Assistant Secretary for Technology Policy

Department of Health and Human Services

Assistant Secretary for Technology Policy/
Office of the National Coordinator for Health Information Technology

FURTHER CONSOLIDATED APPROPRIATIONS ACT, 2024 – ASTP REPORT TO CONGRESS ON CURES ACT PROGRESS

September 2024

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Statutory Requirement

The Joint Explanatory Statement, which accompanied the Further Consolidated Appropriations Act, 2024, directs the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (hereafter ASTP) "to provide a report to the Committees that provides an update on progress implementing the interoperability provisions of the [21st Century] Cures Act [Cures Act] and gaps that remain for full implementation, including patient and clinician access to data, including images, as well as on efforts to ensure standardized capabilities for real-time benefit checks and electronic prior authorization for drugs and services and the enablement of decentralized clinical trials via technology. Such a report shall be made publicly available on ONC's website."

This report also satisfies section 4005(c)(2) of the Cures Act that requires the Secretary of the Department of Health and Human Services (HHS) to submit a report concerning best practices and current trends voluntarily provided by patient safety organizations (PSOs) to improve the integration of health information technology (IT) into clinical practice.

Executive Summary

ASTP is at the forefront of the federal government's digital health efforts. ASTP supports the entire health system with the development and use of health IT and the promotion of nationwide, standards-based health information exchange.

ASTP is responsible for the implementation of certain provisions in Title IV of the Cures Act, including provisions related to the advancement of interoperability and the access, exchange, and use of electronic health information (EHI).

This report focuses on the progress made implementing these interoperability provisions through advancements in health IT standards, health information exchange, health IT certification, patient access and education, and industry coordination, and highlights gaps that remain for full implementation.

Health IT Certification

ONC Health IT Certification Program

Provision Reference: Enhancements to Certification – Section 4002(a) of the Cures Act

The Cures Act requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program (Certification Program). The Certification Program provides for the voluntary certification of health IT. Requirements for certification are established when the Secretary of HHS adopts certification criteria, which may also include standards and associated implementation specifications.

Several regulations shape the Certification Program. The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule), for example, includes a provision to require health IT developers under the Certification Program to publish standardized application programming interfaces (APIs), which allow individuals and clinicians to access structured EHI securely and easily. The rule also includes a provision requiring health IT certified to a particular certification criterion to ensure patients can electronically access all of their EHI at no cost and implements the Cures Act's information blocking provisions. Additional enhancements to the Certification Program have been made through the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule and proposed as part of the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

ONC Health IT Certification Program – Conditions and Maintenance of Certification Requirement

Provision Reference: Enhancements to Certification – Section 4002(a) of the Cures Act

ASTP finalized the Conditions and Maintenance of Certification requirements to express ongoing requirements for health IT developers and their certified Health IT Module(s). There are seven Conditions of Certification[i] with accompanying Maintenance of Certification Requirements to which health IT developers or entities with technology certified under the Certification Program must adhere, including:

1. Information blocking
2. Assurances regarding appropriate exchange, access, and use of electronic health information
3. Communications regarding health IT
4. APIs

5. Real world testing
6. Attestations regarding certain conditions and maintenance of certification requirements
7. Submission of reporting criteria under the Electronic Health Record (EHR) Reporting Program in accordance with section 3009A(b) of the Public Health Service Act

Updates to Conditions and Maintenance of Certification in ASTP Regulation

Provision Reference: Enhancements to Certification – Section 4002(a) of the Cures Act

The HTI–1 Final Rule, published in January 2024, implements provisions of the Cures Act and further advances the ONC Cures Act Final Rule through information blocking updates, new and revised Conditions and Maintenance of Certification requirements, and related new and revised standards, implementation specifications, and certification criteria,[ii,iii] including:

- Discontinuation of year–themed editions of certification criteria to simplify the Certification Program and support more modular and extensible future updates
- Requiring certified health IT developers to update their certified Health IT Modules to the most recently adopted certification criteria and provide that updated certified Health IT Module to its customers in accordance with the dates identified for each revised certification criterion and each applicable standard
- Updating the Assurances Condition and Maintenance of Certification requirements
- Updating the Application Programming Interfaces Maintenance of Certification to revise and standardize the service base URL publication requirement and adoption of the SMART App Launch Implementation Guide v2
- Establishing the Insights Condition and Maintenance of Certification
- Establishing a new Information Blocking exception for actors[iv] and requestors capable of exchange via the Trusted Exchange Framework and Common Agreement™ (TEFCA™)[v]
- Incorporating the use of Health Level Seven International (HL7)® FHIR®-based standards for electronic case reporting to improve the efficiency, accuracy, and timeliness of case reporting using standards-based APIs
- Establishing first-of-its-kind transparency requirements regarding the quality and performance of artificial intelligence (AI) -driven predictive decision support tools that are supplied by developers of certified health IT
- Establishing additional transparency requirements to enable users to know when an evidence-based or predictive decision support intervention (DSI) uses specific data elements that are relevant to health equity, such as race, ethnicity, and social determinants of health

