2024
Indian Health Service
Partnership Conference

IHS Certified Health IT - RPMS/EHR

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'RPMS/EHR & THE CERTIFIED EHR UPDATES FOR THE ONC CERTIFIED HEALTH IT'

THURSDAY, AUGUST15, 2024 10:00 AM

Today's Presentation Objectives

Presentation Topics

- **IHS's compliance with ONC's Certification Criteria for Health IT**
  - **Health Data, Technology, and Interoperability (HTI-1) Final Rule Reporting**

- **IHS Certification History**
  - **2011, 2014, 2015, 21st Century Cures Update, HTI-1**

- **ONC Certification Standardization for Certified EHR Vendors**

- **HTI-1 Update**
  - **Rule**
  - **RPMS Modifications**
  - **USCDI versions 1, 2, 3**
  - **Interoperability**

- **Certified RPMS/EHR releases, timelines for HTI-1**

- **HTI- Information Blocking**

- **HTI-1 Real World Testing/Insights & Conditions of Maintenance**

- **HTI-1 Data Access API**

- **HTI-1 & IHS Central Interoperability Services (CIS)**

- **HTI-1 Patient Privacy**

- **Q&A**

IHS's compliance with ONC's Certification Criteria for Health IT

Why

Health Data, Technology, and Interoperability (HTI-1)

Progressive enhancements to support the meaningful use of electronic health information technology – started in 2010 in response to the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.

◦ The HITECH Act established high-level objectives for health information technology systems related to data privacy and security, clinical data collection, interoperability, reducing medical errors, and many other aspects of providing quality care to patients

◦ The HITECH Act was enacted to encourage the adoption of electronic health record systems with the goal of improving the overall quality of care for patients while at the same time reducing HIPAA violations and the costs of care

◦ HITECH introduced steep penalties for HIPAA violations and laid the groundwork for the incentive payment programs tied to the use of certified health information technology

◦ Through HITECH, the Office of the National Coordinator (ONC) was charged with the responsibility for establishing electronic health record certification criteria and managing the certification program

Certification Reporting Needs

2011 – CMS established the Medicare and Medicaid EHR Incentive Programs (now called Promoting Interoperability Programs).

Each stage of the Program is tied to the corresponding **ONC certification criteria that introduced additional EHR functionality and related quality measure outcomes** to be met through attestation reporting.

CMS payments to eligible hospitals (EH) and eligible providers (EP) are established through these Programs based on the use of certified EHR and reporting on a set of associated clinical quality measures – **hospitals and providers would receive significantly reduced payments (penalties) if not using a certified EHR product**.

Quality Payment Programs (QPP) – introduced through MACRA (Medicare Access and CHIP Reauthorization Act of 2015)
◦ Incentivizes Medicare clinicians to provide high-quality care and reduce payments to those that do not
◦ Merit-based Incentive Payment System (MIPS) – generally the program in which IHS facilities and providers participate

HITSS Investment Management

Strategic Plan – All IHS RPMS/EHR health IT projects must support the goals and objectives established by the IHS Strategic Plan:
- Promoting quality through innovation
- Modernization of Health Information Technology

Annual Planning – The HITSS Investment must balance the operational needs to maintain the existing RPMS system, **provide mandated certified EHR technology**, and address user-requested functionality all within budget limitations and in alignment with the Strategic Plan.

OMB/HHS Compliance Requirements – All IT projects, including health IT systems, must follow standard governance and comply with the following regulations intended to ensure IT systems are developed to meet bona fide needs, ensure data security, and manage taxpayer dollars responsibly
- Information Technology Management Reform Act (Clinger-Cohen Act)
- Federal Information Security Modernization Act (FISMA)
- Federal Information Technology Acquisition Reform Act (FITARA)

Budget Justifications & Reporting - Annual submissions and monthly updates justifying the need for IT investments, current projects, performance metrics, schedule and cost information, risk management, and **demonstrating compliance with applicable regulations** – can affect future funding
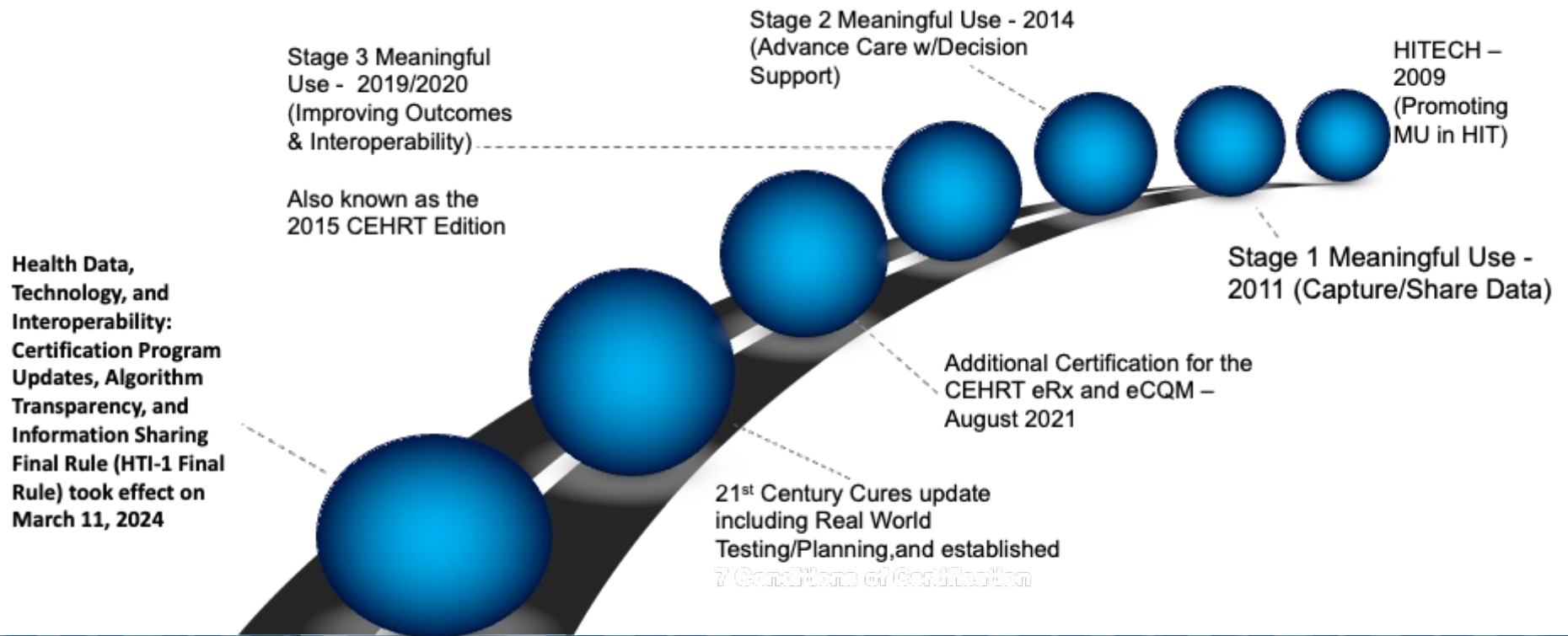
IHS Certification History

MU & Certification History for the IHS RPMS/EHR

Stage 3 Meaningful Use - 2019/2020 (Improving Outcomes & Interoperability)

Also known as the 2015 CEHRT Edition

Stage 2 Meaningful Use - 2014 (Advance Care w/Decision Support)

HITECH – 2009 (Promoting MU in HIT)

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule (HTI-1 Final Rule) took effect on March 11, 2024

Stage 1 Meaningful Use - 2011 (Capture/Share Data)

Additional Certification for the CEHRT eRx and eCQM – August 2021

21st Century Cures update including Real World Testing/Planning, and established 7 Conditions of Certification

The focus of Meaningful Use for a Certified EHR

Stage 1 MU focus:	Stage 2 MU focus:	Stage 3 MU focus:
Electronic capture of health information in standardized format	More rigorous Health Information Exchange	Improving quality, safety, efficiency, leading to improved health outcomes
Using the capture to track key clinical conditions.	Increased requirements for electronic prescribing & incorporation of lab test results	Decision support for national high-priority conditions
Communicating that information for patient care coordination	Electronic transmission of patient care summaries across multiple settings	Patient access to self-management tools
Initiation of the Clinical Quality Measures & Public Health Information	More patient controlled data.	Access to comprehensive patient data through patient-centered HIE
Using information to engage patients & family in their care		Improving population health

HTI-1 Criteria Category Focus

What is included in the ONC Certified Health IT for each Criteria Category

CLINICAL PROCESSES

Computer Provider Order Entry, Demographics, **Implantable Device List**.

CARE COORDINATION

Transition of Care**, Clinical Information Reconciliation (CIR)**, **Electronic Prescribing**, Data Export, Care Plan, Electronic Health Information (EHI) Export, **Decision Support Intervention**.

CLINICAL QUALITY MEASUREMENT

Record & Export, Import & Calculate and Reporting.

PRIVACY & SECURITY

Authentication, Access Control, and Authorization, Auditable Events and Tamper-Resistance, **Audit Report(s), Automatic Access Time-Out , Integrity**.

PATIENT ENGAGEMENT

View, Download, and Transmit to 3rd Party, Secure Messaging, Patient Health Information Capture.

