immediate acceptance.

- **HTI-2-PR-TF-2024_Recommendation 60 –** Recommend that ASTP reconsider the cost estimates listed in section § 170.315(f)(21), Table 42, as we suspect the true costs of certification will be much higher. The estimate of $63.91/hour for developers seems low, given the specialized market, and this does not appear to include costs for project management, business analysis, testing, etc. Similarly, given the number of roles likely to be involved, the benchmark of 1000 hours seems low as well.

- "Syndromic surveillance—receive, validate, parse, and filter" – (f)(22)

  - **HTI-2-PR-TF-2024_Recommendation 61 –** Recommend that ASTP clarify that multiple transport standards be supported beyond Secure File Transfer Protocol (sFTP) and MLLP. We agree with a move away from PHIN-MS that has reached an end of life. Support for multiple modern transport mechanisms is needed to support CMS' Promoting Interoperability Rule. If providers are constrained to using only sFTP, then providers that are routing data through other mechanisms to entities such as QHINs/Health Information Exchanges (HIEs) that are using only other transports with participating providers may face challenges in meeting the measure.

  - **HTI-2-PR-TF-2024_Recommendation 62 –** Recommend that ASTP and its partners, CDC and Associations that operate the CSTE/NSSP CoP, should explore and encourage the development, testing, and the use of FHIR syndromic IG that emulates traditional Syndromic 2.5.1 (ADT and ORU) messages following the HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 - US Realm.

  - **HTI-2-PR-TF-2024_Recommendation 63 –** Recommend that ASTP explore opportunities to reduce payloads and other technical considerations, but this must include the CSTE/NSSP CoP. Recommend additional clarity on what is meant by receive, validate, parse and filter.

- "Reportable laboratory test values/results—receive, validate, parse, and filter" – (f)(23)

  - **HTI-2-PR-TF-2024_Recommendation 64 –** The Task Force is supportive of ASTP certification of ELR functionality to receive, validate, parse and filter. APHL and contractors have developed Rhapsody validation tools that could serve as a model for these certification criteria. The multi-year effort from the American Immunization Registry Association (AIRA) has shown that building consistency between States IIS implementations is possible. Effort to do this for the ELR space should be made but will require significant technical assistance and investment.

- **HTI-2-PR-TF-2024_Recommendation 65–** Recommend caution against over-filtering and validation that could yield to declined submissions that still have very appropriate and relevant data, albeit not complete (i.e., a need to distinguish between data analytics to identify opportunities for improvements vs. filtering/validating the data flow restricting immediate acceptance).

- **HTI-2-PR-TF-2024_Recommendation 66 –** Recommend that ASTP update transmission requirements via updated standards (HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Edition 5, US Realm, May 2024, LRI_PH_COMPONENT_V3)

- **HTI-2-PR-TF-2024_Recommendation 67 –** Recommend additional clarity on what is meant by receive, validate, parse and filter.

- **HTI-2-PR-TF-2024_Recommendation 68 –** Recommend that ASTP certification requirements should consider that public health agencies frequently utilize multiple platforms or components to receive, validate, parse, and filter laboratory data, distinguished from a single EHR system from which to transmit these data. As such, a "one-size fits all" approach may not be possible. Certification requirements will necessitate flexibility and should consider final ingestion and utilization of data feeds.

- **HTI-2-PR-TF-2024_Recommendation 69 –** Recommend that certification should include addressing all functions and data needed to do business (e.g., report laboratory results, including necessary demographic and additional information), including data sourced from systems outside of an EHR that contain data required for inclusion to conform to the production of a complete exchange, consistent with all the certification criteria.

- **HTI-2-PR-TF-2024_Recommendation 70 –** Recommend that ASTP certify use and implementation in real world environments with thresholds for completeness and data quality. Future work could include future insight measures for other public health related performance measures.

- **HTI-2-PR-TF-2024_Recommendation 71 –** Recommend ASTP work with respective federal agencies (CMS, CDC, DOJ, DoD, IHS, VHA, and others) to ensure that all parties affected by these enhanced standards are resourced to make the necessary improvements.

