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**Texas Department of State
Health Services**

Office of the National Coordinator for Health Information Technology: A Primer

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Presentation Overview

- A Brief History of the Office of the National Coordinator (ONC)
- Interoperability Standards
 - United States Core Data for Interoperability
- Trusted Exchange Framework and Common Agreement (TEFCASM)
- Health Information Technology Certification
- Information Blocking
- Artificial Intelligence
- Health Information Technology Advisory Committee
- Discussion and Questions

Office of the National Coordinator- Origins and Background

- Created by Executive Order 13335, signed by President George W. Bush in April 2004.
- Established within the federal Department of Health and Human Services (HHS).
- Charged with “Fulfilling its responsibilities...consistent with a vision of developing a nationwide interoperable health information technology infrastructure...”
- In 2005, investments led to new partnerships and standards development that furthered interoperable health IT.
- Federal Health IT Strategic Plan 2008-2012 was the first national health IT plan.
- The Health Information Technology for Economic and Clinical Health HITECH Act codified ONC in statute and advanced the healthcare system through the adoption and meaningful use of health information technology.

ONC's Program Initiatives

- State Health Information Exchange Cooperative Agreement
- Regional Extension Centers supported small providers' health IT adoption
- Beacon Communities
- The Workforce Development Program
- Health Equity
- Privacy and Security
- Patient Access to Information
- Artificial Intelligence
- Rulemaking and Regulatory Activities
 - Health IT Certification and "Meaningful Use"
 - Standards & Interoperability (S&I)
 - Information Blocking

Interoperability Standards



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Interoperability Standards as a Foundation

- Early recognition that the adoption and utilization of shared standards is a foundational component
- Four key aspects:
 - Agreement on terminology
 - Agreement on syntax
 - Technology support for operationalizing interoperability
 - Security

ONC's Interoperability Standards Advisory (ISA)

- Available at <https://www.healthit.gov/isa/>.
- The ISA process represents ONC's model for the Activities identification, assessment, and determination of "recognized" interoperability standards and implementation specifications for industry use to address health IT interoperability needs.
- Catalog of interoperability standards.
- The ISA is a “living” document.
- An annual reference version has been historically published.

ISA Organization

The ISA has four sections

- Vocabulary/Code Sets/Terminology Standards and Implementation Specifications (i.e., “semantics”).
- Content/Structure Standards and Implementation Specifications (i.e., “syntax”).
- Standards and Implementation Specifications for Services and Exchange (i.e., the infrastructure components deployed and used to address specific interoperability needs)
- Administrative Standards and Implementation Specifications (i.e., payment, operations and other "non-clinical" interoperability needs)

<https://www.healthit.gov/isa/isa-structure>

United States Core Data for Interoperability (USCDI) and USCDI+



What is the USCDI?

- The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.
- A USCDI *Data Class* is an aggregation of Data Elements by a common theme or use case.
- A USCDI *Data Element* is a piece of data defined in USCDI for access, exchange or use of electronic health information.
- <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>