- Adopting the United States Core Data for Interoperability (USCDI) version 3 as the new baseline standard for interoperability, as of January 1, 2026, including for standards-based APIs
- Requiring Health IT Modules certified to the "view, download, and transmit to 3rd party" certification criterion to support an internet-based method for patients to request restrictions on how their EHI is shared

Updates to Conditions and Maintenance of Certification in ASTP Regulation

Provision Reference: Enhancements to Certification – Section 4002(a) of the Cures Act

The HTI-2 Proposed Rule proposes new and revised standards and certification criteria in the Certification Program, which are pertinent to the Conditions and Maintenance of Certification requirements, including, for example:

- Adoption of USCDI v4 as the USCDI standard to include data elements on treatment goals and preferences, among others. This update would make available more information that reflects the patient's understanding and involvement in their own care, helping to address disparities in health outcomes.
- Certification criteria and standards updates that would facilitate electronic prior authorization using certified Health IT Modules in real-time from a health care payer via standards-based APIs.
- Revising specific certification criteria to support the use of hyperlinks to access diagnostic images to promote more consistent and timely access to images for health care providers and for patients as part of their electronically available EHI.
- New certification criteria to enable the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and to identify coverage restrictions and alternatives when they exist via standards-based APIs.

EHR Reporting Program

Provision Reference: EHR Reporting Program – Section 4002(c) of the Cures Act

The Cures Act specified requirements in section 4002(c) to establish the EHR Reporting Program.

To develop the EHR Reporting Program, ASTP engaged the health IT community to identify measures that developers of certified health IT would be required to report on as a Condition and Maintenance of Certification under the Certification Program.[vi]

The HTI–1 Final Rule implements the EHR Reporting Program's health IT developer requirement outlined in the Cures Act by establishing a new Condition and Maintenance of Certification, referred to as the "Insights Condition."

The implementation of the Insights Condition will provide transparent reporting to address information gaps in the health IT marketplace and provide insights on the use of specific certified health IT functionalities.[vii]

Insights Condition and Maintenance of Certification

Provision Reference: EHR Reporting Program – Section 4002(c) of the Cures Act

The Insights Condition will allow ASTP and the health IT ecosystem to gain a better understanding of the use of health IT by providing data on key aspects of interoperability.

Health IT developers participating in the Certification Program are required to submit responses for the measures and related metrics if they meet the minimum reporting qualifications so as not to unduly disadvantage small and startup developers of certified health IT.

The HTI-1 Final Rule adopts seven measures emphasizing four areas of interoperability:

- **Individuals' access to EHI:** this area measures patients' access to their EHI overall, and by using different methods (e.g., apps and patient portals)
- **Public health information exchange:** this area measures the ability of certified Health IT Modules to exchange immunization information with immunization information systems
- **Clinical care information exchange:** this area evaluates the exchange of EHI between health care providers
- **Standards adoption and conformance:** this area examines the adoption and conformance of certified Health IT Modules to interoperability standards

ASTP also published measure specification sheets to provide a more accessible method for the public to view the technical specifications that support the Insights Condition requirements.

Certification of Health IT for Medical Subspecialties and Sites of Service

Provision Reference: Certification of Health IT for Medical Subspecialties and Sites of Service - Section 4001(b) of the Cures Act

ASTP supports the advancement of health IT across the care continuum, including providing resources for health care providers seeking health IT for specialty care and sites of service.[viii]

As directed by section 4001(b) of the Cures Act, ASTP continues to advance recommendations for the voluntary certification of health IT supporting maternal and pediatric care.

In response to the requirements set forth in section 4001(b) of the Cures Act, ASTP has:

- Developed recommendations for the voluntary certification of health IT for pediatric care, maternal health care, and other areas of focus for specialty care and practice settings
- Identified relevant Certification Program certification criteria
- Focused on non-regulatory initiatives that are nimble and responsive to industry, including the development of informational resources to support setting-specific implementation that aligns with the Certification Program

This information on maternal and pediatric health IT compiles relevant clinical priorities, certification functionality, supporting standards, and HHS programmatic resources into a comprehensive resource for clinicians and health IT developers to reference; and builds on the foundation of the ONC Cures Act Final Rule to improve the interoperability of health information for specialty care and sites of service.

Requirement Relating to Registries

Provision Reference: Requirement Relating to Registries – Section 4005(a) of the Cures Act

The Certification Program supports the adoption of standards, implementation specifications, and certification criteria for the interoperable transmission of EHI between clinician systems and clinical registries, including:

- **USCDI standard:** The USCDI standard establishes a core set of data elements and the related content or vocabulary standards for interoperable exchange across a wide range of systems, including between clinical systems and registries.
- **APIs and FHIR:** ASTP adopted standards – HL7 FHIR standard, the US Core Implementation Guide, and the Bulk FHIR implementation guide – to support interoperable exchange of EHI using APIs for individual patient data and bulk patient data across a wide range of settings. Standardized APIs allow for more dynamic data query, exchange, and aggregation across data sources supporting registry activities.
- **Clinical quality measure capture, calculate, report, and filter:** these certification criteria support certified Health IT Modules in identifying the data needed, calculating results, filtering results, and creating a report for electronic Clinical Quality Measure reporting under Medicare programs, including for use with qualified clinical data registries.