- **HTI-2-PR-TF-2024_Recommendation 72 –** Recommend that ASTP clarify the proposed expiration dates. The proposed expiration dates, for existing public health standards, range from January 1, 2027, to January 1, 2028. It is unclear as to whether those dates represent the date by which both the senders and receivers must be able to accommodate the new standards in a production environment, and thus begin re-onboarding existing and new partners, or begin testing. Additionally, 2-3 years to expire an existing standard, particularly ones that are currently already implemented with numerous partners, potentially creates a hardship given the length of time it can take to procure support and new technology, in addition to implementation, within a

jurisdictional governmental environment, let alone sustain the existing interfaces with partners essential to carry out the current day to day business. Given the magnitude of changes across a wide variety of public health certification criteria in a relatively short period of time, it's also reasonable to expect resource challenges for PHAs, especially without promise of adequate resources to begin and sustain the work.

- "Cancer pathology reporting—receive, validate, parse, and filter" – (f)(24)
  - **HTI-2-PR-TF-2024_Recommendation 73 –** Recommend that ASTP consult with partners, including CDC's cancer programs, the National Association of Cancer Registries, and Public Health Agencies (STLT), to identify appropriate test protocols for filtering and validation to determine what constitutes a minimum acceptable level of submission and appropriate validation and submission certification criteria. Future efforts may include the use of FHIR subscriptions to receive updated data for the same patient for more than just the Pathology reports.
  - **HTI-2-PR-TF-2024_Recommendation 74 –** Recommend additional clarity on what is meant by receive, validate, parse and filter.
- "Electronic case reporting—receive, validate, parse, filter electronic initial case reports and reportability response; and create and transmit reportability response" – (f)(25)
  - **HTI-2-PR-TF-2024_Recommendation 75 –** Recommend that ASTP update (f)(25) to reflect: receive, validate, parse, and filter content from the electronic initial case report and reportability response received via HL7 FHIR eCR IG or HL7 CDA eICR IG and HL7 CDA RR IG into destination system(s) for use. Recommend additional clarity on what is meant by receive, validate, parse and filter.
  - **HTI-2-PR-TF-2024_Recommendation 76 –** Recommend that ASTP work with respective federal agencies (HHS:CMS, CDC, IHS; DOJ; DoD; VHA; DHS and others) to ensure that all parties affected by these enhanced standards are resourced to make the necessary improvements.
    - Public Health Agencies will face significant challenges as the limited resources currently allocated to eCR will need to be divided between preparing for FHIR adoption and maintaining the existing eCR infrastructure. This situation creates undue hardship, particularly considering the extended timelines required to procure support, new technology, and implement solutions within jurisdictional government environments. Maintaining current interfaces with partners, which are essential for day-to-day operations, adds to the complexity. Given the substantial scope of changes across numerous public health certification criteria within a relatively short timeframe, resource constraints are likely, especially without guarantees of sufficient funding to initiate and sustain the necessary work. Additionally, since EHRs are unlikely to retire existing standards until close to the January 1, 2028, deadline, public health agencies may not have adequate time to augment their systems with real-world data.

- **HTI-2-PR-TF-2024_Recommendation 77 –** Recommend that a further distinction is needed between public health agencies and public health intermediaries at large. The Reportability Response (RR) is generated by the APHL Informatics Messaging Services (AIMS), on behalf of the STLT public health authorities.

- "Birth reporting—receive, validate, parse, and filter" – (f)(28)

  - **HTI-2-PR-TF-2024_Recommendation 78 –** Recommend that ASTP does not yet include this certification criterion given the limited use and no real-world production implementation of the specified FHIR-based IG. The Task Force suggests that more utilization occur before inclusion into the certification program. Additionally, the Task Force has concerns that any data in the IG that is not in USCDI, but USCDI+ Public Health as well, should be considered for and included in either USCDI or USCDI+ Public Health. The Task Force suggests that USCDI+ may require a vital statistics focused domain to best support the intent, while USCDI cannot be expanded with data that not all health IT, including specialty EHRs, would have to support.

