Public Health Data Systems Task Force

Overview of ONC Health IT Certification Program and Relevant Certification Criteria

August 24, 2022

ONC Certification: The Foundation of Health IT

ONC certification is now the **foundation of the US digital healthcare infrastructure**, covering 400+ health IT products used by 97% of hospitals and over 84% of clinical offices and required by numerous federal programs. Health IT systems regularly certified to keep pace with advances in medicine, technology, and policy.

ONC Health IT Certification:

- Establishes baseline technical capabilities for interoperability
- Promotes the exchange of electronic health information
- Establishes baseline privacy and security requirements
- Increases transparency in the functionality and use of certified health IT
- Promotes competition and choice in health IT
- Provides baseline assurance that a health IT module will perform clinical care and data exchange functions in accordance with interoperability standards and user-centered design

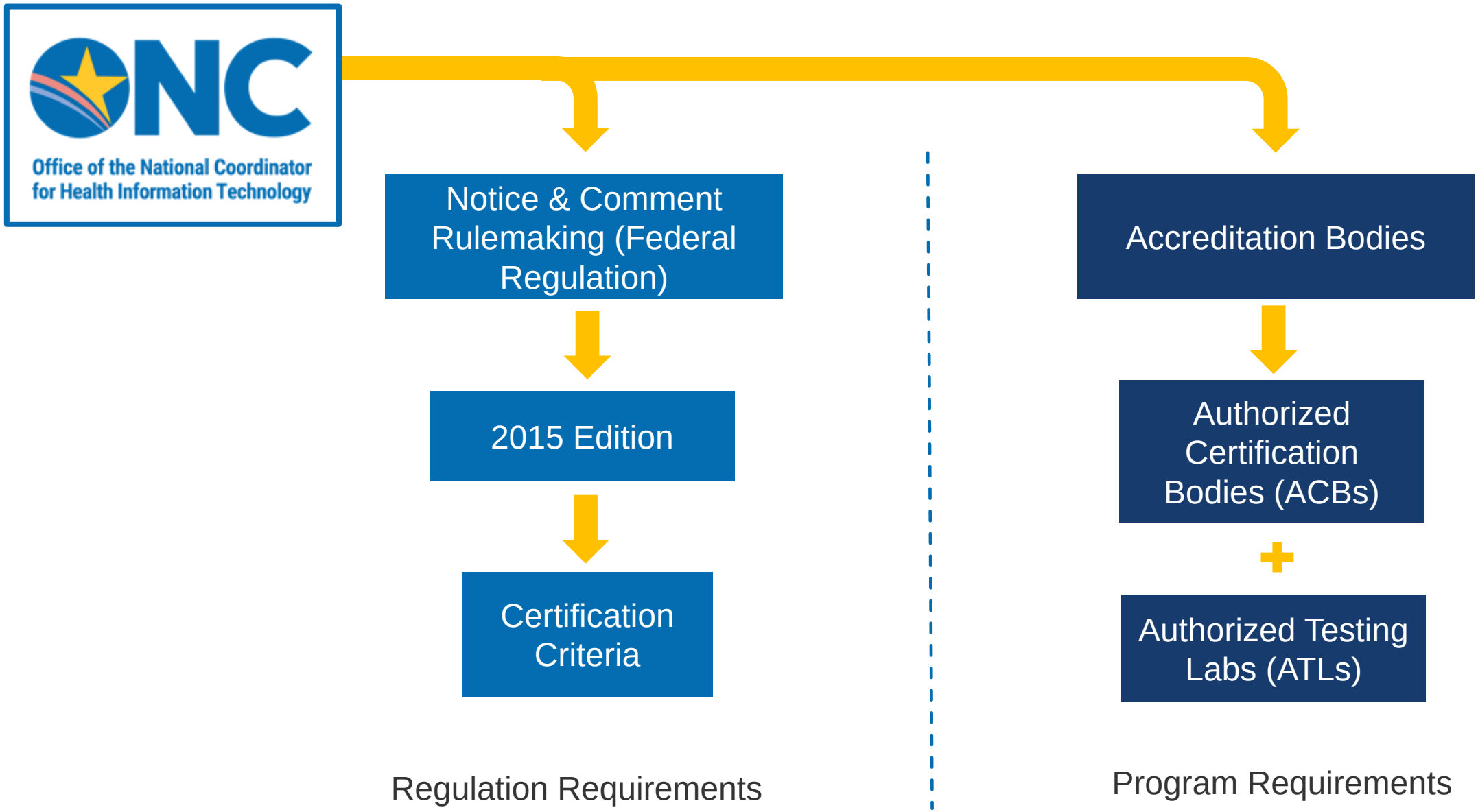
Primary Components of the ONC Health IT Certification Program