- **Public health certification criteria:** these criteria establish functional capabilities and related standards for the public health use cases (e.g., bi-directional immunization information exchange and bi-directional case reporting information exchange). ASTP has proposed certification criteria in HTI-2 for additional use cases for public health data exchange including capabilities to receive, parse, validate, and filter data received from reporter systems.

Health Information Exchange

Trusted Exchange Framework and Common Agreement™

Provision Reference: Support for Interoperable Exchange Network – Section 4003(b) of the Cures Act

Section 4003(b) of the Cures Act requires ASTP to convene public and private communities to develop or support a trusted exchange framework, including a common agreement, among health information networks nationally.

In January 2022, ASTP and The Sequoia Project, serving as the ASTP Recognized Coordinating Entity® (RCE™), released the Trusted Exchange Framework – a common set of principles for policies and practices to facilitate data sharing among health information networks (HINs), and Version 1 of the Common Agreement – the agreement that binds HINs to baseline governance, legal, and technical requirements for secure EHI sharing nationwide.

TEFCA has three goals:

1. To establish a universal governance, policy, and technical floor for nationwide interoperability
2. To simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value
3. To enable individuals to gather their health care information

ASTP released Version 2.0 of the Common Agreement in April 2024, which updates Common Agreement Version 1.1 and includes enhancements and updates to require support for HL7 FHIR-based transactions.

ASTP's recent report to Congress highlights additional details on TEFCA progress.

Implementing TEFCA

Provision Reference: Support for Interoperable Exchange Network – Section 4003(b) of the Cures Act

As of July 2024, there are seven designated Qualified Health Information Networks™ (QHINs™) that support and facilitate TEFCA exchange. Collectively, this set of QHINs covers most U.S. hospitals and tens of thousands of health care providers across the country. Since TEFCA became operational in December 2023, over one million total clinical documents have been exchanged among these QHINs. By working together under TEFCA's common rules of the road, the QHINs' users are now able to connect with each other, regardless of which network they are in.[ix]

In HTI-2, ASTP proposes to add a new part, part 172, to title 45 of the Code of Federal Regulations to implement certain provisions related to TEFCA. These provisions will establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA.

The proposals also cover the procedures governing QHIN onboarding and designation, suspension, termination, and administrative appeals to ASTP. ASTP proposes to adopt these provisions in regulation to support the reliability, privacy, security, and trust within TEFCA, which will support the ultimate success of TEFCA.

Advancing the Provider Digital Contact Information Index

Provision Reference: Provider Digital Contact Information Index – Section 4003(c) of the Cures Act

The ONC Cures Act Final Rule required, as a Condition of Certification, for all certified API developers to make publicly available the digital endpoints of all customer[x] API endpoints that support patient access requests.

ASTP also developed Lantern, a program to help ASTP monitor and publicly provide nationwide analytics about the availability and standardization of FHIR API service base URLs ("FHIR Endpoints") deployed by health care organizations. Lantern gathers information from FHIR Capability Statements returned by these endpoints and provides visualizations to show FHIR adoption and patient data availability.

To provide additional support, ASTP updated certification requirements in the HTI–1 Final Rule, to require certified API developers to use an adopted, standard format and process to publish the patient access endpoints by the end of 2024, which includes the organization's name, location, and facility identifier.

In the HTI-2 proposed rule, ASTP proposes requirements for existing and newly proposed API certification criteria to publish relevant endpoints using a standard format and process. This includes newly proposed certification criteria for patient, payer, and provider access to payer data.

Provider Digital Contact Information Index

Provision Reference: Provider Digital Contact Information Index - Section 4003(c) of the Cures Act

After the enactment of the Cures Act, CMS made enhancements to the National Plan and Provider Enumeration System to allow health care providers to add and update their digital contact information, including Direct addresses, facilitating better health information exchange.

Further efforts advancing the availability of provider information have included the CMS Interoperability and Patient Access Final Rule, which requires certain CMS-regulated health plans to make provider directory information publicly available via a FHIR API.

Additionally, the State Medicaid Agencies (SMA) Endpoint Directory was created to enhance interoperability by allowing SMAs and application developers to easily locate Provider Directory API endpoints. This enables developers to create applications that help patients find in-network providers within their Medicaid plans, providing essential details about participating health care providers and their contact information, specialty, and location. This Endpoint Directory helps SMAs comply with the requirements in 42 CFR 431.70 of the Interoperability and Patient Access Final Rule, which requires SMAs to implement an API that makes complete and accurate provider directory information available through a public-facing digital endpoint on the payer's website. Regulations required the provider directory information to be accessible by January 1, 2021[xi] and to be updated no later than 30 calendar days after the SMA receives the provider directory information or updates to provider directory information.[xii]

Information Blocking Definitions and Exceptions

Provision Reference: Information Blocking – Section 4004 of the Cures Act

Most clinical information is digitized, accessible, and shareable as a result of several technology and policy advances (like the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and Cures Act) that helped make interoperable, EHR systems widely available. The Cures Act also made sharing EHI[xiii] the expected norm in health care and authorized the Secretary of HHS to identify "reasonable and necessary activities that do not constitute information blocking."[xiv]