USCDI v3 Deeper Dive

USCDI v3



Allergies and Intolerances <ul style="list-style-type: none"> <input type="checkbox"/> Substance (Medication) <input type="checkbox"/> Substance (Drug Class) <input type="checkbox"/> Reaction 	Clinical Tests <ul style="list-style-type: none"> <input type="checkbox"/> Clinical Test <input type="checkbox"/> Clinical Test Result/Report 	Health Status/ Assessments <ul style="list-style-type: none"> <input type="checkbox"/> Health Concerns <input type="checkbox"/> Functional Status <input type="checkbox"/> Disability Status <input type="checkbox"/> Mental Function <input type="checkbox"/> Pregnancy Status <input type="checkbox"/> Smoking Status 	Patient Demographics/ Information <ul style="list-style-type: none"> <input type="checkbox"/> First Name <input type="checkbox"/> Last Name <input type="checkbox"/> Middle Name (Including middle initial) <input type="checkbox"/> Name Suffix <input type="checkbox"/> Previous Name <input type="checkbox"/> Date of Birth <input type="checkbox"/> Date of Death <input type="checkbox"/> Race <input type="checkbox"/> Ethnicity <input type="checkbox"/> Tribal Affiliation <input type="checkbox"/> Sex <input type="checkbox"/> Sexual Orientation <input type="checkbox"/> Gender Identity <input type="checkbox"/> Preferred Language <input type="checkbox"/> Current Address <input type="checkbox"/> Previous Address <input type="checkbox"/> Phone Number <input type="checkbox"/> Phone Number Type <input type="checkbox"/> Email Address <input type="checkbox"/> Related Person's Name <input type="checkbox"/> Related Person's Relationship <input type="checkbox"/> Occupation <input type="checkbox"/> Occupation Industry 	Procedures <ul style="list-style-type: none"> <input type="checkbox"/> Procedures <input type="checkbox"/> SDOH Interventions <input type="checkbox"/> Reason for Referral
Assessment and Plan of Treatment <ul style="list-style-type: none"> <input type="checkbox"/> Assessment and Plan of Treatment <input type="checkbox"/> SDOH Assessment 	Diagnostic Imaging <ul style="list-style-type: none"> <input type="checkbox"/> Diagnostic Imaging Test <input type="checkbox"/> Diagnostic Imaging Report 			Provenance <ul style="list-style-type: none"> <input type="checkbox"/> Author Organization <input type="checkbox"/> Author Time Stamp
Care Team Member(s) <ul style="list-style-type: none"> <input type="checkbox"/> Care Team Member Name <input type="checkbox"/> Care Team Member Identifier <input type="checkbox"/> Care Team Member Role <input type="checkbox"/> Care Team Member Location <input type="checkbox"/> Care Team Member Telecom 	Encounter Information <ul style="list-style-type: none"> <input type="checkbox"/> Encounter Type <input type="checkbox"/> Encounter Diagnosis <input type="checkbox"/> Encounter Time <input type="checkbox"/> Encounter Location <input type="checkbox"/> Encounter Disposition 	Immunizations <ul style="list-style-type: none"> <input type="checkbox"/> Immunizations 		Unique Device Identifier(s) for a Patient's Implantable Device(s) <ul style="list-style-type: none"> <input type="checkbox"/> Unique Device Identifier(s) for a patient's implantable device(s)
Clinical Notes <ul style="list-style-type: none"> <input type="checkbox"/> Consultation Note <input type="checkbox"/> Discharge Summary Note <input type="checkbox"/> History & Physical <input type="checkbox"/> Procedure Note <input type="checkbox"/> Progress Note 	Goals <ul style="list-style-type: none"> <input type="checkbox"/> Patient Goals <input type="checkbox"/> SDOH Goals 	Laboratory <ul style="list-style-type: none"> <input type="checkbox"/> Test <input type="checkbox"/> Values/Results <input type="checkbox"/> Specimen Type <input type="checkbox"/> Result Status 		Vital Signs <ul style="list-style-type: none"> <input type="checkbox"/> Systolic blood pressure <input type="checkbox"/> Diastolic blood pressure <input type="checkbox"/> Heart Rate <input type="checkbox"/> Respiratory rate <input type="checkbox"/> Body temperature <input type="checkbox"/> Body height <input type="checkbox"/> Body weight <input type="checkbox"/> Pulse oximetry <input type="checkbox"/> Inhaled oxygen concentration <input type="checkbox"/> BMI Percentile (2 - 20 years) <input type="checkbox"/> Weight-for-length Percentile (Birth - 24 Months) <input type="checkbox"/> Head Occipital-frontal Circumference Percentile (Birth - 36 Months)
	Health Insurance Information <ul style="list-style-type: none"> <input type="checkbox"/> Coverage Status <input type="checkbox"/> Coverage Type <input type="checkbox"/> Relationship to Subscriber <input type="checkbox"/> Member Identifier <input type="checkbox"/> Subscriber Identifier <input type="checkbox"/> Group Number <input type="checkbox"/> Payer Identifier 	Medications <ul style="list-style-type: none"> <input type="checkbox"/> Medications <input type="checkbox"/> Dose <input type="checkbox"/> Dose Units of Measure <input type="checkbox"/> Indication <input type="checkbox"/> Fill Status 	Problems <ul style="list-style-type: none"> <input type="checkbox"/> Problems <input type="checkbox"/> SDOH Problems/Health Concerns <input type="checkbox"/> Date of Diagnosis <input type="checkbox"/> Date of Resolution 	