  - **HTI-2-PR-TF-2024_Recommendation 79 –** Recommend that ASTP should consult with STLTs, CDC, and other partner associations like NAPHSIS to determine when this certification criterion is ready for certification to then determine appropriate testing certification criteria for filtering and validation functions and if these should be at able to be done at the level of the interoperability engine or the registries themselves.

  - **HTI-2-PR-TF-2024_Recommendation 80 –** Recommend that ASTP should consult with the CDC, STLTs, health care providers, and other partner associations like NAPHSIS to identify and address information gaps between what is currently supported in the proposed IG and what is available as a FHIR resource. If the "missing" fields exist as FHIR resources, then the certification criteria should include consideration of the effort required to add additional elements to the transaction. STLT regulations may have legally required fields that need to be taken into account rather than just the data that CDC NCHS has prioritized for national collection.

  - **HTI-2-PR-TF-2024_Recommendation 81 –** Recommend that given the similarities between BFDR and VRDR and that in most jurisdictions these are managed in the same vital statistics program area/Birth and Death Registry system. It may make sense to advance both at the same time, or at least co-invest in the modernization of the infrastructure.

  - **HTI-2-PR-TF-2024_Recommendation 82 –** Recommend that ASTP provide additional clarity on what is meant by receive, validate, parse and filter.

- "Prescription Drug Monitoring Program (PDMP) data—receive, validate, parse, filter prescription data, support query and exchange" – (f)(29)

  - **HTI-2-PR-TF-2024_Recommendation 83 –** Recommend that ASTP follow that maturity model it has used in the development of the Interoperability Standards

Advisory and the USCDI, both of which use an incremental approach to refine standards based on use of the relevant transport protocols and data models in the field.

- **HTI-2-PR-TF-2024_Recommendation 84 –** Recommend that ASTP further harmonize the domain of PDMP to emphasize the health impacts. PDMP applications often are operated outside the scope of STLT public health agencies, and as such it may be premature to develop a public health certification criterion unless it could also apply to Law Enforcement or Boards of Pharmacy implementations. Additionally, there are legal differences between STLTs regarding ability to share and store discrete data by partners.

- **HTI-2-PR-TF-2024_Recommendation 85 –** Recommend that ASTP provide additional clarity on what is meant by receive, validate, parse and filter.

- "New Standardized API for Public Health Data Exchange" – (g)(20)

  - **HTI-2-PR-TF-2024_Recommendation 86 –** Recommend that ASTP limit the scope of the API to support for FHIR IGs that are recognized in regulation, included in the FHIR Public Health Profile, advanced through SVAP, or are being developed as HL7 projects or developed and used by specific public health authorities (PHA) STLTs. Any current requirements for subscription or bulk queries should be removed. There has been insufficient work completed exploring the impacts of subscription and bulk queries on public health's information systems. ASTP should follow that maturity model it has used in the development of the Interoperability Standards Advisory and the USCDI, both of which use an incremental approach to refine standards based on use of the relevant models in the field.

Bulk Data Enhancements

- **HTI-2-PR-TF-2024_Recommendation 87 –** Recommend that ASTP resolve patient matching in context of bulk data queries. For example, HELIOS identified the need for substantive changes before it is ready for use in immunization focused queries. While for a Provider API that may work in context of established attribution lists, in other use cases Bulk Data would not be as ready.

- **HTI-2-PR-TF-2024_Recommendation 88 –** Recommend additional testing of Bulk Data Access implementation prior to certification.

New Requirements to Support Dynamic Client Registration Protocol in the Program

- **HTI-2-PR-TF-2024_Recommendation 89** – Recommend that ASTP add a requirement for certified health IT to require certified health IT vendors to demonstrate successful connection and data exchange with a network partner like (e.g., local or state Health Information Exchange (HIE), eHealth Exchange, CommonWell, or any other network under Carequality or TEFCA). This added requirement will ensure that certified health IT vendor products have demonstrated the successful interoperability of the certified health IT product. This requirement should enable more small providers to accomplish a successful network connection once the provider has implemented the certified health IT product.

