ASTP Assistant Secretary for Technology Policy

ONC Health IT Certification Program Developer Roundtable

September 10, 2025

Disclaimers and Public Comment Guidance

The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.

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3. Enforcement Discretion Notices
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5. 2025 Standards Version Advancement Process (SVAP)
6. CMS EHR Certification ID Update
7. Insights Condition and Maintenance of Certification

Today's Speakers

- Robert Anthony, Certification & Testing
- Jeffery Smith, Certification & Testing
- Shawn Spurlock, Certification & Testing
- Papia Paul, Certification & Testing
- Meghan Gabriel, Technical Strategy and Analysis

HTI-4 Final Rule Draft Test Procedures Comment Period

- ASTP is providing an opportunity for the public to comment on draft test procedures for the ONC Health IT Certification Program criteria that were revised in the HTI-4 Final Rule.
- The comment period opened today and will close on September 24, 2025.
- ASTP will review all feedback and make necessary adjustments to the Test Procedures before publishing the updated criteria Test Procedures around the effective date of the HTI-4 Final Rule.
- For more information, please visit the HTI-4 Public Comment Webpage
  - (www.healthit.gov/topic/certification-ehrs/test-procedure-public-comments-0)

Enforcement Discretion Notices

Robert Anthony, Certification & Testing

Electronic Case Reporting Enforcement Discretion

- On January 31, 2025, President Donald J. Trump signed Executive Order 14192, emphasizing deregulation to reduce compliance costs, enhance economic prosperity, and improve quality of life. In alignment with this, the ASTP/ONC announced enforcement discretion for certain regulatory requirements under the Health IT Certification Program, specifically for electronic case reporting (eCR) standards.
- In HTI-1 we finalized an updated 170.315(f)(5) Specifically, in paragraph (f)(5)(ii), we incorporated by cross-reference the use of either the HL7 clinical document architecture (CDA) eICR standard or the Fast Healthcare Interoperability Resources (FHIR) eCR standard for certification to the criterion with a required effective date of January 1, 2026 (89 FR 1226-31).

In relation to these new requirements, ASTP/ONC is exercising the following enforcement discretion:

For CY 2025	For CY 2026
1. ASTP/ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from certified health IT not complying with the adopted standards finalized in 45 CFR 170.315(f)(5), so long as the certified health IT remains conformant with either 45 CFR 170.315(f)(5)(i) or the requirements in (f)(5)(ii) as follows: a. (ii)(A) Consume and process case reporting trigger codes and identify a reportable patient visit or encounter based on a match with a trigger code value set (e.g., table). b. (ii)(B) Create a case report. c. (ii)(C) Receive, consume, and process a case report response. d. (ii)(D) Transmit a case report electronically to a system capable of receiving a case report. 2. ASTP/ONC will not take any enforcement action under 45 CFR 170.565 against an ONC-ACB based on non-compliance with 45 CFR 170.550 for certifying a Health IT Module that is presented for certification to the "*transmission to public health agencies – electronic case reporting*" certification criterion (45 CFR 170.315(f)(5)), where the Health IT Module demonstrates and maintains conformance with paragraph (f)(5)(i) or the requirements of paragraph (f)(5)(ii) as specified in paragraph 1a through d above.	1.ASTP/ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises from certified health IT not conforming to the adopted standards finalized in 45 CFR 170.315(f)(5)(ii), so long as the certified health IT remains conformant with the requirements in (f)(5)(ii) as follows: a. (ii)(A) Consume and process case reporting trigger codes and identify a reportable patient visit or encounter based on a match with a trigger code value set (e.g., table). b. (ii)(B) Create a case report. c. (ii)(C) Receive, consume, and process a case report response. d. (ii)(D) Transmit a case report electronically to a system capable of receiving a case report. 2. ASTP/ONC will not take any enforcement action under 45 CFR 170.565 against an ONC-ACB based on non-compliance with 45 CFR 170.550 for certifying a Health IT Module that is presented for certification to the "*transmission to public health agencies – electronic case reporting*" certification criterion (45 CFR 170.315(f)(5)), where the Health IT Module demonstrates and maintains conformance with the requirements of paragraph (f)(5)(ii) as specified in paragraph 1a through d above.

https://www.healthit.gov/topic/electronic-case-reporting-certification-criterion-enforcement-discretion-notice

Real World Testing Enforcement Discretion Notice

In consideration of potential future deregulatory actions under the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health Information Technology (ONC) (collectively, "ASTP/ONC") authorities and consistent with EO 14192, ASTP/ONC has identified certain regulatory requirements for which the exercise of enforcement discretion would reduce burden and costs for regulated entities.

Section 3001(c)(5)(D)(v) of Title XXX of the Public Health Service Act (PHSA), as amended by the 21st Century Cures Act (Cures Act), requires, as a Condition and Maintenance of Certification under the ONC Health IT Certification Program (Program), that Health IT developers successfully test the real world use of their technology for interoperability in the type of setting in which such technology would be marketed.