ASTP defined nine exceptions that offer actors certainty that, when their practices with respect to accessing, exchanging, or using EHI meet the conditions of one or more exceptions, such practices will not be considered information blocking.[xv]

The HTI-1 Final Rule information blocking provisions[xvi] added and updated definitions of certain terms and updated certain exceptions to support information sharing, in addition to adding a new "TEFCA Manner Exception." The new TEFCA Manner Exception supports reliance on secure, efficient, and standards-based methods for exchanging EHI among entities that are part of TEFCA. When the exception is met, an actor's

practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information to only via TEFCA will not be considered information blocking.[xvii]

Information Blocking Exceptions

Provision Reference: Information Blocking – Section 4004 of the Cures Act

The HTI-2 Proposed Rule proposes updates to two existing exceptions and proposes to establish two new exceptions, including:

- Revisions to existing exceptions that would expand application of the existing Privacy Exception to further support more actors' practices protecting the privacy of patients' health information and update the existing Infeasibility Exception to offer actors more clarity and more flexibility under certain conditions.
- Proposed new Protecting Care Access Exception that would, under specified conditions, cover actors' limiting EHI sharing to reduce a risk of potentially exposing patients, health care providers, or persons who facilitate care to legal action based on the mere fact that they sought, obtained, provided, or facilitated lawful reproductive health care.
- Proposed new Requestor Preferences Exception that would provide actors a framework under which they can be confident they will not be committing information blocking if they agree to a requestor's request in writing for restrictions on when, under what conditions, and how much EHI is made available to that requestor.

Information Blocking Oversight

Provision Reference: Information Blocking – Section 4004 of the Cures Act

ASTP has implemented a standardized process for the public to report claims of possible information blocking through the Information Blocking Portal since April 5, 2021. Over 1,000 claims were submitted to ASTP as of July 2024. ASTP reviews claims of possible information blocking against developers of certified health IT that may constitute a non-conformity under the Certification Program.

The Cures Act gave the HHS Office of Inspector General (OIG) authority to investigate claims of possible information blocking by health care providers, HINs and health information exchanges, and developers of certified health IT.[xviii]

In June 2023, OIG issued a final rule incorporating the Cures Act civil monetary penalty (CMP) authority for information blocking into CMP regulations. If OIG determines that a HIN, health information exchange, or developer of certified health IT has committed information blocking, the actor may be subject up to a $1 million penalty per violation.

In June 2024, CMS and ASTP issued the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule that establishes appropriate disincentives in certain CMS programs. These disincentives, which became effective on July 31, 2024, apply to health care providers that commit information blocking as determined through an investigation by OIG and for which OIG refers its determination to CMS. In the proposed rule, HHS requested comment on establishing appropriate disincentives for health care providers subject to the information blocking regulations that do not participate in the CMS programs included in the proposed rule and is considering the comments received for future rulemaking.

Promoting Patient Access through Rulemaking

Provision Reference: Use of Health Information Exchanges for Patient Access - Section 4006(a) of the Cures Act

Patients can better and more actively manage their health with better access to their EHI. HHS promoted interoperability of EHI through regulations released in tandem—the ONC Cures Act Final Rule and CMS Interoperability and Patient Access Final Rule.

The ONC Cures Act Final Rule supports patient access to their health information by:

- Enabling patients to securely access their EHI using smartphone applications of their choice through standardized APIs
- Emphasizing under the information blocking "fees exception" that an actor's practice of charging for the electronic access[xix] to EHI by a patient, their personal representative, or another person or entity designated by the patient, would be inherently suspect under an information blocking review
- Permitting actors regulated by the information blocking regulations to educate and advise individuals about privacy and security risks posed by third-party applications (apps), yet fully supporting a patient's right to choose which third-party service or app to share their EHI with—if at all

The HTI-1 Final Rule further supports patients by requiring developers certified to the "view, download, and transmit to 3rd party" certification criterion to support an "internet-based method" for patients to request a restriction on the use or disclosure of their data. The HTI-2 Proposed Rule that is currently available for public comment, aims to further advance patient access through a proposal to adopt a patient access application programming interface certification criterion that would advance the ability of payers to enable patient access to health and administrative information using a health application of their choice.

The CMS Interoperability and Patient Access Final Rule includes policies which require or encourage health care payers to implement APIs to improve the electronic exchange of health care data—sharing information with patients or exchanging information between a health care payer and provider or between two payers.[xx]

CMS also issued the CMS Interoperability and Prior Authorization Final Rule (CMS–0057–F), which requires impacted health care payers to implement and maintain certain HL7 FHIR APIs. These API policies will improve patient, health care provider, and payer access to interoperable patient data and reduce the burden of prior authorization processes.[xxi]

Promoting Patient Access

Provision Reference: Use of Health Information Exchanges for Patient Access – Section 4006(a) of the Cures Act

Recognizing the need to further educate patients on their HIPAA-protected right to access their EHI, ASTP and the HHS Office for Civil Rights (OCR) developed a Guide to Getting & Using Your Health Records to show patients and consumers how to get, check, use and share their EHI.