- **HTI-2-PR-TF-2024_Recommendation 90 –** Recommend that ASTP add a registry to the certified health IT website so that organizations and providers are able to report issues with certified health IT products' ability to perform a successful data exchange, either point to point or within a network environment.

New Certification Criteria for Modular API Capabilities

- **HTI-2-PR-TF-2024_Recommendation 91 –** The Task Force is generally supportive of a more modular approach for clarity and reduced ambiguity on expectations. In combination with role-based certification criteria, the certification criteria can be adopted in a more targeted fashion. This more modular approach should also be considered in (g)(10) and (g)(20) certification criteria and reconciled with the relevant information blocking requirements in that the certification program should enable more health IT to be certified by focusing on the data that the health IT actually manages, thus supporting the much more modular health IT ecosystem that is our reality.

- **HTI-2-PR-TF-2024_Recommendation 92 –** Recommend that ASTP adopt the dynamic registration standard with the following considerations:

    - ASTP consider the ability to draw on the initial experience of dynamic registration under TEFCA and the alignment of that effort with the CARIN initiatives, as these may result in relevant and critical updates to the UDAP/SSRAA IG.

    - Data holders supporting dynamic registration can utilize any one or more trust communities of their choice and require apps and B2B solutions using dynamic registration to have to be part of those specific trust communities.

    - Clarify that data holders are permitted to require the use of dynamic registration instead of current functional registration requirements under the certification program for certain patient and provider apps and B2B solutions considering dynamic registration is either not relevant or not available for certain apps and B2B solutions (e.g., those purchased and used by providers within their health IT infrastructure, or apps engaged in optional programs such as validation programs).

- **HTI-2-PR-TF-2024_Recommendation 93 –** Recommend clarification that revocation can and should be managed by the IT operations supporting clinicians (not the EHR developer), as a more practical approach, as opposed to having this be end user/clinician facing. The Task Force is supportive of the goal to have approaches to revoke tokens.

- **HTI-2-PR-TF-2024_Recommendation 94 –** The Task Force is generally supportive, while noting that keeping this defined to a specific set of scopes that will be most usable for patients. Using all possible granular scopes would be too broad and would add burden to patients. For example, vital signs vs. laboratory is helpful, but not only vital signs on a specific day.

- **HTI-2-PR-TF-2024_Recommendation 95 –** Recommend that ASTP clarify that although the B2B section is referenced, it applies specifically to clinician access user scenarios (B2B is a misleading term in this context). Recommend adding information about B2B definitions.

- **HTI-2-PR-TF-2024_Recommendation 96 –** Recommend that ASTP consider this as optional within (g)(10), noting the limited adoption of health cards. The Task Force notes also that not all EHRs, or other health IT

certifying to (g)(10) would have immunization data to include, which is required to be supported in (j)(22). Recommend aligning across (f)(1), (g)(10), and (j)(22).

- **HTI-2-PR-TF-2024_Recommendation 97 –** Recommend that certified health IT that is certified to (g)(10) and (20) support 2-3 subscriptions of their choice for at least one of the resources covered in (g)(10) and (g)(20) combined. That is, not 2-3 per certification criterion, but 2-3 across both. The Task Force notes that (g)(34) and (g)(35) already cover ePA specific subscription requirements.

Multi-Factor Authentication Criterion

- **HTI-2-PR-TF-2024_Recommendation 98 –** Recommend that ASTP clarifies when a user brings in their own ID/password that multi-factor authentication (MFA) may not be available with the certified software. This already may be obvious as then the user would not use the software as certified.

Revised Computerized Provider Order Entry—Laboratory Criterion

- **HTI-2-PR-TF-2024_Recommendation 99 –** Recommend that ASTP take a modular approach towards adoption of Laboratory Orders Interface (LOI) and Laboratory Results Interface (LRI) IGs enabling maximum use of already existing interfaces, thus minimizing unnecessary replacement of otherwise well-functioning interfaces.

- **HTI-2-PR-TF-2024_Recommendation 100 –** Recommend that ASTP split the § 170.315(a)(2) certification criterion into multiple certification criteria based on the relevant roles and their responsibilities, specifically the ordering provider and the laboratory, where the laboratory may be further specified as a public health laboratory vs. commercial laboratories vs. other performing laboratories for the primary laboratory. For each of these role-based certification criteria the relevant ordering and results responsibilities can then be clearly defined.