HTI-1 Criteria Category Focus

What is included in the ONC Certified Health IT for each Criteria Category

PUBLIC HEALTH

Transmission to: Immunization Registries; Public Health Agencies for Syndromic Surveillance; **Public Health Agencies for Reportable Laboratory Tests And Values/Results**; Public Health Agencies for Electronic Case Reporting, **Antimicrobial Use & Resistance Reporting**.

HEALTH IT DESIGN and PERFORMANCE

Automated Numerator Recording, Automated Measure Calculation, **Safety-Enhanced Design**, Quality Management System, **Accessibility-Centered Design**, **Consolidated CDA Creation Performance**, Application Access criteria.

ELECTRONIC EXCHANGE

Direct Project, Edge Protocol, and XDR/XDM

Interoperability is essential for systems to communicate

Developers can assure their customers that their product meets recognized standards and functionality

Clinicians & Hospitals have tools for clinical processes, care coordination, and quality improvement

Patients can access and send their health information electronically

How has the development for a Certified EHR helped in delivery of patient care?

§170.315 (f)(3) *Transmission to public health agencies – reportable laboratory tests and value/results—*

COVID-19 Lab result interface with State PHAs and the CDC.
<u>CY 2023</u>: **39,678 COVID test results transmitted for IHS.**

The electronic transmission has improved the timeliness and quality of reports.

Eliminates redundant data entry and potential clerical errors.

Laboratory (LR, BLE)

How has the development for a Certified EHR helped in delivery of patient care?

§170.315 (d)(8) *Integrity*

COVID-19 Vaccination Data to the CDC

BCOM development from the d8 Data Certification Criteria - Integrity .

BCOM Utility updated from a standard SFTP to **Secure Hashing algorithms** for transfer of patient vaccine data.

Immunization Package (ICE, BYIM, BI)

How has the development for a Certified EHR helped in delivery of patient care?

§170.315 (d)(9) *Trusted Connection*

RPMS Direct Secure Messaging (RPMS Direct) now referred to as **Direct Secure Messaging (Direct)**

Direct Secure Messaging (Direct) is a secure web-based messaging service, specifically designed to meet Certified Electronic Health Record requirements for transmitting and receiving Protected Health Information/Personally Identifiable Information (PHI/PII) electronically.

Messages Exchanged Monthly

	2023 July	2023 August	2023 September	2023 October	2023 November	2023 December	2024 January	2024 February	2024 March	2024 April	2024 May	2024 June
Messages	3,965	4,458	4,114	4,688	4,215	4,157	3,442	4,220	3,973	5,477	6,315	7,821
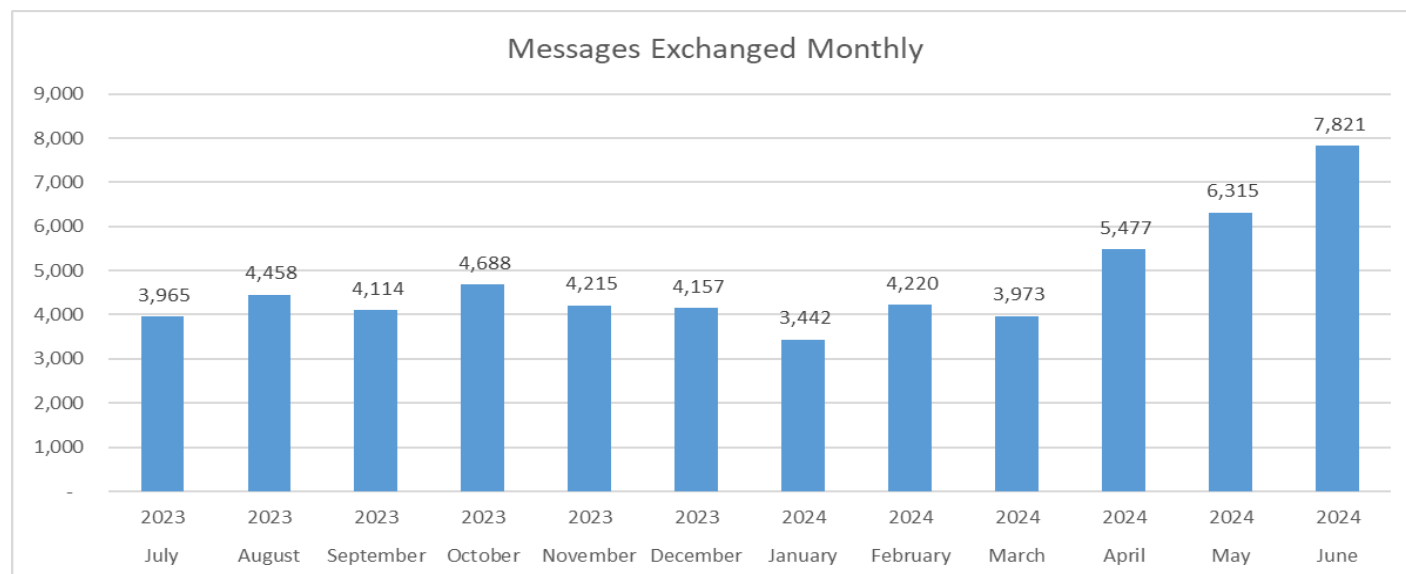
ONC Certification **Standardization** for Certified EHR Vendors

Standardization

One of the goals of any certification program is standardization

How much attention is needed to interpret a stop sign when they are all different?

Standardization - Benefits

Benefits

◦ Simplified training

◦ Simplifies error identification & remediation

◦ Economies of Scale can be realized for processes

◦ Can reduce the amount of resources dedicated to operations and maintenance

◦ Increases ability to inter-operate with different systems and organizations

◦ Increases the reliability of reporting for both quality and performance indicators

◦ Increases the ability of an EHR to span episodes of care, including care from disparate organizations, allowing the EHR to become more patient-centric and enhancing continuity of care between providers

◦ Provides pathways to add clinical decision support from multiple sources that require less customization

Standardization - Issues

Issues

- Reduces the ability to introduce unique local solutions
- Increases the importance of "getting it right the first time"
- Requires consensus between larger groups of stakeholders to effect change
- **May disrupt existing workflows during the implementation period**

Standardization - Development

<u>Development Activities</u>

- New development may be required to align with standard processes as they are defined
- Reporting to identify how closely the current systems align with the "standard"
- Application changes to implement interoperability with other systems
- Application changes to take advantage of decision support systems
- Application changes to implement new or changed reporting

HTI-1 Update for the Certified EHR

HTI-1 Final Rule OVERVIEW

In this final rule, ONC implements provisions of the 21st Century Cures Act, makes updates to the ONC Health IT Certification Program (Certification Program) including new and updated standards, certification criteria, and implementation specifications in 45 CFR Part 170, establishes a new baseline version of the United States Core Data for Interoperability (USCDI), and provides enhancements to support information sharing through updates to the information blocking regulations.

ONC Certified Health IT / HTI-1 – FINAL RULE

1. New Regulatory Approach for Certification Criteria ("edition-less"):

• discontinue the year-themed editions and establish a single set of certification criteria

2. Certification Standards and Functionality Updates:

• new and revised standards and certification criteria

3. Decision Support Interventions (DSI) and Algorithmic Transparency:

• revises existing CDS certification criteria, simplifies and streamlines requirements, and narrows the scope of impacted predictive DSI

4. Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program):

• provide details on what needs to be reported when (frequency) by whom and how they will be measured. It also provides a reporting timeline

5. Information Blocking:

• provides detailed definitions and exceptions

RULE HIGHLIGHTS

• Discontinuing Year-Themed Editions for Health IT Certification Criteria To simplify the Certification Program and support more modular and extensible future updates, the HTI-1 final rule discontinues year-themed editions of certification criteria. This change also supports broader use of certification criteria and standards adopted by ONC for other federal agencies and programs

• Implements the Cures Act's "EHR Reporting Program" to require transparent reporting on different types of certified health IT metrics through the new "Insights" Condition and Maintenance of Certification.

• Provides updates to the information blocking regulations in response to feedback from affected parties.

• Adopts United States Core Data for Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the baseline USCDI standard as of January 1, 2026.

• Updates the Certification Program's standards, criteria, and requirements, including: • • • • Standardized application programming interfaces (APIs), including adoption of the SMART App Launch Implementation Guide v2; Electronic case reporting using HL7® Consolidated Document Architecture (CDA) and HL7 Fast Healthcare Interoperability Resources (FHIR ®)-based specifications; A revised decision support intervention (DSI) certification criterion based on the prior clinical decision support certification criterion that includes new capabilities and transparency requirements for Health IT Modules; and New functionality that enables an "internet-based method" for a patient to request a restriction on the use and disclosure of their EHI.