ASTP also partnered with OCR to create Your Health Information, Your Rights!, an educational infographic to help patients understand their right under the HIPAA Privacy Rule to get, check and use their health information.[xxii]

In addition, ASTP launched the Trusted Exchange Framework and Common Agreement (TEFCA). TEFCA enables network-to-network exchange and focuses on establishing a common set of expectations for how data can be accessed and securely shared via QHINs, which includes health information exchanges, networks, and others. Among its many benefits, it supports patients accessing their health care information through individual access services (IAS) connections and the care ecosystem.[xxiii]

Industry Coordination

Health IT Advisory Committee

Provision Reference: Health IT Advisory Committee – Section 4003(e) of the Cures Act

Established by the Cures Act, the Health IT Advisory Committee (HITAC) provides recommendations on policies, standards, implementation specifications, and certification criteria to the Assistant Secretary for Technology Policy/National Coordinator for Health IT.

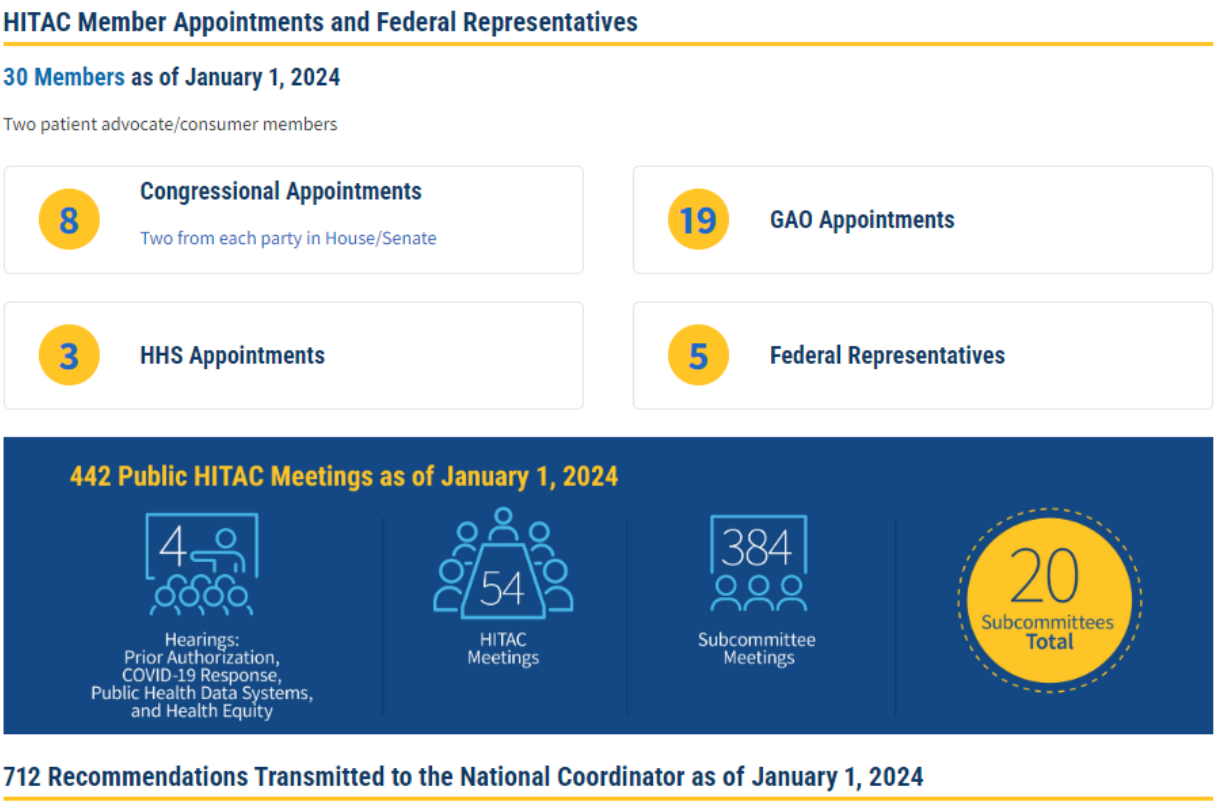
HITAC recommendations have focused on five target areas: Design and Use of Technologies that Advance Health Equity, Use of Technologies that Support Public Health, Interoperability, Privacy and Security, and Patient Access to Information.

ASTP establishes the objectives and benchmarks against which to measure the advancement of the target areas and inform the development of the HITAC Annual Report. ASTP has defined the benchmarks as progress in activities related to standards, certification, exchange, and coordination.

ASTP charged HITAC to annually convene the Annual Report Work Group to inform, contribute to, and review draft and final versions of the HITAC Annual Report.

Health IT Advisory Committee Members and Recommendations

Provision Reference: Health IT Advisory Committee – Section 4003(e) of the Cures Act



Priority Uses of Health Information Technology

Provision Reference: Priorities for Adoption of Standards, Implementation Specifications, and Certification Criteria - Section 4003(f) of the Cures Act

The Cures Act requires the HITAC, in collaboration with the National Institutes of Standards and Technology, to annually review and publish priorities for the use of health IT, standards, and implementation specifications to support those priorities.