Certification Criteria – Roughly 60 criteria across 8 categories of functionality

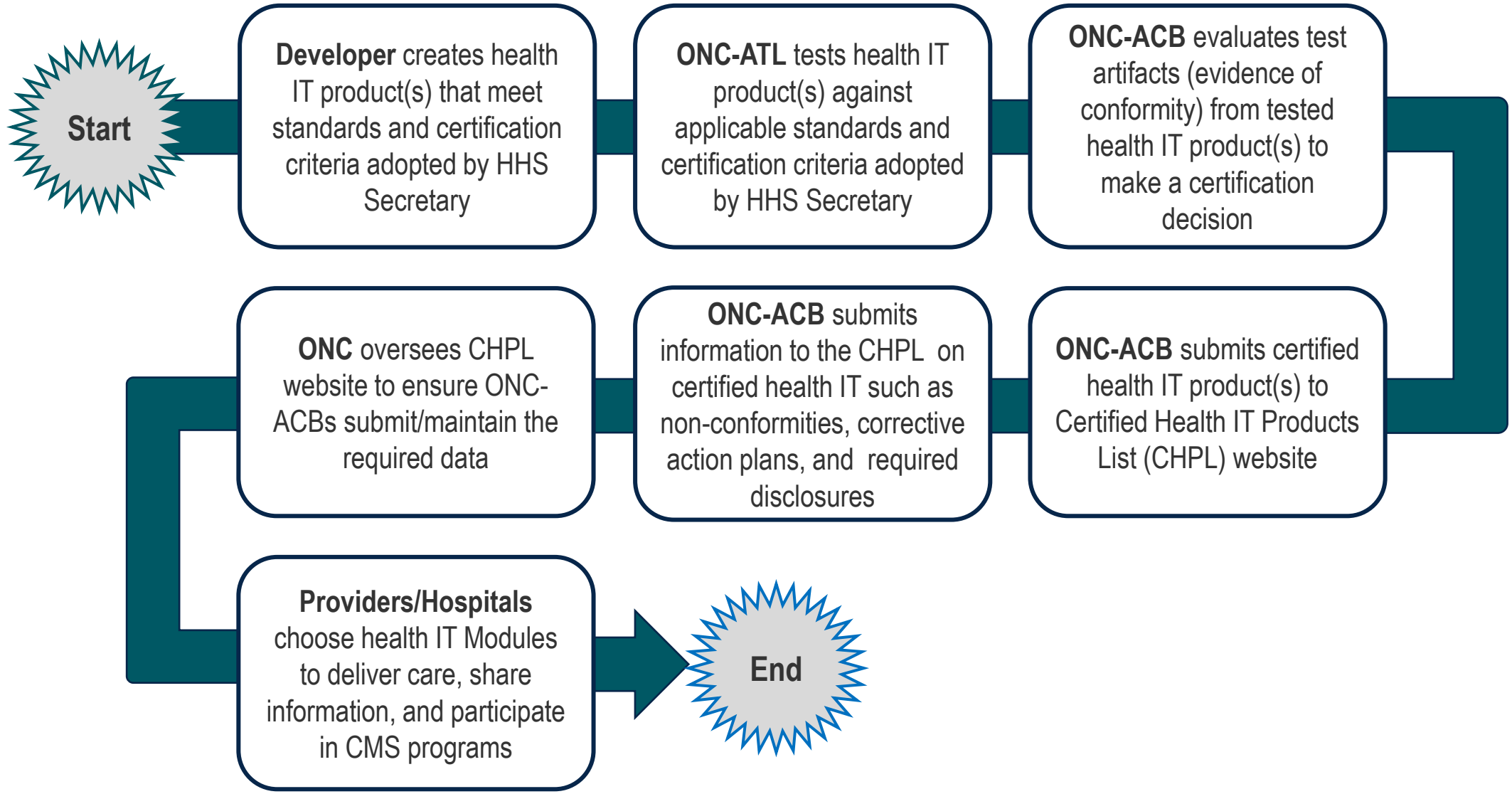
Standards Coordination – Establish US Core Data for Interoperability (USCDI)

Conditions of Certification – Six conditions, which are ongoing business and behavioral requirements for certified health IT developers

How Does ONC Health IT Certification Work?