Historically --> Health IT Future

Interoperability:
HL7,CCDA,eRX,LOINC

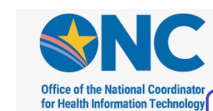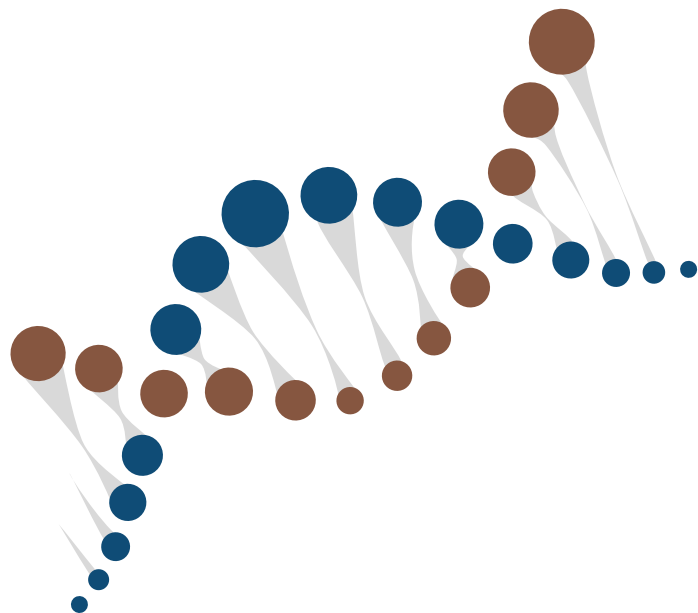**ONC Programs:**
MU2,MACRA,CQM

Engagement:
Personal Health Record
portal

Data Related:
Care Management, Care
Coordination

ONC
Office of the National Coordinator
for Health Information Technology

HTI-1

COMPLIANCE:

- **New/Revised Criteria**
- **USCDIv3**
- **Information Blocking**
- **Open APIs (FHIR)**
- **Emphasizing Algorithmic Transparency**
- **Predictive/Evidence-Based Decision Support Interventions**
- **Critical standards for information sharing among healthcare providers**

Change s to the CEHRT !

New

Decsion Support Intervention

Revised

Electronic Case Reporting, *Clinical Decision Support*, Standardized API for Patient and Population Services, View, Download, and Transmit to 3rd Party (PHR), Patient Demographics and Observations Certification Criterion, Transitions of Care

Removed

Problems, Meds, Med Allergy List, Clinical Decision Support

Smoking Status, CCDS Summary Record

Formulary & Preferred Drug List, Data Export, Clinical Decision Support

ONC Certified Health IT continues with the Conditions of Certification
for CEHRT Maintenance
from the Century Cures Act enacted in May 2020

THE 21ST CENTURY CURES ACT ESTABLISHED

7 Conditions of Certification

and most have an accompanying Maintenance of Certification Requirement.

INFORMATION BLOCKING

ASSURANCES

COMMUNICATIONS

(FUTURE) ELECTRONIC HEALTH RECORD (EHR) REPORTING CRITERIA SUBMISSION

APPLICATION PROGRAMMING INTERFACES (APIS)

ATTESTATIONS

REAL WORLD TESTING

Conditions of Certification (CoC)

CoC – <u>Information Blocking</u> – (§ 170.401)	As participants in the ONC Health IT Certification Program – IHS cannot block patient information and could be subject to a steep fine.
CoC – <u>**Assurances**</u> –	Requires IHS to report that it does not inhibit the appropriate exchange, access, and use of Electronic Health Information (EHI).
CoC – <u>**Communications**</u>	IHS HIT development cannot restrict communication of the usability, interoperability, or security of its HIT or user experiences, business practices related to Electronic Health Information, or the manner in which the technology is used.
New EHR Reporting Criteria for submission	Both *NEW* & Revised listed on prior slide (#27) as applicable for the IHS RPMS/EHR.
CoC – <u>**Application Programming Interfaces (API)**</u>	Develop and implement the use of an API for data sharing.
CoC – Initial <u>**Attestations**</u>	IHS will comply with the Conditions and Maintenance of Certification requirements – every six months.
CoC – <u>**Real World Testing**</u>	Think 'accreditation inspection checklist' for the IHS Certified RPMS/EHR modules. IHS RPMS/EHR end users can demonstrate the certified functionality in a real world setting vs a testing lab. Evidence of Compliance.

Putting the **Patient First** in Health Technology:
improve care experience for individual patients by improving access to more interoperable data

Ease of Access to Their Records..

Protecting Patient Privacy and Security. Improve security through adoption of enhanced authentication and authorization requirements.

Promoting the Ability to Shop for Care and Manage Costs

The Final Rule supports a Patient Requested Restrictions. Enabling a user a process to restrict data from use or disclosure in response to a patient request.

The rule supports secure patient access to their electronic medical record data. Patients will be able to use applications they authorize to receive data from their medical record. (SMART App Launch)

Final Rule looks to expand patient and payer choice in health care by increasing the availability of data that can support insights about care quality and costs.

HTI-1 Final Rule for our IHS Providers & Hospitals

Making Patient Data Requests Easy and Inexpensive

HIT to easily provide patients with access to their information in a fully automated, low-cost manner.

Implementation

Prohibits information blocking & defines the practices considered reasonable & necessary activities that would not constitute information blocking.
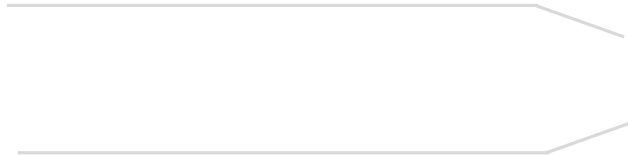
Algorithmic transparency for Clinical Decision Support

Detailed source attribute information for evidence-based, predictive DSIs. This requirement is crucial for ensuring that healthcare providers can make informed decisions based on transparent and updated information regarding the DSI.
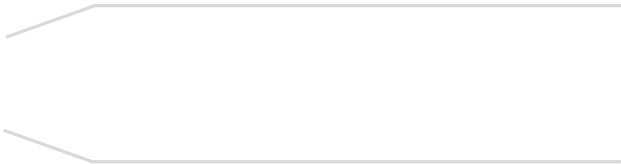
Improving Patient Safety

The final rule aims for a thoughtful balance between patient and clinician needs while protecting patient privacy.

deploy

What our Providers & Hospitals should know

Like the previous 21st Cures Act Rule, the HTI-1 Rule is a federal regulation; therefore, it applies to **ALL providers including IHS providers**.

While the regulation was written by the Office of the National Coordinator (ONC), it will be enforced by the Office of the Inspector General (OIG); both under the direction of the Department of Health & Human Services (HHS).

A reminder that with Information Blocking penalties for each confirmed incidence of Information Blocking are very costly and will be covered under the Information Blocking topic.

In addition, HTI-1 will help IHS and its partner agencies such as CMS and the CDC in fulfilling their missions through certified health IT

HTI-1 Final Rule for the IHS RPMS/EHR
as HIT Developer

As with the 21st Century Cures Act, the HTI-1 Rule requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for health IT developers participating in the ONC Health IT Certification Program.   -   Includes API to be covered with specificity.

Transparency Conditions

Fees Conditions

Openness and Pro-Competitive Conditions

API Maintenance of Certification Requirements
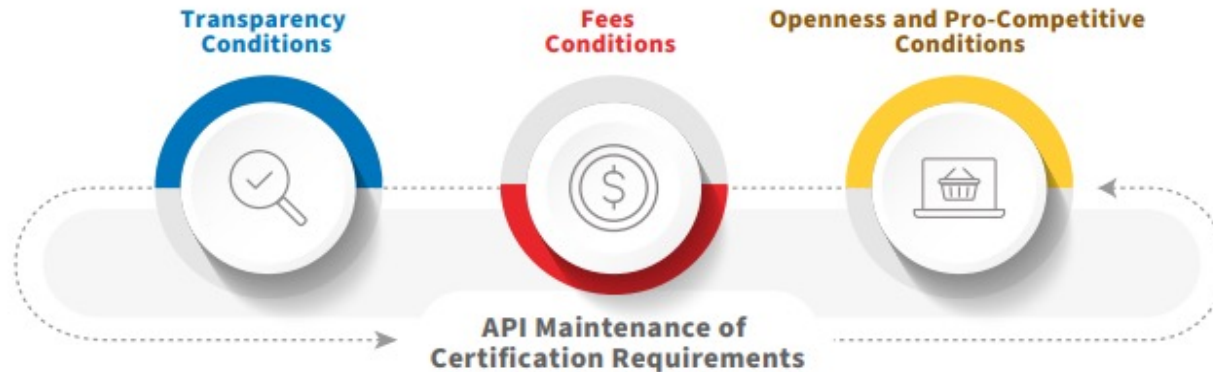
HTI-1 Mandate - for IHS for Health IT

Importance for the IHS RPMS/EHR and why the functional changes required to meet the regulation & rule are so important.

The specific provisions of HTI-1 provisions ensures that the IHS RPMS/EHR will support:

➢Predictive Decision Support Intervention
➢Electronic Case Reporting
➢Information Blocking
➢API Updates
➢USCDIv3

HTI-1 Key Dates

2029
- Insights Condition Year 4
  - CY 2029: health IT developers collect data for all Insights Condition Measures.
  - July 2029, health IT developers submit report for all Insights Condition measures

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

2027
- Insights Condition Year 2
  - CY 2027: health IT developers collect data for Insights Condition Years 1 and 2 measures.
  - July 2027, health IT developers submit Insights Condition report for Year 1 measures.

2026
- Insights Condition Year 1
- Updated standards compliance
  - Calendar Year (CY) 2026: health IT developers collect data for Insights Condition Year 1 Measures.
  - Starting January 1, 2026, all HTI-1 updated standards in certification criteria are solely applicable for compliance purposes.

2025
- USCDI v3
- All other Certifcation Program updates
  - 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.
  - Starting January 1, 2025, the decision support interventions certification criterion:
    - Replaces the clinical decision support certification criterion in the Base EHR definition.
    - "Assurances" Maintenance of Certification requirement for decision support interventions begins (170.402(b)(4)).