★ New Data Classes and Elements
 ★ Data Element Reclassified
 ★ Name and Other Changes to Existing Data Classes/Elements

USCDI Information

- USCDI v3 *must* be utilized by January 1, 2026.
 - Users *may* utilize v3 today.
 - Version 1 is the required minimum for today's use.
- USCDI Version 5 is being finalized now and is expected to be released later this summer
- USCDI *facilitates* data exchange, US Core provides the technical standards regarding how to achieve it.
- Maintained in ONDEC, ONC's standard maintenance and commenting tool.
- Recognized in regulation.

USCDI Plus (USCDI+)

- USCDI+ is a companion/extension to USCDI.
- The USCDI+ initiative supports the identification and establishment of domain or program-specific data element lists that operate as extensions to the existing USCDI. USCDI+ is a service ONC provides to federal and industry partners to establish, harmonize, and advance the use of interoperable data element lists that extend beyond the core data in the USCDI in order to meet specific programmatic and/or use case requirements.
- takes things one step further by facilitating domain or program-specific data element lists as extensions to USCDI. ONC is advancing this initiative in the Public Health and in the Quality Measurement domain categories, and as a service to federal and industry partners.

Specific Standards and Definitions Updates in HTI-1

- United States Core Data for Interoperability (USCDI) Version 3 (v3)
 - *Must* utilize v3 by January 1, 2026; *May* utilize today (Version 1 required minimum).
 - USCDI Version 5 is being finalized now.
- C-CDA Companion Guide Release 4.1
- US Core Implementation Guide 6.1.0
- “Minimum Standards” Code Sets Updates
 - LOINC Database version 2.72, February 16, 2022; NDC – Vaccine NDC Linker, updates through July 19, 2022; CDC Race and Ethnicity Code Set Version 1.2 July 2021; RxNorm July 5, 2022.
 - Developers of certified health IT may use newer versions of these adopted standards on a voluntary basis.
- Electronic Case Reporting (§ 170.315(f)(5))

Trusted Exchange Framework and Common Agreement (TEFCASM)