In relation to these new requirements, ASTP/ONC is exercising the following enforcement discretion:

For CY 2025	For CY 2026
➢ ASTP/ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from a health IT developer not complying with 45 CFR 170.405(b)(1). This means that a developer with a Health IT Module(s) certified to one or more of the criteria referenced in 45 CFR 170.405(a) is not expected to submit an annual real world testing plan to its ONC-Authorized Certification Body (ONC-ACB) for the 2026 real world testing year. ➢ ASTP/ONC will not conclude that an ONC-ACB has failed to adhere to 45 CFR 170.523(p)(1) and (3), find a violation of 45 CFR 170.560(a), or take any enforcement action under 45 CFR 170.565 against an ONC-ACB for not reviewing CY 2026 real world testing plans and submitting the plans to ASTP/ONC for public availability	➢ ASTP/ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from a health IT developer not complying with 45 CFR 170.405(b)(2), except with respect to Health IT Modules certified to the certification criteria specified in 45 CFR 170.315(g)(7) through (10). This means that ASTP/ONC only expects a developer with a Health IT Module(s) certified to the (g)(7) through (10) certification criteria, as of August 31, 2024, will submit a CY 2025 real world testing results report to its ONC-ACB by March 2026. ➢ ASTP/ONC will not conclude that an ONC-ACB has failed to adhere to 45 CFR 170.523(p)(2) and (3), find a violation of 45 CFR 170.560(a), or take any enforcement action under 45 CFR 170.565 against an ONC-ACB if an ONC-ACB does not review and confirm that applicable health IT developers submit real world testing results reports, except with respect to Health IT Modules certified to the criteria specified in 45 CFR 170.315(g)(7) through (10).

https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement

HTI-4 Final Rule

Jeffery Smith, Certification & Testing

Published as part of the FY 2026 Hospital Inpatient Prospective Payment System (IPPS) Final Rule (CMS-1833-F)

Date: August 4, 2025

URL: https://www.federalregister.gov/documents/2025/08/04/2025-14681/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-ipps-and

Health Data, Technology, and Interoperability (HTI-2) Proposed Rule (August 5, 2024)

Proposed a wide-ranging set of updates to the ONC Health IT Certification Program, including:

- Minimum standards code set updates
- Electronic prescribing and public health exchange
- Electronic prior authorization
- United States Core Data for Interoperability (USCDI) v4
- Exceptions related to information blocking
- Provisions of the Trusted Exchange Framework and Common Agreement (TEFCA)

Proposed to expand standards and certification for:

- Real-time benefit tools
- Modular and foundational API capabilities
- Access to billing and payment transactions
- Implementing the 21st Century Cures Act Real-Time Prescription Benefits

What does the HTI-4 Final Rule do?

- Finalizes a limited subset of the proposals from the HTI-2 proposed rule:
  - Electronic prescribing
  - Real-time prescription benefit
  - Electronic prior authorization
- These updates intersect with and support CMS policy initiatives.
- Published as part of the FY 2026 Hospital Inpatient Prospective Payment System (IPPS) Final Rule (CMS-1833-F)

What is the purpose of the HTI-4 Final Rule?

- Support HHS efforts to reduce administrative burdens for clinicians
- Improve patients' ability to receive timely, affordable, and evidence-based care
- Facilitate exchange of electronic health information across the care continuum

Electronic Prescribing

BENEFITS

- The “electronic prescribing” criterion supports the availability of certified health IT to enable the exchange of prescription information among prescribers, pharmacies, intermediaries, and payers.
  - With electronic prescribing, health care providers can securely transmit prescription information to pharmacies. When a pharmacy receives a request, it can begin filling the medication right away.
- New NCPDP SCRIPT standard version 2023011 has new benefits and enhancements to the existing standard
  - Improved extensibility & organization that will support more granular and logical structuring of product and drug information, supporting advanced clinical decision support and analytics.
  - Enhanced support for electronic prior authorization and medication history, supporting faster, more accurate, and transparent prescription workflows.
- Aligns with recent updates to the Medicare Part D program.

Electronic Prescribing

PROVISION

- ASTP/ONC finalized updates to the “electronic prescribing” criterion in 45 CFR 170.315(b)(3) to incorporate an updated version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011.
- Developers certifying a Health IT Module to 45 CFR 170.315(b)(3) may use either the NCPDP SCRIPT standard version 2023011 or the NCPDP SCRIPT standard version 2017071 up to and including December 31, 2027.
- After January 1, 2028, Health IT Modules certified to the “electronic prescribing” criterion must be updated to the Health IT Module to the NCPDP SCRIPT standard version 2023011.
- ASTP/ONC also finalized a requirement to support previously optional electronic prior authorization transactions when using the NCPDP SCRIPT standard version 2023011.
- ASTP/ONC also removed transactions currently identified as optional for the certification criterion, simplifying Program requirements and focusing on priority functionalities.