Testing and Certification Process



Public Health Reporting Criteria

Criterion Citation	Criterion Name
§ 170.315(f)(1)	Transmission to immunization registries
§ 170.315(f)(2)	Transmission to public health agencies — syndromic surveillance
§ 170.315(f)(3)	Transmission to public health agencies — reportable laboratory tests and value/results
§ 170.315(f)(4)	Transmission to cancer registries
§ 170.315(f)(5)	Transmission to public health agencies — electronic case reporting
§ 170.315(f)(6)	Transmission to public health agencies — antimicrobial use and resistance reporting
§ 170.315(f)(7)	Transmission to public health agencies — health care surveys

All criteria point to specific standards and implementation guides and are eligible for SVAP

Test Tooling

- NIST hosts test tools for 5 of the 7 ONC public health criteria where visual demonstration to specified standards is required
  - HL7 CDA Cancer Registry Reporting Validation Tool
  - HL7v2 Immunization Test Suite
  - HL7v2 Syndromic Surveillance Test Suite
  - HL7v2 Electronic Laboratory Reporting (ELR) Validation Tool (2014 and 2015 Edition)
  - HL7 CDA National Health Care Surveys Validator
- CDC hosts the AU/AR tool (based on HL7 standard) for § 170.315(f)(6)
  - NHSN Data Validation Tool for AUR
- Currently, electronic case reporting (§ 170.315(f)(5)) does not have a test tool and is demonstrated through self-attestation conformance method

Existing Public Health Criteria

- (f)-criteria **Do**
  - Represent report generation and transmission functionalities
  - Require Health IT Modules to adhere to specific standards and implementation guides
  - Provide assurances that the Health IT Module (aka “the product”) performs as intended

- (f)-criteria **Do Not**
  - Cover all functionalities that may be of interest
    - Immunization Integration Partnership (an ONC-Authorized alternative test method (ATM))
  - Certify data quality
  - Certify the entity or organization using the technology

Questions

Contact ONC

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Health IT Feedback Form:
https://www.healthit.gov/form/healthit-feedback-form

Twitter: @onc_healthIT

LinkedIn: Office of the National Coordinator for Health Information Technology

Youtube:
https://www.youtube.com/user/HHSONC

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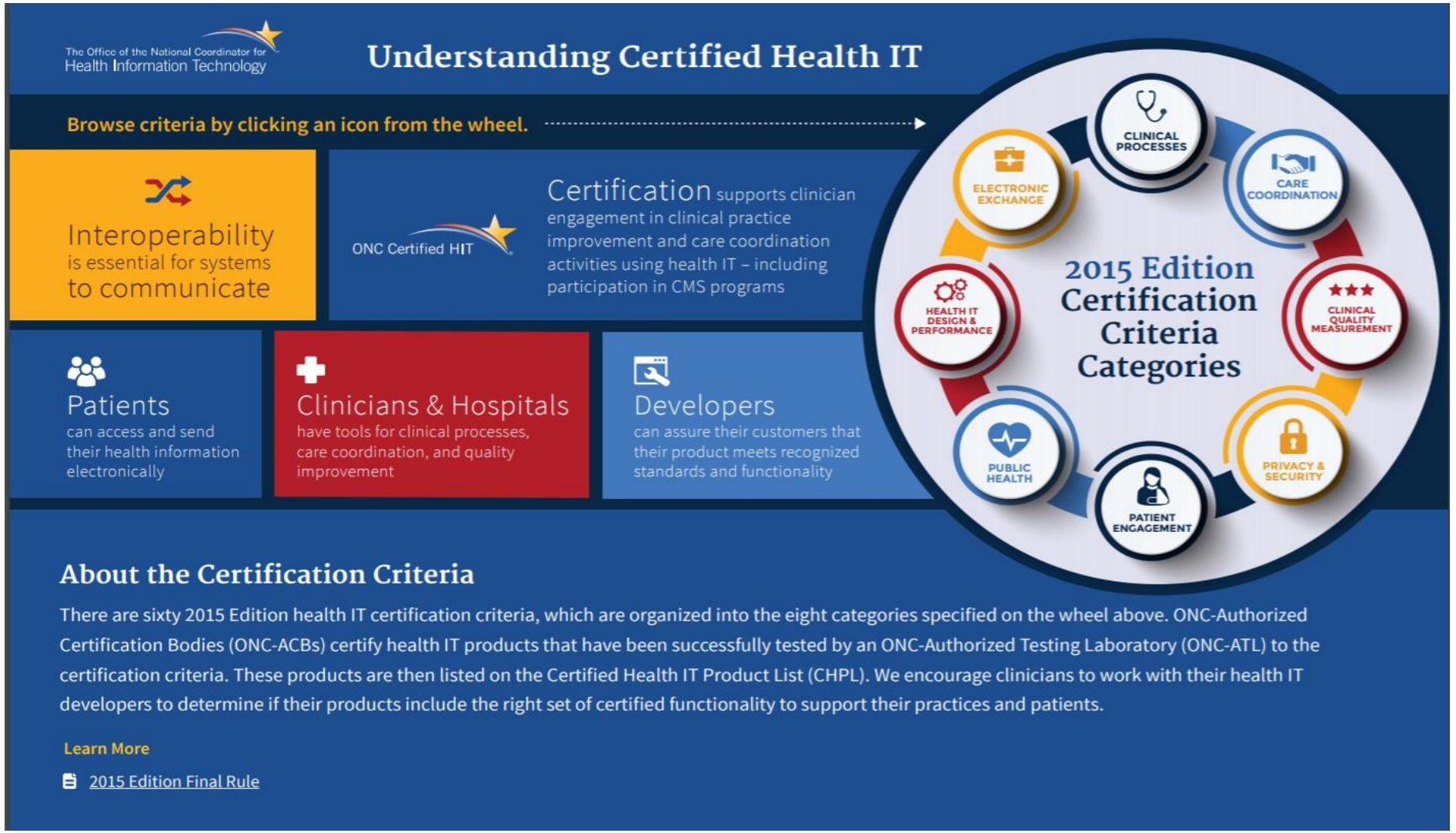
Extra Slides