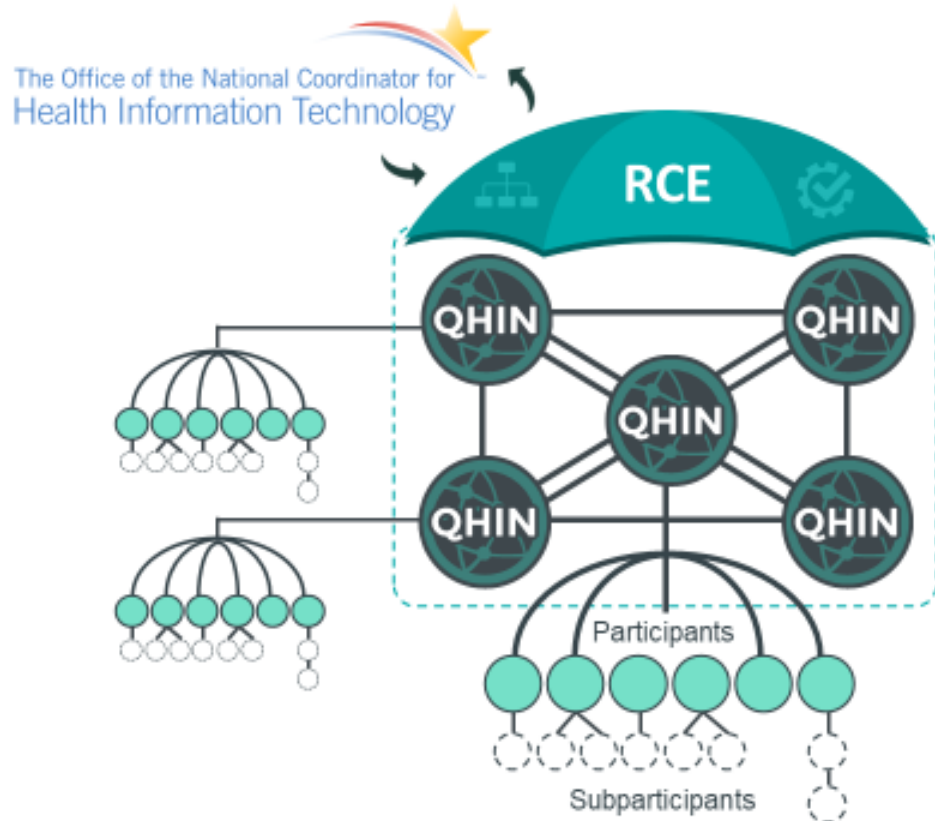
TEFCASM Defined

“The Trusted Exchange Framework and Common AgreementSM, also known as TEFCASM, outlines a common set of principles, terms, and conditions to support the development of a Common Agreement that helps enable the nationwide exchange of electronic health information (EHI) across disparate health information networks (HINs).”

[https://rce.sequoiaproject.org/tefca/#:~:text=The%20Trusted%20Exchange%20Framework%20and%20Common%20Agreement%E2%84%A0%2C%20also%20known,health%20information%20networks%20\(HINs\)](https://rce.sequoiaproject.org/tefca/#:~:text=The%20Trusted%20Exchange%20Framework%20and%20Common%20Agreement%E2%84%A0%2C%20also%20known,health%20information%20networks%20(HINs))

Data Exchange Through TEFCASM

How will exchange work under TEFCA?



← ONC defines overall policy and certain governance requirements.

← RCE provides oversight and governing approach for QHINs.

← Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.

← Each QHIN connects Participants, which connect Subparticipants.

TEFCASM Goals

➤ Goal 1

- Establish a universal governance, policy, and technical floor enabling the nationwide exchange of health data.

➤ Goal 2

- Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.

➤ Goal 3

- Enable individuals to gather their health care information.

Key TEFCASM Terms

- Common Agreement
- Responsible Coordinating Entity (RCE)
- Qualified Health Information Network (QHIN)
- QHIN Technical Framework (QTF)
- Exchange Purposes/Permitted Use
- Standard Operating Procedure (SOP)
- Flow-down provisions
- Participant
- Sub-participant
- Public Health Authority (PHA)
- Principal
- Delegate
- Hybrid

TEFCASM Components/Dependencies



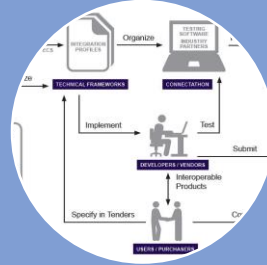
Trusted
Exchange
Framework



Common
Agreement



Standard
Operating
Procedures



QHIN Technical
Framework



Metrics



Governance

TEFCASM Timeline

- 2016- TEFCA development included in 21st Century Cures Act
- 2018- Office of the National Coordinator released Common Agreement (CA) v1 Draft 1
- 2019 (April)- ONC released CA v1 Draft 2
- 2019 (August)- ONC contracted with The Sequoia Project as the RCE
- 2021 (August)- RCE and ONC released draft QTF v1 and elements of the Common Agreement
- 2023 (February)- First applications accepted for testing
- 2023 (December)- TEFCA released into production
- 2024 (January)- RCE released Common Agreement v2 Draft 1