- **HTI-2-PR-TF-2024_Recommendation 101 –** Recommend that ASTP adopt the most current published versions for both IGs, i.e., R5.

  For Orders

- **HTI-2-PR-TF-2024_Recommendation 102 –** Recommend that ASTP address the different context in which laboratory orders are placed and may or may not require additional data for public health reporting that the laboratory needs to have:

    - Laboratories internal to a health care provider's organization, e.g., hospital laboratories - neither the LOI IG nor LRI IG should be required as order and result data flows vary based on internal configurations and consequent need to share data beyond what is relevant to perform the test and support the initiation of charging and billing.

    - Laboratories external to the health care provider's organization, e.g., commercial laboratories or public health laboratories.

        - Orders to public health laboratories - require LOI with public health components, aligning with ETOR requirements.

        - Orders to laboratories that have public health reporting requirements - require the Public Health Profile component only that can be included in existing HL7 v2 messages (v2.3, v2.3.1, etc.) already deployed. This profile component must be used when ordering laboratory tests subject to electronic laboratory reporting to public health." 2.3 or 2.3.1 messaging, especially usage of ORM messages will be insufficient for downstream reporting to public health. Specifically, the lack of specimen details typically contained in the SPM segment of the 2.5.1 OML message will be problematic, as will inconsistent implementation of AOEs.

    - Orders between two laboratories – as these reverse reference/performing labs do not have reporting requirements (they remain with the initiating laboratory), limited LOI capabilities could be identified, but should not include the Public Health profile component as they have no need for that data.

For Results

- **HTI-2-PR-TF-2024_Recommendation 103** – Recommend that ASTP support the support for LRI aligned with ETOR requirements.

For Future

- **HTI-2-PR-TF-2024_Recommendation 104 –** Recommend that ASTP explore the use case of follow-up queries by public health using (g)(10) and (g)(20) capabilities to obtain the relevant data for laboratory result reporting to public health that are otherwise not needed to perform the laboratory tests.

Revised Standardized API for Patient and Population Services Criterion to Align with Modular API Capabilities

- The Task Force reviewed this proposal and had no comments or recommendations in this area.

Patient, Provider, and Payer APIs

- **HTI-2-PR-TF-2024_Recommendation 105 –** For § 170.315(g)(30), recommend that ASTP align its proposal with the CMS rule proposal (in regard to functional use of IGs being recommended) and modify language to focus on payer API for clinical and administrative information.

- **HTI-2-PR-TF-2024_Recommendation 106 –** For § 170.315(g)(31), recommend that ASTP align its proposal with the CMS rule proposal (in regard to functional use of IGs being recommended) and change language to specify that the client in this case is the provider referenced in the 'provider access API - provider client'.

- **HTI-2-PR-TF-2024_Recommendation 107 –** For § 170.315(g)(32), recommend that ASTP align its proposal with the CMS rule proposal (in regard to functional use of IGs being recommended) and change language to specify that the server in this case is the payer referenced in the 'provider access API - payer server'.

- **HTI-2-PR-TF-2024_Recommendation 108 –** For § 170.315(g)(33), recommend that ASTP align its proposal with the CMS rule proposal (in regard to functional use of IGs being recommended).

- **HTI-2-PR-TF-2024_Recommendation 109 –** For § 170.315(g)(34), recommend that ASTP align its proposal with the CMS rule proposal (in regard to functional use of IGs being recommended, not required, to support flexibility as prior authorization workflows continue to evolve).

- **HTI-2-PR-TF-2024_Recommendation 110 –** For § 170.315(g)(35), recommend that ASTP align its proposal with the CMS rule proposal (in regard to functional use of IGs being recommended, not required, to support flexibility as prior authorization workflows continue to evolve).

- **HTI-2-PR-TF-2024_Recommendation 111 –** For § 170.315(g)(36), recommend that ASTP clarify language to be more explicit that the API is for patient-facing use and change the name to 'provider directory API - patient-facing health plan coverage'.