ONC's 2015 Edition Has Roughly 60 Criteria Across 8 Categories



Conditions and Maintenance of Certification

The 21st Century Cures Act (Section 4002) requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program

The Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified Health IT Module(s).

Any noncompliance with the proposed Conditions and Maintenance of Certification requirements would be subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program.

There are seven Conditions of Certification with accompanying Maintenance of Certification Requirements. They are:

1. **Information Blocking**
2. **Assurances**
3. **Attestations**
4. **Communications**
5. **Real World Testing**
6. **Application Programming Interfaces (APIs)**
7. ***(Future) Electronic Health Record (EHR) Reporting Criteria Submission***

Example Certification Criteria in 42 CFR 170.315

Clinical Processes & Care Coordination Criteria:
- CPOE
- Demographics
- CDS
- Transition of Care
- CIRI
- eRx
- Care Plan

Patient Engagement Criteria:
- View, Download, Transmit
- Secure Messaging
- Patient Health Information Capture

Privacy & Security Criteria:
- Authentication, Access Control, and Authorization
- End-user Device Encryption
- Audit report(s)

Public Health Criteria:
- Immunization Registries
- Syndromic Surveillance
- Electronic Case Reporting

For more info, check out: https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method

Standardized Application Programming Interface (API) for Patient and Population Services – 170.315(g)(10)

- Established a new API certification criterion that requires health IT developers to support standardized APIs for single patient and population services.
- Certification criterion is limited to API-enabled “read” services using the HL7® Fast Healthcare Interoperability Resources (FHIR) Release 4 standard**, namely FHIR Release 4.0.1**
- The use of the FHIR standard and a set of implementation specifications provides known technical requirements against which third-party apps can be developed.
    - App registration, Authentication, Patient authorization & revocation, Token Introspection, etc.

Supports two types of API-enabled services:

» Services for which a **single patient’s data** is the focus

» Services for which **multiple patients’ data** are the focus

US Core Data for Interoperability v3

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

Immunizations
- Immunizations

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

Medications
- Medications ★
- Dose ★
- Dose Units of Measure ★
- Indication ★
- Fill Status ★

Patient Demographics/ Information ★★
- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix ★★
- Previous Name
- Date of Birth
- Date of Death ★
- Race
- Ethnicity
- Tribal Affiliation ★
- Sex ★★
- 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