2024
- "Decision Support Interventions"
- Standardized "FHIR endpoints"
  - By December 31, 2024, developers with health IT certified to the clinical decision support certification criterion adopted at 170.315(a)(9) must:
    - Update their certificate(s) for the decision support interventions certification criterion at 170.315(b)(11) and
    - Provide such certified health IT to customers.
  - By December 31, 2024, Certified API Developers must publish their customers' service base URL information (FHIR Endpoints) according to specific adopted standards.

HealthIT.gov

Review of Phase 1 development requirements for meeting the HTI-1 Mandate and IHS RPMS/EHR considerations

IHS OIT/DIT Development considerations for HTI-1. Examples for the RPMS/EHR:

- ◦ Decision Support Intervention
- ◦ CCDA and TOC
- ◦ Clinical Quality Measures

<u>NOTE:</u>

The work for the HTI-1 is coordinated in conjunction with RPMS/EHR sustainment and new quality payment, reporting priorities, and new initiatives. In addition to RPMS/EHR enhancement requests and the ongoing operation & maintenance for HIT sustainment.

Due to ONC-mandated cutoff dates, the HTI-1 development is a priority. The criteria teams for CEHRT and the HTI-1 access development for meeting the criteria in addition to understanding how criteria requirements are to be incorporated into the IHS RPMS/EHR workflow. Business owners and subject matter experts are consulted.

RPMS/EHR Modifications for HTI-1 –
Decision Support Intervention

§170.315(b)(11) **Decision Support Intervention**

RPMS/EHR development and testing are in progress for HTI-1 certification & planned Health IT release.

The development required for associated RPMS/EHR Namespaces:

- PXRMp1014 - Clinical Reminders
- EHRp37 – Electronic Health Record (EHR)
- BCERv8.2 - RPMS Certified EHR version checker

HTI-1 Relevance:

New development focuses on the requirements to create and format Transition of Care (ToC) documents according to the Consolidated CDA (CCDA) Release 2.1 standard **and incorporating United States Core Data for Interoperability (USCDI) data set.**

RPMS/EHR Modifications for the Cures Update –
Electronic Prescribing

(b)(3) **Electronic Prescribing**

This Certification Criteria is currently in beta testing with the pending EHRp31 release.

Development Changes Required:
- EHR v1.1 p31 – Electronic Health Record
- APSP v7.0 p1028 – IHS Pharmacy modification
- BEPR v2.0 p4 – e-Prescribing Productions

CURES Relevance:

The RxChange functionality will allow the user to electronically respond to change prescription requests received from the pharmacy. Receive/Process RxChange Messages: (RXCHG) / (CHGRES)

Certification for eRX including Medication History to be performed on August 19, 2021 with ONC Authorized Certification Body (ACB) – UL.

RPMS/EHR Modifications for the Cures Update –
Clinical Quality Measures

(c)(3) Clinical Quality Measures – Report

Certification live testing to be performed at the same time as the eRX. Release date slated for 2021.

Development Changes Required:
- BCQM v1p8 – IHS Code Mapping
- BQRE v4 – eCQM Export Tool
- ECQM v4 – eCQM Engine

CURES Relevance:

Perform required annual updates including addition of new measures to meet objective and regulation.

Added three new measures - Stakeholders requested the addition of three new measures for CMS reporting.

New EH Measure: CMS506v3 Safe Use of Opioids - Concurrent Prescribing

New EP Measure: CMS22v9 Preventive Care and Screening: Screening for High Blood Pressure

New EP Measure: CMS147v10 Preventive Care and Screening: Influenza Immunization

The HTI-1 Update and demonstrating IHS need for Interoperability
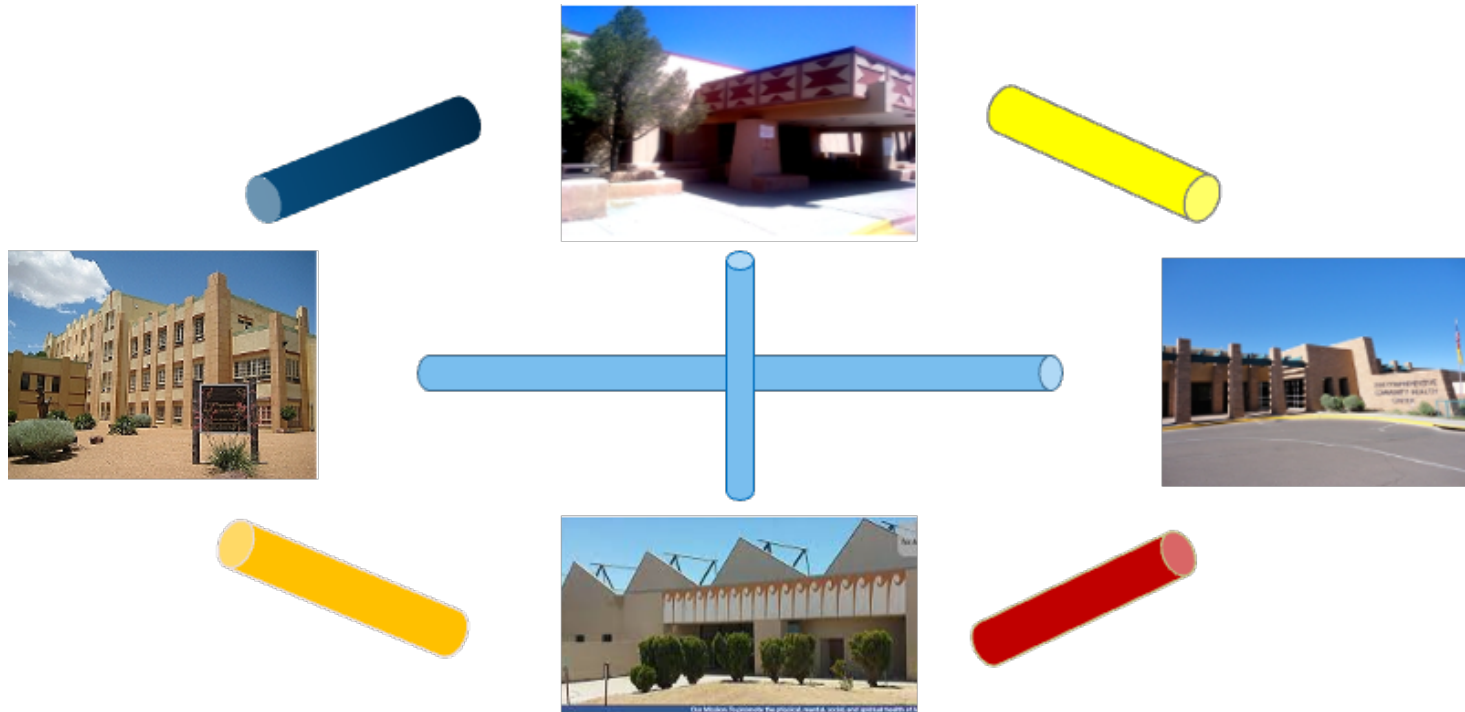
HTI-1 Rule
United States Core Data for Interoperability (USCDI)

What is USCDI and its importance for IHS.

Since 2009, DHHS has been on a mission to provide patients with seamless access to their medical health records. This is about the time that paper charts became more obsolete.   And the introduction of... Electronic Health Records!

This led to the need for interoperability for electronic health systems.

Due to this increased need for interoperability, there is also an increased necessity for standardized core data.

Fast forward to present day. The USCDI *nteroperability* is a collective of standard clinical **Data Elements** that HIT vendors must comply. Including IHS for the Certified RPMS/EHR.

- Example from ONC: Date of Birth is a Data Element rather than its component Day, Month, or Year. Because Date of Birth is the unit of exchange.

USCD*Interoperability* continued…

The USCDI is the most granular level at which a piece of patient data is exchanged between HIT systems.

Is the latest evolution of a patient-centered healthcare data set

More USCDI...

- ONC's goal is to implement the USCDI and utilize a standard template for digitizing patient clinical data.

- With HTI-1, ONC continues to move beyond the current "Common Clinical Data Set" (CCDS) standard, and will require the exchange of the "U.S. Core Data for Interoperability" (USCDI) data supports interoperability and data exchange. USCDI and not CCDS.

- Establishes what information Health IT systems should be able to share.

- And expands strategically over time.
  ◦ HTI-2!

Demo,Patient A 01/01/1990   WBG results

Welcome Demo, Patient A to your PHR.
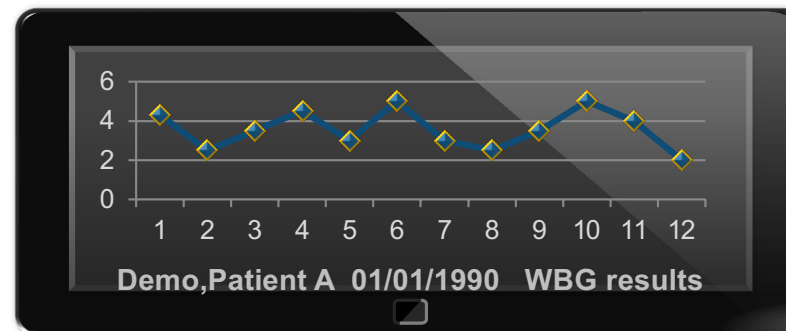
Excellent! So what is captured for USCD*Interoperability*?