Conditions and Maintenance of Certification Requirements—Insights and Attestations

Insights Condition and Maintenance of Certification Requirements

- **HTI-2-PR-TF-2024_Recommendation 112 –** Strongly recommend stratification “by IIS” in Year 1. Without this, a certified health IT vendor will submit a single number for each of the 4 metrics and the results will be heavily skewed by the volume of administrations in heavily populated jurisdictions. This may obscure other successes or gaps in other jurisdictions, noting that the top 5 jurisdictions (CA, TX, FL, NY, PA) account for 36% of the U.S. population.

- **HTI-2-PR-TF-2024_Recommendation 113 –** Recommend removing “The number of submissions that did not receive an acknowledgement” measure from the optional list, unless there is something to differentiate it from Metric 4 for year 1 (and 8 for year 2). The optional measure of “The number of submissions that did not receive an acknowledgement” in the list of optional measures seems the same as Metric 4 for year 1 (and 8 for year 2): “The number of immunizations administered that were electronically submitted to an IIS where an acknowledgement from an IIS is not received by certified health IT overall”.

- **HTI-2-PR-TF-2024_Recommendation 114 –** Recommend that patients who opt out should be excluded from metric 3. Texas, for example, will likely have a lot of these, and ideally providers in Texas should not be penalized for this.

- **HTI-2-PR-TF-2024_Recommendation 115 –** Recommend that ASTP focus insight measures on technical performance, not programmatic performance.

Attestations Condition and Maintenance of Certification Requirements

The Task Force reviewed this proposal and had no comments or recommendations in this area.

Administrative Updates

HTI-2-PR-TF-2024_Recommendation 116 – Recommend that ASTP remove the word surveillance seen twice within bullet two of this rule and insert the word oversight. This would prevent any plausible confusion to suggest

a certified health IT developer is under investigation or punitive monitoring by any government agency as the word surveillance might infer.

Information Blocking Enhancements

Defined Terms – Health Care Provider

HTI-2-PR-TF-2024_Recommendation 117 – The Task Force supports the proposed language from ASTP. The Task Force further recommends that ASTP summarize those scenarios in which the proposed rule treats an actor that is a covered entity differently than an actor that is not a covered entity. In each case, examples of actors that are not covered entities would help. The Task Force is supportive of the language but requests further regulatory guidance to clarify from ASTP.

Defined Terms – Health Information Technology or Health IT

HTI-2-PR-TF-2024_Recommendation 118 – The Task Force supports the proposed language from ASTP.

Defined Terms – Business Day

HTI-2-PR-TF-2024_Recommendation 119 – The Task Force supports the proposed language from ASTP.

Defined Terms - Interfere with, Interference

HTI-2-PR-TF-2024_Recommendation 120 – The Task Force supports the proposed language from ASTP.

Privacy Exception

HTI-2-PR-TF-2024_Recommendation 121 – Recommend that the TEFCA Manner Exception be modified so that both the requester and responder must agree on the mechanism (FHIR or other transmission protocol described under the flexibility of ASTP) within TEFCA used to exchange information to accommodate TEFCA participants that have not yet enabled FHIR transactions via TEFCA.

Infeasibility Exception

- **HTI-2-PR-TF-2024_Recommendation 122 –** Recommend that ASTP provide a clearer definition of a non-covered entity or provider. The Task Force is supportive of the overall purpose of the language that attempts to clarify what situations can be deemed infeasible.

- **HTI-2-PR-TF-2024_Recommendation 123 –** The Task Force believes ASTP is leaving the definition as described in the HIPAA policy. The Task Force recommends ASTP clarify this definition to fit the TEFCA rule.

- **HTI-2-PR-TF-2024_Recommendation 124** – Recommend that ASTP provide examples of non-provider entities according to the flexibility of ASTP There may be a provider (for example, an MD physician) who is deemed non-covered but is involved in the exchange of EHI. If they are indeed a provider of care, should they not be treated as a covered provider and subject to the applicable rules under TEFCA?