To meet this requirement, ASTP convened HITAC from 2018 - 2021 through the Interoperability Standards Priorities Task Force (ISP Task Force) and the USCDI Task Force. In 2022, ASTP merged these efforts into the Interoperability Standards Workgroup (IS Workgroup). The IS Workgroup convenes annually to review and provide recommendations to ASTP on interoperability standards.

HITAC provided over 200 recommendations to ASTP on priority uses of health IT and related standards, implementation specifications, and certification criteria from 2018 – 2024. These recommendations continue to inform updates to the Certification Program, including the USCDI standard, public health data exchange, real-time benefits check, and electronic prior authorization.

Adopted Standards and Implementation Specifications

Provision Reference: Setting Priorities for Standards Adoption – Section 4003(f) of the Cures Act

The Cures Act requires ASTP to convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to:

- Maintain the use of such standards and implementation specifications
- Phase out such standards and implementation specifications

To meet these requirements, ASTP charged HITAC to convene the Adopted Standards Task Force, consisting of HITAC members and other relevant experts. In September 2022, HITAC transmitted its recommendations to the Assistant Secretary for Technology Policy (dually titled as the National Coordinator for Health IT).

In addition to review of the adopted standards and implementation specifications referenced in the ONC Cures Act Final Rule, the Adopted Standards Task Force reviewed Standards Version Advancement Process, Interoperability Standards Advisory, and Standards Development Organizations' current published standards as input to their recommendations.

ASTP maintains the current set of standards and implementation specifications referenced by ASTP regulations on the ONC Standards Hub.[xxiv] The Cures Act requires ASTP repeat this process every three years. ASTP plans to charge HITAC in 2025 to fulfill this requirement.

Patient Safety Best Practices

Provision Reference: Treatment of Health Information Technology Developers with Respect to Patient Safety Organizations – Section 4005(c) of the Cures Act

The Cures Act requires the Secretary of HHS to submit a report concerning best practices and current trends voluntarily provided[xxv] by Patient Safety Organizations (PSOs)[xxvi] to improve the integration of health IT into clinical practice.

ASTP has been coordinating with the Agency for Healthcare Research and Quality (AHRQ) to seek voluntary PSO submissions highlighting best practices related to improving the integration of health IT into clinical practice. After analysis of those submissions, ASTP and AHRQ report the below best practices and trends that PSOs identified to improve patient safety within clinical care delivery.

Problem Addressed	Best Practice
1. Ensuring that health IT safety is a shared responsibility throughout my organization	Convening health IT developers, implementers, and users in a safe environment to establish and nurture a culture of safety
2. Health IT alarm fatigue	Creating institutional policies to coordinate optimal clinical IT alerts
3. Opioid prescription overuse	Optimizing postoperative analgesic opioid prescribing using health IT to inform process improvements and health care provider feedback
4. Assessing institutional health IT optimization to avoid safety events	Using institutional malpractice claims to create an institutional safety assessment and tailored specific health IT mitigation strategies
5. Minimizing diagnostic error	Using six health IT strategies for improving test tracking for diagnostic tests and minimizing patient information falling through the cracks
6. Real-time changes in individual patient safety	Analyzing real-time clinical information to create individual dynamic patient safety risk assessments

Patient Safety Trends

Provision Reference: Treatment of Health Information Technology Developers with Respect to Patient Safety Organizations – Section 4005(c) of the Cures Act

PSOs work with health care providers, health IT developers, and others to adopt effective practices to improve care quality and safety through integration of health IT with clinical practice. Some PSOs that focus on the intersection of health IT and safety have identified the following trends:

- **Challenges with Home-Use Medical Devices:** The increasing complexity of home-based health care and the growing use of medical devices by patients and caregivers without adequate training pose significant risks. This trend highlights the need for better education and support for patients using medical devices at home.
- **Increased Adoption of AI in Health Care:** Increased adoption of AI tools in health care presents promising opportunities and also requires a comprehensive approach to monitoring and guiding its responsible use. Concerns about biased algorithms, cybersecurity threats, and unintended consequences of AI applications are rising. Some PSOs have emphasized the need for robust governance and security measures to ensure patient safety and data privacy. Responsive to such concerns, Executive Order (EO) 14110 (October 30, 2023), entitled the "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence" calls for a robust governance structure and "developing and helping to ensure the availability of testing environments, such as testbeds, to support the development of safe, secure, and trustworthy AI technologies." The EO further calls for the establishment of "a common framework for approaches to identifying and capturing clinical errors resulting from AI deployed in healthcare settings as well as specifications for a central tracking repository for associated incidents that cause harm, including through bias or discrimination, to patients, caregivers, or other parties."
- **Diagnostic Errors and Health IT:** Health IT can both contribute to and help prevent diagnostic errors. PSOs have highlighted the complexity of this issue and the need for further research and development of tools to support accurate diagnosis.

Throughout the broader patient safety community, the foundational pillars of preventing patient harm in the complex sociotechnical environment of an IT-enabled health care delivery system emphasizes culture, leadership, patient engagement, learning systems, and workforce well-being. Health IT plays a critical role in supporting these foundational drivers of safety, enabling better communication, collaboration, and data-driven decision-making.