HTI-1 will include both USCDI v2 data elements (example below) and USCDI v3

Sexual Orientation and Gender Identity (SOGI)

Social Determinants of Health (SDOH) • SDOH Assessment • SDOH Goals • SDOH Problems/Health Concerns • SDOH Interventions

DATA CLASS	DATA ELEMENT
Assessment and Plan of Treatment	**SDOH Assessment** *Structured evaluation of risk for any Social Determinants of Health domain such as food, housing, or transportation security.*
Goals	**SDOH Goals** *A future desired condition or change in condition related to an SDOH risk established by the patient or provider.*
Procedures	**SDOH Interventions** *A service offered to a patient to address identified SDOH concerns, problems, or diagnoses.*
Problems	**SDOH Problems/Health Concerns** *An SDOH-related condition or diagnosis.*

With HTI-1 and USCDI v3, there are 20+ added data elements, effective December 31, 2024.

Draft USCDI Version 3

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment

Care Team Member(s)
- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests
- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Type
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Goals
- Patient Goals
- SDOH Goals

Health Insurance Information ★
- Coverage Status ★
- Coverage Type ★
- Relationship to Subscriber ★
- Member Identifier ★
- Subscriber Identifier ★
- Group Number ★
- Payer Identifier ★

Health Status
- Health Concerns ➡
- Functional Status ★
- Disability Status ★
- Mental Function ★
- Pregnancy Status ★
- Smoking Status ➡

Immunizations
- Immunizations

Laboratory
- Test
- Values/Results
- Specimen Type ★
- Result Status ★

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Middle Name (Including middle initial)
- Suffix
- Previous Name
- Date of Birth
- Date of Death ★
- Race
- Ethnicity
- Tribal Affiliation ★
- Sex (Assigned at Birth)
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name ★
- Related Person's Relationship ★
- Occupation ★
- Occupation Industry ★

Problems
- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures
- Procedures
- SDOH Interventions
- Reason for Referral ★

Provenance
- Author Organization
- Author Time Stamp

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic blood pressure
- Diastolic blood pressure
- Heart Rate
- Respiratory rate
- Body temperature
- Body height
- Body weight
- Pulse oximetry
- Inhaled oxygen concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

★ **New Data Classes and Elements** ➡ **Data Element Reclassified**

Interoperability

EHRs are designed to share a patient's information with authorized providers **and** staff from more than one organization.

IHS RPMS/EHR
Interoperability & Success

COVID-19 lab test reporting & vaccine administration

Infectious Disease Reporting to Public Health Agencies

Electronic Prescribing

Immunization Registries

CCDA, TOC, CIR

Personal Health Record

API – Data Access

CIS / Four Directions Hub (4DH) – pilot in progress

Technical Evolution of Patient Data
for Entry, Share & View

NEW EHR Reporting Criteria for submission – one of the 7 CoC(s)

Certification Criteria #	Certification Criteria	Primary Lead	Testing	Release Date *
(b)(10)	Electronic Health Information - Export	Glenn Janzen	UL	Sep 2023
(g)(10)	Standardized API for Patient and Population Services	Glenn Janzen	UL	Sep 2022
(d)(12)	Encrypt Authentication Credentials	Charles Cross	Self Declaration (SD)	
(d)(13)	Multi-Factor Authentication (MFA)	Charles Cross	SD	

Revised EHR Reporting Criteria for submission – one of the 7 CoC(s)

Certification Criteria #	Certification Criteria	Primary Lead	Testing	Release Date *
(b)(3)	Electronic Prescribing	Bradley Bishop	UL	Aug 2021
(b)(7)	Security Tags: Summary of Care – Send	James Garcia	UL	Sep 2022
(b)(8)	Security Tags: Summary of Care – Receive	Sharon Pang	UL	Sep 2022
(c)(3)	Clinical Quality Measures - Report	Marcie Platero	UL	Oct 2021
(d)(2)	Auditable Events and Tamper-Resistance	Charles Cross	Self Declaration (SD)	
(d)(3)	Audit Report(s)	Charles Cross	SD	

RPMS/EHR Timeline in support of the HTI-1 Criteria

RELEASE Roadmap

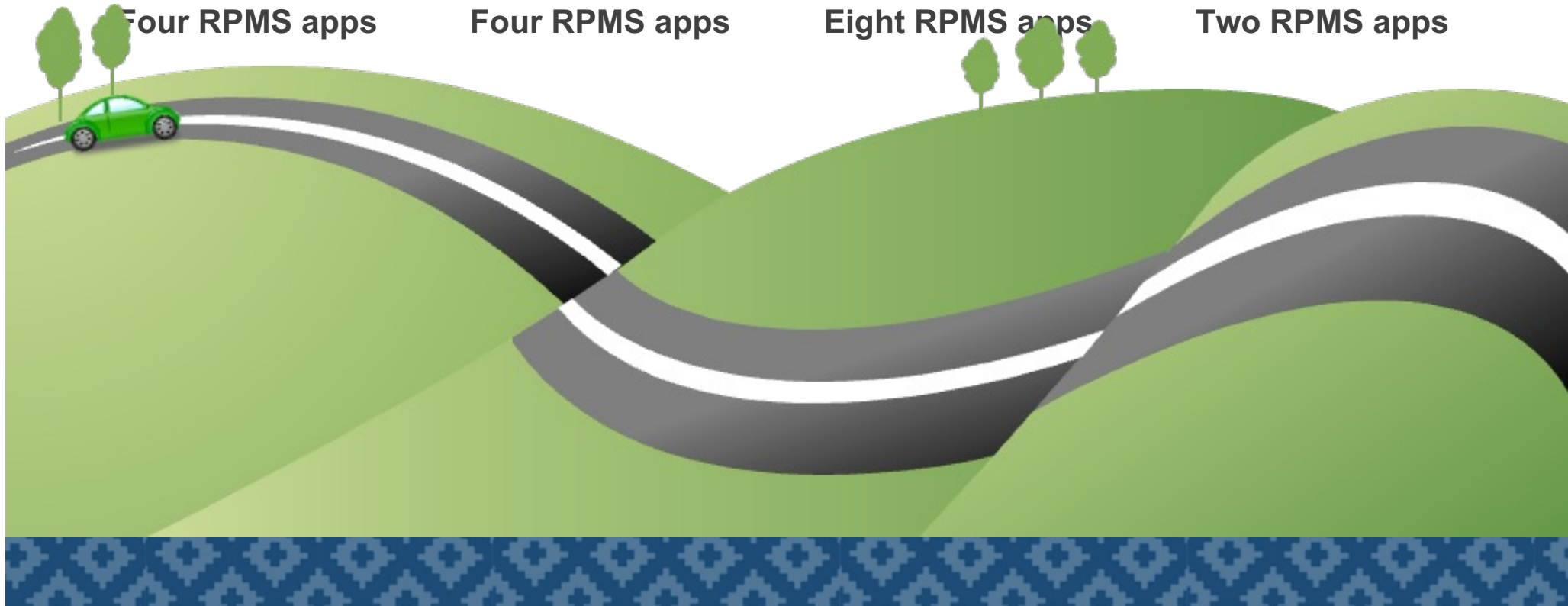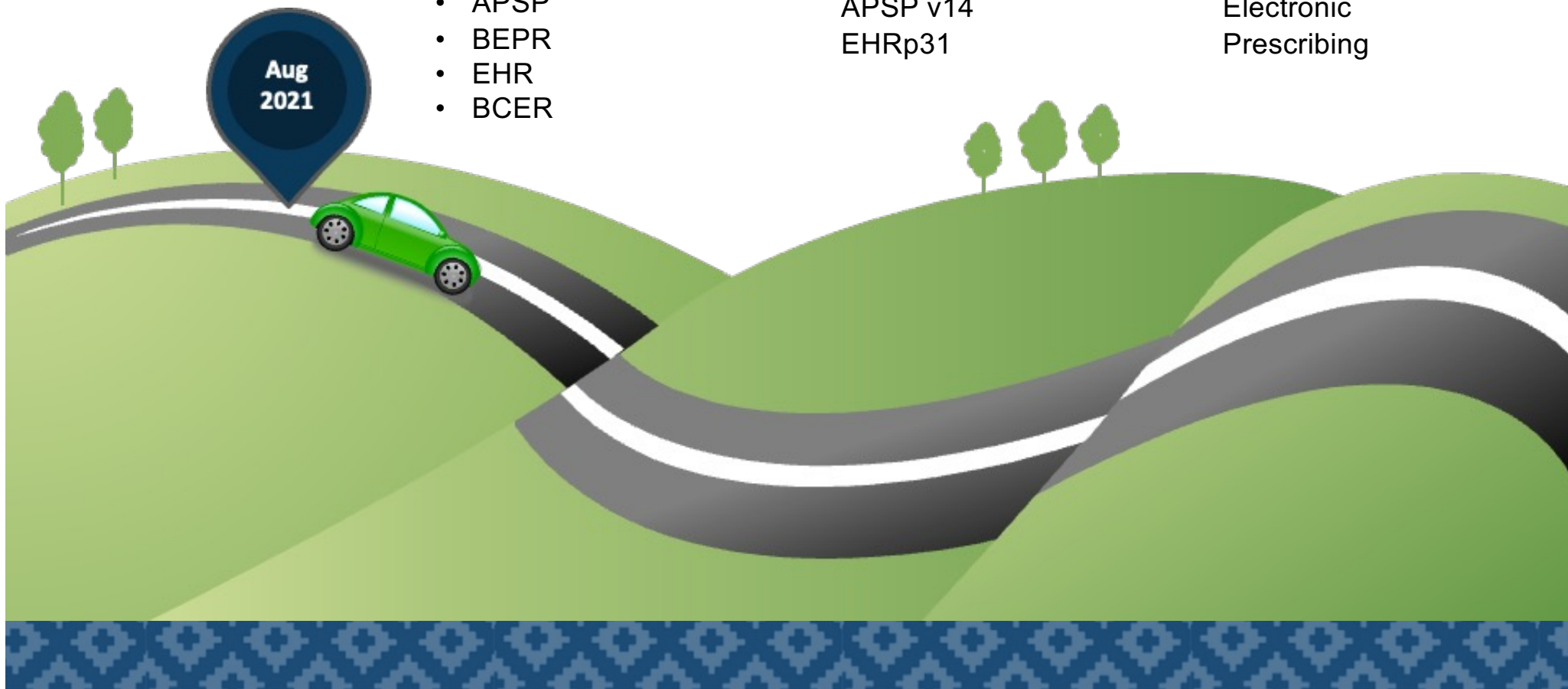| Aug 2021	Oct 2021	Sept 2022	Sept 2023
Four RPMS apps	Four RPMS apps	Eight RPMS apps	Two RPMS apps