- **HTI-2-PR-TF-2024_Recommendation 125 –** Recommend that ASTP adopt 10 business day(s) for turnaround of infeasibility notification.

Protecting Care Access Exception

- **HTI-2-PR-TF-2024_Recommendation 126** – The Task Force is supportive of the recommended language.
    - The Protection Care Access rule attempts to protect actors from accusations of information blocking when they decline in clinical situations to share information where they are protecting patients' and/or caregivers' privacy and their preference for privacy are honored by the care provider/team. While ASTP cannot create rules that supersede applicable laws, the Task Force believes this rule goes to the extent that it can assure protection from any charges of information blocking, provided the parties are engaged in an ethical and standard clinical practice relationship.

- **HTI-2-PR-TF-2024_Recommendation 127** – Recommend that ASTP add explicit language that any actor who, in good faith, adopts an expansive interpretation of reproductive care is covered by the Protecting Care Access Exception. 45 CFR 171.201- The actor engaging in the practice must hold a reasonable belief that the practice will substantially reduce a risk of harm to a patient or another natural person that would otherwise arise from the access, exchange, or use of electronic health information affected by the practice.

Requestor Preferences Exception

- **HTI-2-PR-TF-2024_Recommendation 128 –** Recommend that ASTP consolidate the existing "Manner" Exception to cover both the content and manner in which Electronic Health Information (EHI) is provided, reducing redundancy and simplifying the regulatory framework.

- **HTI-2-PR-TF-2024_Recommendation 129** – Recommends that ASTP provide clear guidance to prevent health care providers or IT developers from unintentionally steering requestors towards easier or more convenient options for sharing EHI, ensuring that requestors can make fully informed choices without undue influence.

- **HTI-2-PR-TF-2024_Recommendation 130** – Recommend that ASTP provide further clarification on the differences between Manner Exception.

Exceptions That Involve Practices Related to Actors' Participation in The Trusted Exchange Framework and Common Agreement™ (TEFCA™)

- **HTI-2-PR-TF-2024_Recommendation 131 –** The Task Force supports ASTP position for this proposal.

Trusted Exchange Framework and Common Agreement™

- **HTI-2-PR-TF-2024_Recommendation 132** – The Task Force supports the proposed language from ASTP. The Task Force further recommends that ASTP summarize those scenarios for a 5% threshold as an individual or collusion with multiple individuals to work as a group to reach a threshold over 25%.

- **HTI-2-PR-TF-2024_Recommendation 133** – The Task Force recognizes there is no TEFCA and Common Agreement for advisory boards, including that there are no details for selections nor are these advisory

boards mentioned in the proposed rule. The Task Force recommends that ASTP consider recognizing advisory boards under TEFCA, including or referencing groups like patients, providers, payors, and public health within the Recognized Coordinating Entity (RCE). (STLTS and CDC).

- **HTI-2-PR-TF-2024_Recommendation 134** – The Task Force has found data quality to be the missing gap that is fundamental to health IT sharing and TEFCA. Therefore, the Task Force recommends ASTP refer to, prioritize as a goal, recognize, or focus on high-quality data within data sharing as its goal to create an atmosphere of trust.

- **HTI-2-PR-TF-2024_Recommendation 135** – Recommend that ASTP continue efforts to create more equal information exchange to advance interoperability between USCDI and across health IT.

- **HTI-2-PR-TF-2024_Recommendation 136** – Recommend that ASTP foster QHINs' support for all Exchange Purposes for health IT, including the one they prefer to address.

- **HTI-2-PR-TF-2024_Recommendation 137 –** The Task Force recognizes and understands a QHIN may disappear due to financial stability within the start-up. Therefore, the Task Force recommends that ASTP create a workflow or enforce a QHIN continuity plan if a QHIN is terminated or is sanctioned, including migration support for participants/sub participants.

- **HTI-2-PR-TF-2024_Recommendation 138 –** Recommend that ASTP provide guidance on the potential of a QHIN's lack of adoption for FHIR after standardization occurs for QHINs that do not fully implement FHIR complete interoperability.