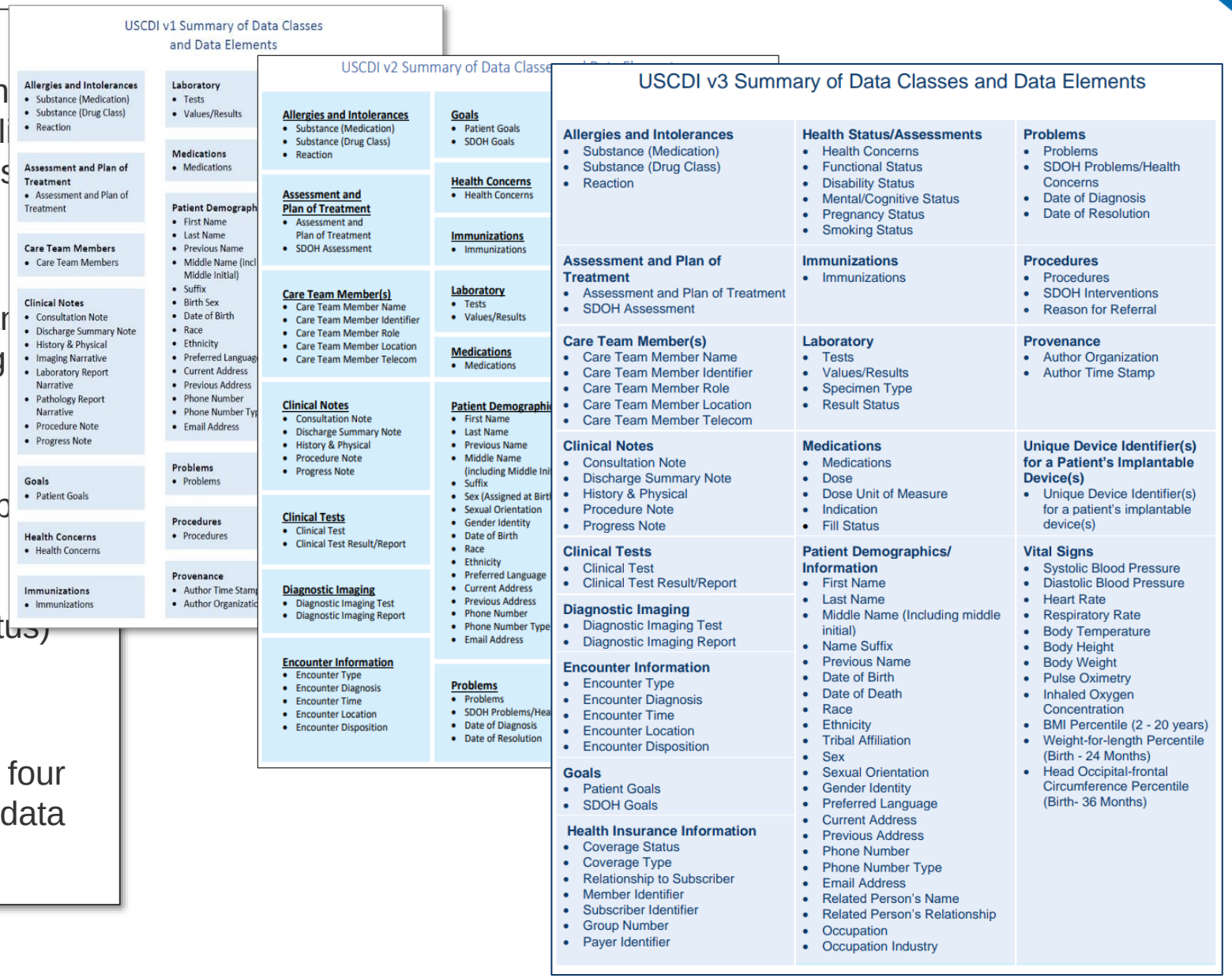
Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

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 - 24 Months) ★★
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

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

USCDI Evolution Supports 21st Century Cures Act

- USCDI v1 is required by Cures Act Fin
  Rule and added four data elements: cl
  notes, provenance, pediatric vital signs
  address
- USCDI v2 added three data classes ar
  data elements in support of advancing
  health equity (SOGI and SDOH)
- Draft USCDI v3 addressed equity, disp
  and public health data interoperability.
  Proposed two data classes (Health
  Insurance Information and Health Status)
  and 20 data elements
- USCDI v3 adopts draft USCDI v3 and four additional elements in the Medication data class (≈ 80 data elements)



USCDI v1 Summary of Data Classes and Data Elements

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

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Members
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demograph
- First Name
- Last Name
- Previous Name
- Middle Name (incl Middle Initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Languag
- Current Address
- Previous Address
- Phone Number
- Phone Number Ty
- Email Address

Problems
- Problems

Procedures
- Procedures

Provenance
- Author Time Stamp
- Author Organizatio

USCDI v2 Summary of Data Classe

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 Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographi
- First Name
- Last Name
- Previous Name
- Middle Name (including Middle Ini
- Suffix
- Sex (Assigned at Birt
- Sexual Orientation
- Gender Identity
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems
- SDOH Problems/Hea
- Date of Diagnosis
- Date of Resolution

USCDI v3 Summary of Data Classes and Data Elements

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/Assessments
- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Smoking Status

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results
- Specimen Type
- Result Status

Medications
- Medications
- Dose
- Dose Unit of Measure
- Indication
- Fill Status

Patient Demographics/ Information
- First Name
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- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- 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

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