Applications

- APSP
- BEPR
- EHR
- BCER

Aug 2021

Dependencies

APSP v14
EHRp31

Cures Update

Electronic Prescribing

Applications

- BCQM
- BQRE
- eCQM
- BCER

Dependencies

N/A

Cures Update

Clinical Quality Measures

Oct 2021

Applications

- BREH
- BCER

Dependencies

DTS – Cycle TBD

Cures Update

EHI Export
4DH Rollout

Sept 2023

HTI-1 Real World Testing
and *NEW* Insights & Conditions of
Maintenance

Real World Testing Overview

Real World Testing (RWT) is a process by which Health IT Developers demonstrate interoperability and functionality of their ONC Certified Health IT in real-world settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL).

Is an annual process, which demonstrates real-time compliance and real-time interoperability by:

◦ Enabling secure exchange of EHR information with, and use of EHR information from, other Health IT technology without significant effort by the user.

◦ Allowing complete access, exchange, and authorized use of EHR information as applicable to state or federal law.

◦ It proves that the ONC Certified Health IT EHR continues to incorporate and utilize the CHIT, for which the 2015 Edition was successfully certified.

◦ Performing real-world scenarios in production environments for each care setting (Ambulatory and Inpatient)

◦ **No information blocking.**

Real World Testing Requirements

Per the Office of National Coordinator (ONC) for the ONC Certified Health IT:

- Submit RWT Plan (RWTP) to ONC-ATL for approval by October 15, Calendar Year.
- Publicize RWTP by December 15, Calendar Year, which includes ACB update to CHPL.
- Perform necessary tests per the RWTP between January 1, Calendar Year and December 31, Calendar Year
  - Any non-conformities found during RWT must be reported to ONC-ATL within 30 days of finding.
- Submit RWT results to the ONC-ATL by the following January 15, Calendar Year.
- Make RWT results publicly available by March 15, Calendar Year, which includes an update by the ONC-ATL to CHPL website.

Note: The above process is completed annually for any specified criteria the IHS ONC Certified Health IT is certified to by August 31st of the RWTP submission year.

Real World Testing Criteria - IHS

Care Coordination
✓ § 170.315(b)(1): Transitions of Care
✓ § 170.315(b)(2): Clinical Information Reconciliation and Incorporation
✓ § 170.315(b)(3): Electronic Prescribing
✓ § 170.315(b)(7): Security tags – summary of care - send)
✓ § 170.315(b)(8): Security Tags – summary of care – receive)
✓ § 170.315(b)(11): Decision Support Intervention

Clinical Quality Measures
✓ §170.315(c)(1)Record and Export CQMs
✓ §170.315(c)(2)Import and Calculate CQMs
✓ §170.315(c)(3) Data File Creation

Application Programming Interfaces
✓ §170.315(g)(7)Application Access-Patient selection
✓ §170.315(g)(9)Application Access - All data request
✓ §170.315(g)(10)Standardized API for patient and population services

Patient Engagement & Electronic Exchange
✓ §170.315(e)(1) View, Download, Transmit
✓ §170.315(h)(1) Direct Project

Public Health
✓ §170.315(f)(1) Transmission To Immunization Registries
✓ §170.315(f)(2) Transmission To Public Health Agencies
✓ §170.315(f)(3) Transmission To Publich Health Agencies–
✓ Reportable Laboratory Tests And Value/Results
✓ §170.315(f)(5) Transmission To Public Health Agencies–electronic Case Reporting.
✓ §170.315(f)(6) Transmission To Public Health Agencies– Antimicrobial Use & Resistance.

August 31 is the cutoff date for each RWT planning & reporting year.

Real World Testing Needs

Need site participation to complete RWT annually and demonstrate compliance, as RWT:

- Must be performed in a production environment
- Must include Ambulatory and Inpatient care settings
- Use cases must be applicable in real-world scenarios
  - How users use the CEHRT to perform criteria functions, such are transitioning care to another provider, electronically prescribing medications, and etc.
- Must document use case RWT results

OIT will provide annual RWTPs that is:

- Based on feedback from participating sites
- Standardized (Use cases must be approved by ONC-ATL)

Risk losing certification status:

- If not performed with results documented and published;

HTI-1 – Update & today's Presentation Navigation

Reviewed ←

Next Topics ↑

Rest Area →

✓HTI-1 Act & Seven Conditions of Certification (CoC)

✓USCDInteroperability (USCDI)

✓Why USCDI?

✓*NEW* EHR Reporting Criteria

➢ Information Blocking (IB)

➢ Application Programming Interfaces (API)

➢ Real World Testing (RWT)

➢ Polices ensuring Patient Protection

We'll resume in 5-10 minutes

Information Blocking

Information Blocking

General definition:

◦ A practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information (EHI).

Regulated categories of "actors"

◦ Health Care Provider

◦ Health Information Network (HIN) or Health Information Exchange (HIE)

◦ Health IT Developer (IHS)

Examples of Information Blocking

◦ Restrict authorized access, exchange, or use of such information for treatment and other permitted purposes, including transitions between certified health information technologies (health IT)

◦ Implementing nonstandard ways that increase the complexity or burden of accessing, exchanging, or using EHI

◦ Implementing ways that are likely to restrict the access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between health IT systems

◦ Implementing ways that lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health IT

Information Blocking Exemptions

General Exemption Definition:

- Exceptions support seamless and secure access, exchange, and use of EHI and offer actors certainty that practices that meet the conditions of an exception will not be considered information blocking. <u>Practices that constitute information blocking and authorizes the Secretary of Health and Human Services (HHS) to</u> identify reasonable and necessary activities that do not constitute information blocking are referred to as "exceptions".

- In short – Takes executive action by the Secretary of HHS to identify and approve any exemption.

Exemption Categories

- Exceptions that involve not fulfilling requests to access, exchange, or use EHI.
  - Preventing Harm
  - Privacy
  - Security
  - Infeasibility
  - Health IT Performance
- Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI.
  - Content and Manner
  - Fees
  - Licensing

Information Blocking Compliance

Beginning April 5, 2021, an actor must respond to a request to access, exchange, or use EHI with, at a minimum, all requested EHI identified by the data elements represented in the USCDI standard.

- ◦ USCDI standard is the USCDI data elements currently recorded in the CEHRT at the time of the current certification.

Beginning October 6, 2022, an actor must respond to a request to access, exchange, or use EHI with EHI to the extent that it would be included in a designated record set (DRS). EHI does not include:

- ◦ Exceptions that involve not fulfilling requests to access, exchange, or use EHI.
    - ◦ Psychotherapy notes.
    - ◦ Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

Compliance

- ◦ Do not implement any functions, processes, or methods that may lead to one or more of the information blocking examples.
- ◦ Do not modify or alter certified software in a manner that may constitute information blocking.

Information Blocking Consequences

Reported Claims are investigated and if found guilty of information blocking, one or more of the following could occur:

- Penalties:
    - Health IT Developers, HIN, and HIE: $1 million per violation
    - Health Care Providers: Appropriate disincentives
- Conditions of Certification:
    - Certification ban; and
    - Public listing of certification bans and termination

The Standardized API & the Four Directions Hub
with Charles Cross

Standardized All Data Access API

Requirements are to establish access for a patient and/or provider to healthcare data via a standardized Application Programming Interface (API)

- Standardized: Using the specifications in the ONC 2015 Edition Cures Update for the §170.315 (g)(10) criteria

- Utilizing industry standard OAuth – OpenID framework for authentication and authorization, e.g. banking, social media, telecomm companies

- Healthcare data is in a new standardized format utilizing Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)

  - The FHIR standard has been adopted across the Healthcare industry and is becoming the de-facto standard. Adopters include Cerner, EPIC, Apple, Microsoft, and others…

API differences (g8, g9, and g10)

For the CHIT 2015 requirements, the PHR included (g)(8) API criteria that allowed patients to connect with an external application.

For 21st Century - 2015 Edition Cures Update, the (g)(8) API is replaced by a new API requirement, (g)(9), that includes more security and all of the new fields for the United States Core Data for Interoperability (USCDI) data set.

The (g)(9) and (g)(10) criteria differ in that (g)(9) is based on the USCDI and is a C-CDA document. (g)(10) is based on JSON FHIR resources know as resource nodes. FHIR resource nodes are more granular, allowing for complete record requests or optional ad-hoc data queries.

G9 will be part of PHR and is limited to patient use.