Remaining Interoperability Gaps

Despite the substantial progress made through the Cures Act, several gaps persist. These gaps hinder the full realization of seamless, nationwide interoperability within the health care system.

Gap	Addressing Gap
Information Blocking: Various practices that may be neither required by law nor covered by an information blocking exception continue to impede the seamless sharing of health information, which may inhibit the appropriate exchange, access, and use of EHI. HHS does not have the authority to issue binding advisory opinions on whether a practice would be information blocking according to a specific set of facts and circumstances.	Binding advisory opinions would offer more timely and direct clarity to requesting parties about the legality of their practices before operationalizing them, providing a clear path to compliance, and would further support both requestors and other users of health IT to exchange EHI more seamlessly and avoid engaging in information blocking.
Data Segmentation of Sensitive Health Data: Under the HIPAA Privacy Rule, covered entities, as defined in 45 CFR 160.103, are required to allow individuals to request a restriction on the use or disclosure of their PHI for treatment, payment, or health care operations, and certain other disclosures, such as disclosures made to family members of persons involved in the individual's care. HIPAA does not specify a particular process to be used by individuals to make such requests or for the entity to accept or deny the request. A technical means can be used to enable individuals to request a restriction on their data. ASTP certifies capabilities of Health IT Modules to perform specific functions in many circumstances using specific standards (e.g., data tagging to enable segmentation activities). These are generally restricted to technical standards and capabilities. The user of the technology may also need to comply with certain requirements established by federal, state, territory, local or tribal law, which may require particular requirements for processing.	In the HTI-1 Proposed Rule (see, for example, 88 FR 23821), ASTP proposed requirements for certified Health IT Modules to support workflows and expand the capabilities of health IT to enable covered entities to execute processes to honor an individual exercised right to request restriction of uses and disclosures under the HIPAA Privacy Rule. ASTP ultimately decided not to finalize these proposals after considering public comments with respect to the significant concerns regarding implementation feasibility. ASTP adopted a proposed update for internet-based requests that would allow patients to submit restriction requests electronically. However, without additional clarity on the requirements for processing and honoring such requests, and significant additional standards development work, there are still major challenges to automated privacy workflows. In particular, there are persistent technology gaps between the ability to identify a necessary or approved restriction and the application of appropriate security labels, as well as between the identification of valid security labels and the appropriate disposition of the information. See discussion in HTI-1 Final Rule 89 FR 1298-1305.

Gap	Addressing Gap
Registries: While ASTP adopted standards and certification criteria can advance requirements for technologies capable of interoperable exchange between systems – including as it relates to registry systems and HIPAA covered entities or business associates – ASTP authority to require registries to adopt and use such technologies and standards is limited.	ASTP is working within HHS and with HHS partners, such as CDC grant programs and CMS quality programs, to streamline registry requirements with the goal of achieving a consistent set of requirements for registries to advance the use of interoperable healthcare standards. Use of interoperable content, vocabulary, and exchange standards for health IT enables interoperable exchange of health information between and across disparate systems (e.g., healthcare providers, registries, researchers, quality improvement organizations, public health agencies, and even patients). This is an essential step to removing data silos and ensuring that essential health information can be aggregated, parsed, and used to improve outcomes for patients. This work is ongoing.
TEFCA: Despite robust initial interest and participation in TEFCA, some health care providers and networks remain unaware or unsure about TEFCA. Many of these entities, like rural hospitals and state health information exchange organizations, are a lifeline to patients and health care organizations across the country but lack the resources or sufficient information to participate.[xxvii] Additional participation in TEFCA will improve interoperability and access to information for a wider population of providers and patients.	Technical assistance for navigating the onboarding process and grants to health care providers and networks to make the necessary investments to join TEFCA may be needed to ensure all Americans are connected to their health data.
APIs: Standards-based APIs are now the default for all developers of certified health IT and are a common way digital health companies integrate their technology with EHRs;[xxviii] however, the costs and effort for companies to complete these integrations remain high. Although current authority allows ASTP to regulate how these companies, to the extent they participate in the ONC Health IT Certification Program, can connect and securely access real patient data, availability of standardized test data to support access and integration remains limited.	Increase coordination around the availability of standardized test data to potential integrators to foster consistency across testing and real production environments. This harmonization would streamline the integration process and ensure greater interoperability from the start.

Gap	Addressing Gap
EHR Reporting Program: While ASTP has been able to implement the first set of measures that developers of certified health IT are required to report on (Insights Condition), ASTP has not yet been able to implement the voluntary user-reported measures.	Data collection from both developers of certified health IT, and voluntary user-reported measures would improve the transparency and quality of health IT in the marketplace, as well as help better understand the interoperability, usability, and security of certified health IT.

Monitoring Implementation Progress on the Cures Act Interoperability Provisions

ASTP annually updates Congress by describing actions taken by the federal government, barriers, and recommendations to achieve a nationwide system for the access, exchange, and use of EHI.