The TEFCASM Operating Environment

- **Authorized Exchange Purposes**

- Health Care Treatment
- Payment
- Health Care Operations
- Individual Access Services
- Government Benefits Determination
- Public Health

- **Document-Based Exchange**

- Clinical Document Architecture (CDA) document
- HL7 V2.x message (lab order/result, Immunization registry report, etc.)
- FHIR Transactions (under Version 2)

- **Exchange Modalities**

- QHIN Query (Patient Discovery and Document Query & Retrieve) (Pull)
- QHIN Message Delivery (Push)

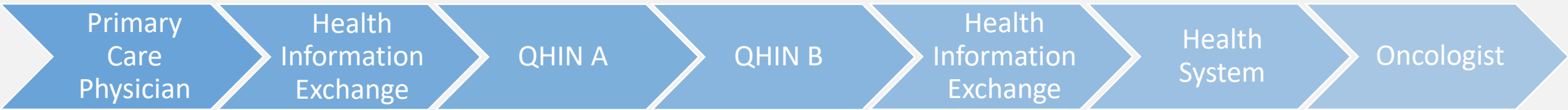
- **Participant Directories**

- **TEFCA Agreement Version 2 Released**

- **Support for Fast Healthcare Interoperability Resources (FHIR)**

TEFCASM Data Exchange Example

Treatment Purpose



Information Blocking



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Information Blocking Overview

- Statutory basis provided in 21st Century Cures Act.
- Regulatory framework is managed by ONC.
- Affected entities include HIT developers of certified health IT, those that “offer HIT,” health care providers, health information exchanges, and other identified entities.
- Regulations establish exceptions where information blocking may be allowable.
- Penalties for HIT developers/providers may be up to \$1,000,000 per incident.
- Penalties for health care providers include reduction in scores within the Promoting Interoperability programs that can reduce reimbursements under Medicare.
- Enforcement began September 2023.

Information Blocking Exceptions

- Preventing Harm Exception
 - It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met
- Privacy Exception
 - It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.
- Security Exception
 - It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.
- Infeasibility Exception
 - It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met
- Health IT Performance Exception
 - It will not be information blocking for an actor to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met

More Information Blocking Exceptions

- Licensing
 - It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met
- Fees
 - It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.
- Manner Exception
 - An actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information will not be considered information blocking when the practice follows certain conditions.
- TEFCA Manner Exception
 - The “TEFCA Manner” Exception applies where an actor and requestor are both part of TEFCA. Where the exception is met, an actor’s practice of fulfilling certain requests for access, exchange, or use of EHI only via TEFCA will not be considered information blocking.

Certification of Health Information Technologies



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About ONC Health IT Certification

- ONC's Health IT Certification Program is composed of functional requirements known as “certification criteria.”
- Developers certify their Health IT Modules by demonstrating conformance to these certification criteria, using test procedures (that may have associated test tools and/or test data) approved by the National Coordinator.
- A Health IT Module presented for certification must meet criteria as outlined in regulation that relate to privacy, security, design, and performance requirements for the Health IT Module. See the [Master Table of Related and Required Criteria](#).
- A list of certified technologies is maintained at <https://chpl.healthit.gov/#/resources/overview#main-content>.

HTI-1 Changes in HIT Module Certification

- Transition of themed editions (e.g., 2015 Edition) to an evolving single catalog of certification criteria, “ONC Certification Criteria for Health IT.”
- Establishes timeline for expiration dates for prior versions of a criterion when a revised version of the criterion is adopted.
- Impacts
 - *Ensuring all parties are cognizant of then-current requirements may be challenging.*
 - *Adherence to implementing support for changing criterion in a timely manner is critical.*

Conditions and Maintenance of Certification Requirements

- Federal regulations impact HIT developers
 - Provide assurances that the HIT developer will not take any action that constitutes information blocking, or any other action that may inhibit the appropriate exchange, access, and use of electronic health information.
 - Not take any action to interfere with a user's ability to access or use certified capabilities,
 - A health IT developer may not prohibit or restrict communication regarding the following subjects for Certified Health IT Modules:
 1. The usability of its health IT,
 2. The interoperability of its health IT,
 3. The security of the health IT,