G10 will be part of 4DH and will be available to authorized patients and providers.

Four Directions Hub (4DH)

The 4DH is the new Health Information Exchange (HIE) suite of tools that allow providers to:

◦ Data is aggregated from the existing C-CDA and MPI data feeds

◦ Allows access a consolidated view of a patient's health information from visits throughout Indian Health Service.

◦ Allows access a patient's health information from visits outside of IHS through eHealth Exchange. Partners connecting through eHealth Exchange include the VA and the DoD as well as other private/public entities.

The 4DH is needed because the current HIE is C-CDA document-based, which doesn't allow a consolidated cross site or domain view of patient information.

The 4DH stores the data elements parsed from the C-CDA, allowing expandability.

The current HIE and MPI are in their final phase of life and are slated for retirement.

The 4DH is critical for the 21st Century Act - 2015 Edition Cures Update ONC certification of the §170.315 (g)(10) standardized API using FHIR.

The Protection of Patient Information

Protecting Patient Information

Updating Indian Health Manual (IHM)
- Part 2 Chapter 7 (HIPAA & the Privacy Act)
- Part 3 Chapter 3 (Health Information Management)
- **Part 8 Chapter 23 (RPMS Network)**

Privacy Impact Assessment (4DH)

Notice of Privacy Practices

Privacy Act System of Record Notice (PASORN)

Engaging with Stakeholders as technical solutions evolve
- Security
- Privacy
- HIM/Business Office
- Clinical Informatics
- Other users

Objectives: What to expect with the recent ONC Certified Health IT updates!

Why are we here for Health IT?

Rule, agencies

These are the Changes

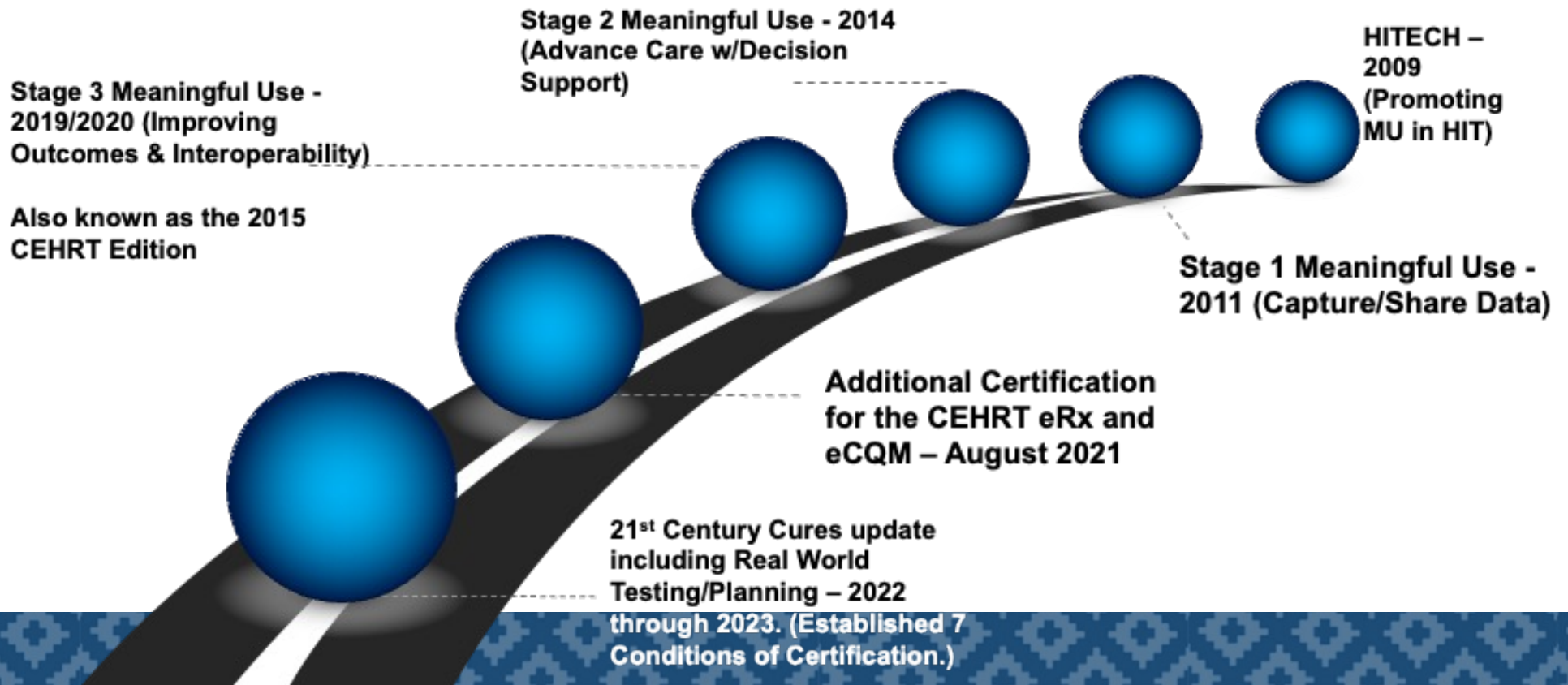Timelines for implementation

Impact on the RPMS/EHR Certified EHR

Electronic Health Record – Certification History for IHS
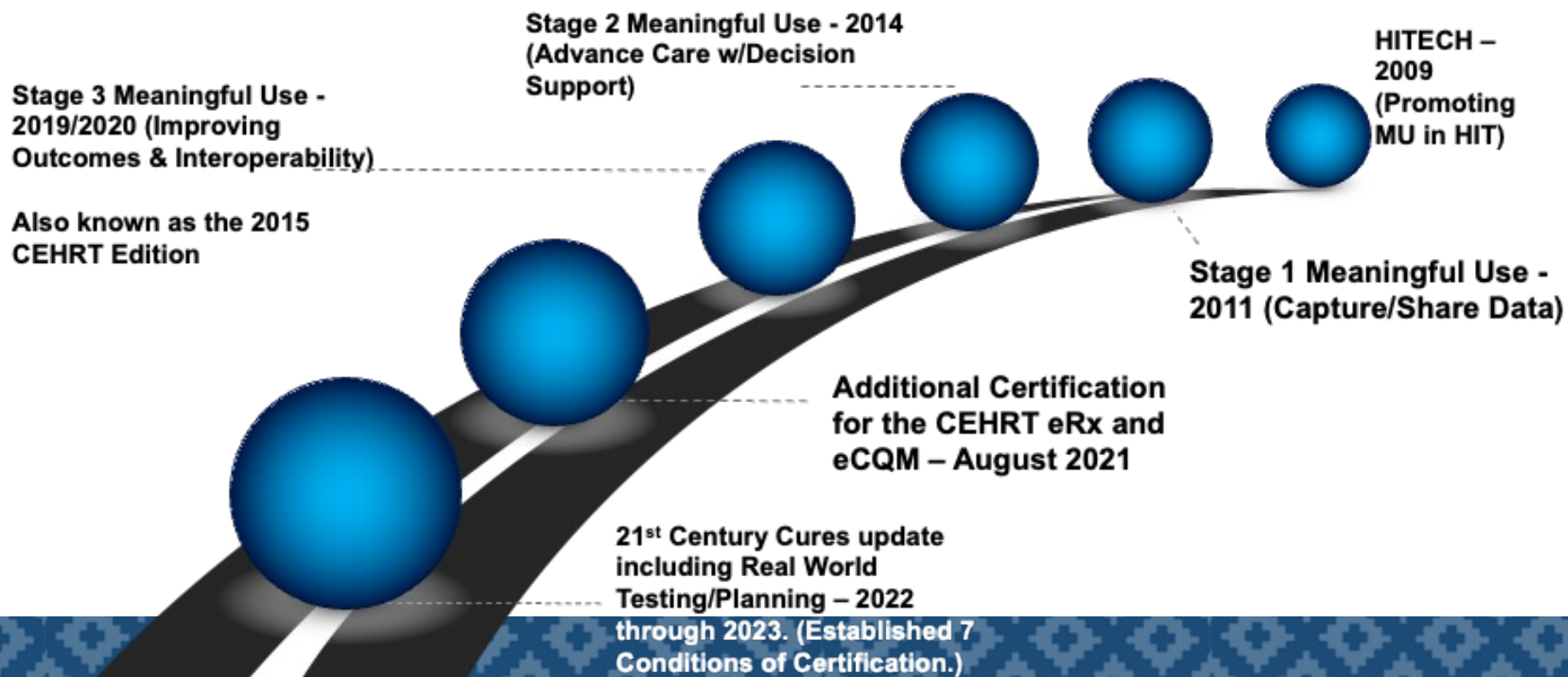
REVISIT IHS RPMS/IHS CEHRT

ROADMAP

Meaningful Use & Certification History for the IHS RPMS/EHR

Stage 2 Meaningful Use - 2014 (Advance Care w/Decision Support)

HITECH – 2009 (Promoting MU in HIT)

Stage 3 Meaningful Use - 2019/2020 (Improving Outcomes & Interoperability)

Also known as the 2015 CEHRT Edition

Stage 1 Meaningful Use - 2011 (Capture/Share Data)

Additional Certification for the CEHRT eRx and eCQM – August 2021

21st Century Cures update including Real World Testing/Planning – 2022 through 2023. (Established 7 Conditions of Certification.)

