

**CHIME Cheat Sheet – ASTP’s HTI-1, 2, & 3 Regulations
Overview, Background, & Outlook
January 15, 2025**

The Assistant Secretary for Technology Policy (ASTP) has released a series of “Health Data, Technology, and Interoperability” (HTI) regulations over the last two years.

ASTP first released a notice of proposed rulemaking (NPRM) on April 18, 2023 – Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing – referred to as “HTI-1” or the “HTI-1 proposed rule.” CHIME submitted [a comment letter](#) on June 20, 2023. On December 16, 2023, the [HTI-1 final rule](#) was issued; you can find our Cheat Sheet on the final rule [here](#).

ASTP’s sweeping Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule was published August 5, 2024, in the *Federal Register*, and CHIME [submitted comments](#) on October 4, 2024. The Department of Health and Human Services (HHS) press release stated: “The HTI-2 proposed rule is a tour de force. We have harnessed all the tools at ONC’s disposal to advance HHS-wide interoperability priorities,” said Micky Tripathi, Ph.D., national coordinator for health information technology.”

On December 16, 2024, ASTP published [a final rule](#) titled Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA) – known as the “HTI-2 final rule.” ASTP’s HTI-2 regulation finalizes certain TEFCA-related proposals from the HTI-2 proposed rule to advance interoperability and support the access, exchange, and use of electronic health information (EHI). The HTI-2 final rule also amends the information blocking regulations by including definitions related to the TEFCA Manner Exception. Further, it implements provisions to support the reliability, privacy, security, and trust within TEFCA. You can find a fact sheet [here](#).

On December 17, 2024, ASTP released [a final rule](#) titled Health Data, Technology, and Interoperability: Protecting Care Access (HTI-3); you can find a fact sheet [here](#). ASTP’s HTI-3 final rule reflects ASTP’s focused efforts to improve information sharing while protecting patient privacy. Additionally, it finalizes information blocking regulatory enhancements that were included in the HTI-2 proposal.

HTI Regulations Timeline		
Regulation	Release Date	Effective Date
HTI-1 Proposed Rule	April 18, 2023	NA
HTI-1 Final Rule	December 16, 2023	February 8, 2024
HTI-2 Proposed Rule	August 5, 2024	NA
HTI-2 Final Rule (TEFCA)	December 16, 2024	January 15, 2025
HTI-3 Final Rule (Protecting Access to Care)	December 17, 2024	December 17, 2024
HTI-4 Final Rule*	March 2025*	TBD*
<i>*This final rule is subject to major changes under a new administration, and/or may not be released</i>		

Moving Forward

After dividing sections from the HTI-2 proposed rule into two final rules issued at the end of 2024, ASTP plans to issue the “HTI-4” final rule in March of 2025; however, under a new administration – the future of this rulemaking is not certain. The incoming administration has [a variety of ways](#) to review, amend, or repeal pending regulations and “midnight regulations.” Midnight regulations are regulations and regulatory activity that occurs after the election and before the incoming administration takes over.

In the HTI-2 final rule, ASTP states that they “have reviewed and responded to comments on a narrowed set of proposals.” ASTP further notes in the HTI-3 final rule: “Comments related to proposals not discussed in this final rule or the HTI-2 Final Rule may be the subject of subsequent final rules related to such proposals in the future.” In other words – if you submitted feedback about proposals that aren’t covered in these two final rules, they could be addressed in future rulemaking.

There were numerous, significant changes from the HTI-2 proposed rule that were not finalized. As [listed in](#) the *Unified Agenda*, the “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability” final rule would “advance interoperability [...] through provisions related to: standards adoption; public health IT certification; expanded uses of certified application programming interfaces (APIs), such as for electronic prior authorization, patient engagement, care management, and care coordination; and information sharing under the information blocking regulations.”

Thus, we expect ASTP to continue working on the HTI-4 rule unless and until a new head of ASTP is appointed, and/or the new administration issues an expected regulatory “freeze.” During a regulatory freeze, the President has effectively paused rulemaking within federal agencies, giving the new administration time to assess and determine which regulations to advance and which to discard.

Worth Noting

On July 25, 2024, HHS announced a reorganization that, among other things, renamed the Office of the National Coordinator for Health Information Technology (ONC). ONC is now dually titled as the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) per the *Federal Register* [notice](#) published on July 29.

There are flexibilities which allow federal agencies to adapt to changing priorities and policies set by the current – and any new – administration. If the Trump administration (or any future administration) wanted to undo the reorganization of HHS that renamed the ONC to the ASTP/ONC, they could do so through the standard processes for federal agency management. Reorganizations of federal agencies, such as name changes or shifts in scope, are relatively common and reversible. This is part of the broader executive authority to manage and reorganize federal agencies to align with evolving priorities, political strategies, and/or policy goals. In short – the Biden administration changed the ONC to ONC/ASTP, a subsequent administration, including the Trump administration, could revert it back to ONC if they chose to do so.

What’s Next?

While the future of the recently released HTI final rules, including HTI-2 and HTI-3 is still shaky, and the HTI-4 final rule in limbo – there are a series of deadlines finalized in the HTI-1 final rule that are known.

Additionally, as noted previously – the HTI-2 final rule is effective on January 15, 2025, and the HTI-3 final rule is effective as of December 17, 2024.

HTI-1 Timeline

(further details on specific certification criterion available [here](#))

2024 – “Decision Support Interventions” (DSI); Standardized “FHIR endpoints”

- **By December 31, 2024:**
 - Developers with health IT certified to the clinical decision support certification criterion must update their certificates to the decision support interventions certification criterion.
 - Certified API Developers must publish their customers' service base URL information (FHIR Endpoints).

2025 – USCDI v3; all other Certification Program updates

- **By January 1, 2025:**
 - The DSI certification criterion replaces the clinical decision support (CDS) certification criterion in the Base EHR definition. *ASTP resource for clinicians [here](#).*
 - “Assurances” Maintenance of Certification requirement for DSI begins.
- **By December 31, 2025:**
 - Health IT developers must update and provide to their customers certified health IT that conforms to new and revised standards and certification criteria included in the HTI-1 Final Rule. Includes: new baseline version of the USCDI standard to USCDI Version 3; HL7 FHIR US Core Implementation Guide STU 6.1.0 in support of USCDI v3; HL7 SMART Application Launch Framework Implementation Guide Release 2.0.0; minimum standards code set updates; electronic case reporting; patient-requested restrictions (i.e., view, download, and transmit to 3rd party); and others.

2026 – Insights Condition Year 1; Updated standards compliance

- **Starting January 1, 2026:**
 - All HTI-1 updated standards in certification criteria are solely applicable for compliance purposes.
 - Health IT developers collect data for Insights Condition Year 1 measures.

2027 – Insights Condition Year 2

- **Calendar Year (CY) 2027:**
 - Health IT developers collect data for Insights Condition Years 1 and 2 measures.
- **By July 2027:**
 - Health IT developers submit Insights Condition report for Year 1 measures.

2028 – Insights Condition Year 3

- **CY 2028:**
 - Health IT developers collect data for all Insights Condition measures (Years 1, 2, and 3).
- **By July 2028:**
 - Health IT developers submit Insights Condition report for Year 1 and 2 measures.

2029 – Insights Condition Year 4

- **CY 2029:**
 - Health IT developers collect data for all Insights Condition measures.
- **By July 2029:**
 - Health IT developers submit report for all Insights Condition measures.