- **HTI-2-PR-TF-2024_Recommendation 139 –** The Task Force recognizes there is no general investigator or Office of Inspector General for independent review or monitoring within the TEFCA agreement. Therefore, the Task Force recommends that ASTP create and/or provide an oversight board or element from the Office of Inspector General. Additionally, the Task Force recommends to ASTP that a mechanism for patient-identified issues should be included and promoted.

Additional Recommendations for Future Consideration

- **HTI-2-PR-TF-2024_Recommendation 140 –** Recommend that ASTP add a component to their certified health IT website so that organizations are able to report issues and problems with certified health IT products. In addition, recommend that the certified health IT website include a public facing component that allows users of the certified health IT to report their reviews and experience with the product (similar to what the FDA enables for devices) - https://www.fda.gov/patients/learn-about-drug-and-device-approvals/device-development-process.

- **HTI-2-PR-TF-2024_Recommendation 141 –** Recommend that ASTP increase or expand their audit capacity for performance of certified health IT to ensure certified health IT products are in compliance with the certified health IT rules and certification criteria and post summaries of their audit findings publicly. Recommend that ASTP incorporate feedback from health IT vendor customers and other users such as patients on the adequacy of the functionality of health IT vendors as part of the certification criteria.

- **HTI-2-PR-TF-2024_Recommendation 142 –** Recommend that ASTP incorporate feedback from health IT vendor customers and other users such as patients on the adequacy of the functionality of health IT vendors as part of the certification criteria. There is currently no mechanism to incorporate feedback from health IT vendor customers and patients to verify that required data elements and functionality required as part of the certification process are supported and function adequately for the purposes that they are intended. This feedback process could mirror Medical Device Reporting (MDR) by the FDA that provides a mechanism for users to report issues with approved devices as a post market surveillance tool. We also recommend creation of education and marketing content to support health IT vendor customers and users to provide feedback and report challenges with health IT functionality.

Health IT Modules Supporting Public Health Data Exchange

- General Comment
    - **HTI-2-PR-TF-2024_ Recommendation 143 –** ASTP should consider the dates of certification expiration and align these dates with other program requirements such as CDC reporting and Promoting Interoperability program reporting.

Appendix

Task Force Roster

Name	Organization
Bryant Thomas Karras* (Co-Chair)	Washington State Department of Health
Mark Sendak* (Co-Chair)	Duke Institute for Health Innovation
Rochelle Prosser* (Co-Chair)	Orchid Healthcare Solutions
Suresh Balu	Duke Institute for Health Innovation (DIHI)
Shila Blend*	North Dakota Health Information Network
Hans Buitendijk*	Oracle Health
Sooner Davenport	Southern Plains Tribal Health Board
Derek De Young*	Epic
Steven Eichner*	Texas Department of State Health Services
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine
Hannah Galvin*	Cambridge Health Alliance
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network
Gillian Haney	Council of State and Territorial Epidemiologists (CSTE)
Joel Hartsell	Association of Public Health Laboratories
Steven Hester*	Norton Healthcare
Erin Holt Coyne	Tennessee Department of Health
Jim Jirjis**	Centers for Disease Control and Prevention
Mary Beth Kurilo	American Immunization Registry Association (AIRA)

Name	Organization
Hung S. Luu*	Children's Health
Dominic H. Mack	Morehouse School of Medicine
Meg Marshall**	Department of Veterans Health Affairs
Anna McCollister*	Individual
Katrina Miller Parrish*	Patient.com
Kris Mork	Leidos
Alex Mugge**	Centers for Medicare and Medicaid Services
Shantanu Nundy	Accolade
Eliel Oliveira*	Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan*	Pegasystems
Randa Perkins*	H. Lee Moffitt Cancer Center & Research Institute
Dan Riskin*	Verantos
Fillipe Southerland*	Yardi Systems, Inc.
Zeynep Sumer-King*	NewYork-Presbyterian
Naresh Sundar Rajan*	CyncHealth
Sheryl Turney	Elevance Health
Rachel (Rae) Walker	University of Massachusetts Amherst
Thomas M. Wilkinson	U.S. Department of Homeland Security