<https://www>

[.healthit.gov/topic/certification-ehrs/conditions-maintenance-certification](https://www.healthit.gov/topic/certification-ehrs/conditions-maintenance-certification)

Enhancing Interoperability through Expansion of HIT Certification Requirements

- There is increasing recognition of interoperability issues because not all parties are using HIT that is certified/meets certification requirements.
- Requirements to use CEHRT are limited to select Medicare provider types.
- There are no federal requirements for any Medicaid provider to use certified HIT technology.
- Development of a technology certification program for Clinical Laboratory Improvement Amendments (CLIA) laboratories is under consideration.
- Development of a technology certification program for public health data systems is under consideration.

Health Information Technology and Artificial Intelligence (AI)



Artificial Intelligence (AI) and Health Information Technology

- **HTI-1 addresses AI**
 - **Algorithm Transparency** requirements for the artificial intelligence (AI) and other predictive algorithms that are part of certified health IT.
 - HHS' leading-edge regulatory approach will promote responsible AI and make it possible for clinical users to access a consistent, baseline set of information about the algorithms they use to support their decision making and to assess such algorithms for fairness, appropriateness, validity, effectiveness, and safety.
- Equity implications

Health Information Technology Advisory Committee



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About the Health Information Technology Advisory Committee

- Established by the 21st Century Cures Act (P.L. 114-255)
- Governed by the provisions of the Federal Advisory Committee Act (FACA), P.L. 92-463, as amended (5 U.S.C. App. 2).
- The HITAC will recommend to the National Coordinator for Health Information Technology policies, standards, implementation specifications, and certification criteria relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information.
- HITAC replaces the Health Information Technology Policy Committee and the Health Information Technology Standards Committee.

<https://www.healthit.gov/hitac/committees/health-information-technology-advisory-committee-hitac>

Health Information Technology Advisory Committee Overview

Recent Accomplishments

- Review and make recommendations on the HTI-1 Proposed Rule.
- Review and make recommendations regarding draft USCDI prior to finalization.
- Continuing to evaluate the needs of public health data systems.
- Exploring ways to improve pharmacy interoperability.

Subcommittees/Work Groups/Task Force Examples

- Annual Report Workgroup.
- HTI-1 Proposed Rule Task Force.
- Interoperability Standards Workgroup.
- Pharmacy Interoperability and Emerging Therapeutics Task Force.
- Public Health Data Systems Task Force.

See <https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it>

HITAC Annual Workgroup Charges

Overarching Charge:

The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the Secretary of Health and Human Services and to Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.

Specific Charge:

Provide specific feedback on the content of the report as required by the 21st Century Cures Act including:

- Analysis of HITAC progress related to the target areas
- Assessment of health IT infrastructure and advancements in the target areas
- Analysis of existing gaps in policies and resources for the target areas
- Ideas for potential HITAC activities to address the identified gaps

Annual Report Workgroup Topic Areas



Interoperability:

Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information



Privacy and Security:

The promotion and protection of privacy and security of health information in health IT



Patient Access to Information:

The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information



Use of Technologies that Support Public Health:

The facilitation of bidirectional information sharing between the clinical and public health communities



Design and Use of Technologies that Advance Health Equity:

Applying health information technology to help all people attain their full health potential

Other Topics Addressed in HTI-1

- Artificial Intelligence and Computer Decision Support Integration
- Patient Preferences in Restricting Data Disclosures
- Insights Condition: Measuring EHR use
 - Measure 1: Submission of immunization data to Immunization Information Systems (IIS).
 - Measure 2: Retrieval/receipt of immunization history and forecasts from IIS.
 - Reporting is required in Calendar Years 2026 and 2027 by certified HIT Module developers.

Discussion, Questions, and Contact Information

Discussion and Questions

Thank You!

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