Meaningful Use & Certification History for the IHS RPMS/EHR

The Important Players

GOVERNMENT AGENCIES FOR VENDOR CERTIFIED HEALTH INFORMATION TECHNOLOGY

ONC

CMS

IHS

# Office of the National Coordinator for Health Information Technology (ONC)

- Founded in 2004 by executive order, established in statute in 2009

- ONC is charged with formulating the **federal government's health information technology (IT) strategy** to advance national goals for better and safer health care through an **interoperable nationwide health IT infrastructure**

HITECH* Act 2009

21st Century Cures Act 2016

Laying the foundation of electronic health records (EHRs) across the industry

- $40B CMS investment to subsidize EHRs for hospitals and ambulatory providers
- ONC certification of EHR systems to support HHS programs

*Health Information Technology for Economic and Clinical Health
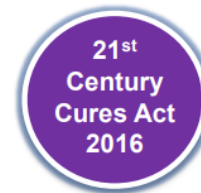
Leveraging EHRs to drive value

- Information blocking: Prohibits providers, technology developers, and health information networks from interfering with access, exchange, and use of electronic health information
- Standards: Data and application programming interface (API) standards for access "without special effort"
- Trusted Exchange Framework and Common Agreement (TEFCA): Nationwide governance for health information exchange networks
- Health IT Alignment Policy: Leveraging all HHS health IT investments to support health IT standards.

Important Acryonyms

What is HTI-1?

Implementing the 21st Century Cures Act

- EHR Reporting Program

- APIs that allow EHI to be accessed, exchanged, and used without special effort

- Reasonable and necessary activities that do not constitute information blocking

Achieving the Goals of the President's Administration Executive Orders

- E.O. 13994 "Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats"

- E.O. 13985 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" and E.O 14091 "Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"

- E.O. 14110 "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence"

Leveraging Health IT and Advancing Interoperability

- HITECH Act

- Interoperability Advancement

- ONC Health IT Certification Program

1. New Regulatory Approach for Certification Criteria ("edition-less")

 2. Certification Standards and Functionality Updates

3. Decision Support Interventions (DSI) and Algorithmic Transparency

4. Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program)

5. Information Blocking

New Regulatory Approach for Certification Criteria ("Edition-less")

Discontinuing Year-Themed "Editions"

HTI-1 Final Rule

Discontinues the year-themed editions and establish a single set of certification criteria, "ONC Certification Criteria for Health IT"

Benefits

• Allows the Certification Program and health IT developers to more effectively utilize new and updated standards and functionality in a timely manner

• Allows users of health IT to work in partnership with health IT developers to update their systems for new standards or functionality in the manner that works best for their unique needs

• Assists health care industry participants in other HHS programs that reference Certification Program standards and criteria, such as CMS's Promoting Interoperability Program, by ensuring developers provide timely updates for any new or updated certification criteria

• Supports users of health IT by reducing potential confusion of tracking use of different editions of certified health IT

Establishing Applicability and Expiration Dates for Certification Criteria and Standards

HTI-1 Final Rule

• Establishes the dates by which a prior version of a criterion is no longer applicable when a revised version (including new and revised standards) of that criterion is adopted

• Establishes applicable timelines, including expiration dates, for the adoption of standards when a new, revised, or updated version of the standard is adopted for the same purpose

Benefits

• Supports establishment of clear timelines associated with the specific criterion or standard

• Facilitates ease of reference for federal, state, local or tribal programs seeking to align their program requirements to the standards and implementation specifications available in certified health IT

• Ensures that customers are provided with timely technology updates

Two Forms of Compliance

Certification Criteria

Health IT developers with a Health IT Module certified to any revised certification criterion must update their Health IT Modules and provide such update to their customers in accordance with the dates identified for each revised criterion and/or standard included in § 170.315.

Assurances Condition and Maintenance of Certification Requirements Condition:

A health IT developer must provide an assurance that it will not interfere with a customer's timely access to interoperable health IT certified under the Program. Maintenance of Certification:

• Update: A health IT developer must update a Health IT Module, once certified to a certification criterion adopted in § 170.315, to all applicable revised certification criteria, including the most recently adopted capabilities and standards included in the revised certification criterion;

• Provide: A health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers

• Timeliness: A health IT developer must follow the timeliness requirements identified in the rule.

Certification Standards and Functionality Updates

Select New and Revised Standards and Certification Criteria

Standards

• United States Core Data for Interoperability Standard Version 3

• C-CDA Companion Guide Release 4.1

• US Core Implementation Guide 6.1.0

• "Minimum Standards" Code Sets Updates

• SNOMED, RxNorm, LOINC, NDC, etc.

## Revised Certification Criteria

• Electronic Case Reporting § 170.315(f)(5)

• Clinical Decision Support § 170.315(a)(9) ((as Decision Support Intervention § 170.315(b)(11))

• Standardized API for Patient and Population Services in § 170.315(g)(10)

• View, Download, and Transmit to 3rd Party § 170.315(e)(1)

• Patient Demographics and Observations Certification Criterion in § 170.315(a)(5)

• Transitions of Care Criterion in § 170.315(b)(1)

USCDI Background

Standard established by ONC in the 2020 21st Century Cures Act Final Rule

• Minimum dataset required for interoperability

• Defines required data elements and vocabulary standards

• Focuses on patient access/care coordination use cases

• Updated on an annual cycle with federal agency and industry input

• Updates based on multiple criteria including standards maturity and public/industry priority
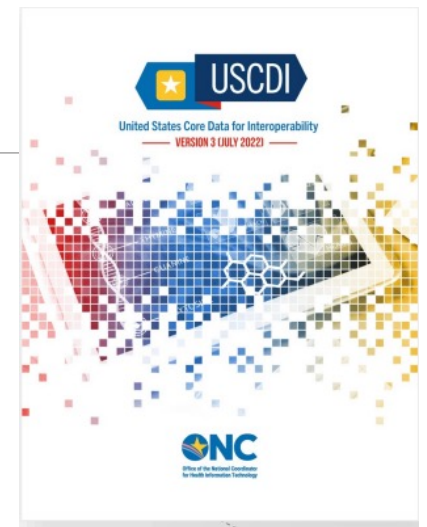
USCDI Core Principles

Core Principles

Comprises a core set of data needed to support patient care and facilitate patient access using health IT

Establishes a consistent baseline of data for other use cases

Expands over time via a predictable, transparent, and collaborative **public** process

USCDI

Why USCDI Matters

Established in the ONC Cures Act Final Rule in 2020

• Required for new Certification Criterion API to access patient data, using Fast Healthcare Interoperability Resources® (FHIR®) US Core

• USCDI v1 replaces the Common Clinical Data Set in existing Certification Criteria, using Health Level Seven International® (HL7®) Consolidated Clinical Data Architecture (CCDA) or FHIR US Core:

• Transitions of Care documents (create, send, and receive)

• Clinical Information reconciliation and incorporation

• Patient View, Download, and Transmit their health data to a 3rd party

• Electronic case reporting to public health agencies*

• Create C-CDA document • Access to data via APIs

• USCDI also defines required data for other uses, such as CMS Patient Access and Payer-to-Payer API

• **USCDI v3 proposed to be required in Health Data, Technology, and Interoperability (HTI)-1 Notice of Proposed Rule Making (NPRM)**

USCDI: Transparent, Predictable, Collaborative

• USCDI v1 is required by Cures Act Final Rule and added data classes clinical notes and provenance, and data elements pediatric vital signs and address

• USCDI v2 added three data classes and 22 data elements in support of advancing health equity (sexual orientation and gender identity [SOGI] and social drivers of health [SDOH])

• **USCDI v3 added 24 data elements focused on factors promoting equity, reducing disparities, and supporting public health data interoperability.**
   o **Proposed as new required version in HTI-1, with an effective date of December 31, 2024**

Prioritization Criteria for New USCDI Data Elements

- Healthcare disparities and inequities

- Underserved communities

- Behavioral health

- Public health

- Key additions over past USCDI versions

- Modest burden for

- Standards and implementation guide developers

- Health IT developers

- Providers and health systems implementing updates

- Aggregate lift for all new data elements

USCD*Interoperability Version 3*

Assessment & Plan of Treatment	**Laboratory** ✓ Tests ✓ Values & Results	**Smoking Status**	**Provenance *NEW*** ✓ Author ✓ Author Time Stamp ✓ Author Organization
Care Team Members		**Unique Device Identifiers for a patient's Implantable Device.**	
Clinical Notes *NEW* ✓ Consultation Note ✓ Discharge Summary Note ✓ History & Physical ✓ Imaging, Lab, Pathology report narratives ✓ Procedure Note ✓ Progress Note	**Medications** ✓ Medications ✓ Medication Allergies	**Pediatric Vital Signs *NEW*** BMI Weight for age/length/sex Occipital-frontal circumference	**Vital Signs** ✓ Diastolic Blood Pressure ✓ Systolic Blood Pressure ✓ Body Height ✓ Body Weight ✓ Heart Rate ✓ Respiratory Rate ✓ Body Temperature ✓ Pulse Oximetry ✓ Inhaled Oxygen Concentration
	Patient Demographics/Information ✓ First Name ✓ Last Name ✓ Middle Name (includes middle initial) ✓ Previous Name ✓ Suffix ✓ Birth Sex	**Patient Demographics/Information** ✓ Date of Birth ✓ Race ✓ Ethnicity ✓ Preferred Language	
Goals – Patient Goals			
Health Concerns		✓ Address *NEW* ✓ Phone Number *NEW*	
Immunizations	**Problems**	**Procedures**	

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