ASTP intends to prioritize the following areas for measuring progress related to the interoperability provisions of the Cures Act:

- **USCDI:** Adoption and use of a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange
- **Certified Health IT:** Widespread use of modern health IT capabilities certified through the Certification Program, focusing on:
  - Standardized APIs for patient and population services
  - EHI export for a single patient and for an entire patient population
  - DSI information to improve transparency on how a predictive DSI was designed, developed, trained, evaluated, and should be used
  - EHI exchange between providers and public health agencies and between providers and payers
  - Support for electronic prior authorization in real-time using certified health IT
  - Real-time prescription benefit tools for informed decision-making at the point of care
- **TEFCA:** Qualified Health Information Networks support secure EHI exchange for the purposes of treatment, payment, health care operations, public health, government benefits determination, and individual access services
- **Information Sharing Consistent with the Information Blocking Regulations:** Health information is appropriately exchanged across care settings, and information blocking conduct is reduced or eliminated

Appendix: References

[i] The Conditions and Maintenance of Certification requirements are defined in Subpart D of the Cures Act Final Rule. Compliance dates have been updated per the Interim Final Rule, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency.

[ii] Certification Program Regulations. https://www.healthit.gov/topic/certification-ehrs/certification-program-regulations

[iii] Criteria Updates Quick Reference: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule. https://www.healthit.gov/sites/default/files/2024-03/HTI-1_Quick_Reference_2024_508.pdf

[iv] Three categories of "actors" are regulated by the information blocking section of the ONC Cures Act Final Rule, including health care providers, health information networks or health information exchanges, and health IT developers of certified health IT.

[v] HTI-1 At-A-Glance Fact Sheet: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule. https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_At-A-Glance_fact%20sheet_508.pdf

[vi] Detailed background and history on the overall process, and the Urban Institute's reports, can be found in the April 18, 2023 Proposed Rule, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. https://www.federalregister.gov/citation/88-FR-23832

[vii] HTI-1 Overview Fact Sheet: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule. https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_Gen-Overview_factsheet_508.pdf

[viii] Health IT in Health Care Settings. https://www.healthit.gov/topic/health-it-health-care-settings/health-it-health-care-settings

[ix] 2023 Report to Congress: Update on the Access, Exchange, and Use of Electronic Health Information through Trusted Networks. https://www.healthit.gov/sites/default/files/page/2024-04/2023-HITECH_Report_to_Congress.pdf

[x] users of EHRs/health IT, like health care providers and health systems

[xi] CMS previously announced it would not enforce this requirement prior to July 1, 2021.

[xii] Implementation of the CMS Interoperability and Patient Access Final Rule and Compliance with the ONC 21st Century Cures Act Final Rule. https://www.medicaid.gov/federal-policy-guidance/downloads/sho20003.pdf

[xiii] consistent with patients' privacy preferences and applicable law

[xiv] Information Blocking. https://www.healthit.gov/topic/information-blocking

[xv] Cures Act Final Rule Information Blocking Exceptions. https://www.healthit.gov/sites/default/files/2024-04/IB_Exceptions_Fact_Sheet_508_0.pd

[xvi] HTI-1 Information Blocking Fact Sheet: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule. https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_IB_factsheet_508.pdf

[xvii] HTI-1 Information Blocking Fact Sheet: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_IB_factsheet_508.pdf

[xviii] Information Blocking. https://www.healthit.gov/topic/information-blocking

[xix] Electronic access means an internet-based method that makes electronic health information available at the time the electronic health information is requested and where no manual effort is required to fulfill the request.

[xx] CMS Interoperability and Patient Access Final Rule (CMS-9115-F). https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-patient-access-final-rule-cms-9115-f

[xxi] CMS Interoperability and Prior Authorization Final Rule CMS-0057-F. https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f

[xxii] Your Rights Under HIPAA. https://public3.pagefreezer.com/browse/HHS.gov/22-12-2022T07:33/https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html

[xxiii] TEFCA for Individuals - Individuals can access their health information via TEFCA. https://rce.sequoiaproject.org/rce-tefca-for-individuals/

[xxiv] Final Report of the Health Information Technology Advisory Committee on ONC Adopted Standards and Implementation Specifications. https://www.healthit.gov/sites/default/files/page/2022-10/2022-09-14_ONC_Adopted_Standards_and_Implementation_Specifications_Transmittal_Letter_508.pdf

[xxv] This requirement must be met without identifying individual providers or disclosing or using protected health information or individually identifiable information.

[xxvi] PSOs serve as independent, external experts who collect and analyze data voluntarily reported by health care providers to help improve patient safety and health care quality.

[xxvii] TEFCA Awareness and Planned Participation Among U.S. Hospitals: 2023. https://www.healthit.gov/data/data-briefs/tefca-awareness-and-planned-participation-among-us-hospitals-2023. ONC Data Brief No. 72, July 2024.

[xxviii] Wesley Barker, Natalya Maisel, Catherine E Strawley, Grace K Israelit, Julia Adler-Milstein, Benjamin Rosner, A national survey of digital health company experiences with electronic health record application programming interfaces, *Journal of the American Medical Informatics Association*, Volume 31, Issue 4, April 2024, Pages 866–874, https://doi.org/10.1093/jamia/ocae006