Real-Time Prescription Benefit

BENEFITS

- Real-time benefit tools empower providers and their patients to address affordability issues at the time that a product is prescribed, by comparing the patient-specific cost of a product to the cost of a suitable alternative and comparing prescription costs at different pharmacies.
- Will improve the ability of pharmacy benefit managers to provide cost and coverage information in a format that all EHRs certified to the criterion will be able to consume, reducing their need to implement specific, proprietary APIs for different health IT vendors.
- Research has shown that patients and clinicians want this information and that access to real-time prescription benefit may increase medication adherence and reduce out-of-pocket costs.
- Aligns with requirements for real-time benefit tools established by Medicare Part D plans to adhere to the NCPDP standard version 13.

Real-Time Prescription Benefit

PROVISION

- ASTP/ONC finalized a new "real-time prescription benefit" certification criterion in 45 CFR 170.315(b)(4).
- Supports certified health IT which allows clinicians to access patient-specific out-of-pocket costs and coverage information for the prescription drugs, vaccines, and Medicare Part D-covered medical supplies that they order.
- Implements Section 119(b)(3) of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).
- Incorporates the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13.
- Will be included in the Base EHR definition after January 1, 2028.
- Any Health IT Module presented for certification to the “electronic prescribing” criterion must also be certified to the “real-time prescription benefit” criterion.

Electronic Prior Authorization

BENEFITS

- Supports HHS agency-wide approach to electronic prior authorization that meets the Department's interoperability and burden reduction goals.
- Addresses processes that have contributed significantly to patient and provider burden, for instance, delays experienced by patients and clinicians as they seek to satisfy the requirements associated with prior authorization rules set by payers.
- Multiple criteria support certification flexibility for developers wishing to support only a part of electronic prior authorization technology stack.
- Use of technology meeting the certification criteria for electronic prior authorization will help to enable exchange of information that promotes a more effective marketplace, increases competition, and provides benefits to patients.

Electronic Prior Authorization

PROVISION

- ASTP/ONC adopted three new certification criteria in 45 CFR 170.315(31) – (33) to support more efficient management of electronic prior authorization tasks and reduce administrative burden for providers.
- These criteria are based on Fast Healthcare Interoperability Resources (FHIR®) implementation specifications developed by the HL7® Da Vinci project
  - Provider Prior Authorization API – Coverage Requirements Discovery: Defines a workflow to allow health care providers to request information from payers about coverage requirements.
  - Provider Prior Authorization API – Documentation Templates and Rules: Provides a mechanism for clinicians and other EHR users to navigate and quickly assemble the information needed to support a prior authorization request according to a payer's requirements.
  - Provider Prior Authorization API – Prior Authorization Support: enables direct submission of prior authorization requests from health IT systems using FHIR, as well as supporting follow-up tasks such as checking the status of a previously submitted request.

Modular API Criteria

PROVISION

ASTP/ONC finalized two supporting certification criteria (and two FHIR specifications) referenced by other criteria for electronic prior authorization included in HTI-4.

- 45 CFR 170.315(j)(20) *Workflow Triggers for Decision Support Interventions — Clients*
- 45 CFR 170.315(j)(21) *Subscriptions — Client*

BENEFITS

- These criteria establish minimum requirements to support CDS Hooks and Subscriptions FHIR capabilities for prior authorization, though these capabilities may be applicable to many other use cases
- CDS Hooks provides a framework for fast decision support in provider workflows (e.g., payer coverage at order sign).
- Subscriptions enable a user to be proactively notified of an event or data update of interest.

Certification to the (g31)-(g)(33) and the (j)-criteria

- Certification to (g)-criteria that cross-reference (j)-criteria in regulation text demonstrates conformance to both criteria
  - Example: A Health IT Module certified to *(g)(31) provider prior authorization API – coverage requirements discovery* requires support for the capabilities in paragraph (j)(20) for CDS Hooks and specifies support for the "order-sign" CDS Hook.
  - Certifying to (g)(31) means the Health IT Module also supports (j)(20) thus does not need to separately certify to (j)(20).
  - (j)-criteria are "modular" and standalone:
    - If a Certified Health IT developer wishes to certify only to (j)(20) (or any other (j)-criterion), they may do so without certifying to any (g)-criterion that cross references that (j)-criterion

Adoption of Standards for Patient, Provider, and Payer APIs

- ASTP/ONC finalized a series of implementation specifications related to the exchange of clinical and administrative data with payers as well as the sharing of formulary and provider directory information.
- In addition to the three specifications supporting the criteria finalized for electronic prior authorization, ASTP/ONC adopted other specifications recommended by CMS for use by payers implementing the APIs established in the Interoperability and Patient Access and the Interoperability and Prior Authorization Final Rules.
- Only the prior authorization IGs are referenced in certification criteria at this time.

- *HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1—STU 2*
- *HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1—STU 2*
- *HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.0.1—STU 2*
- HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version 2.0.0—STU 2 US
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version 1.1.0—STU 1.1 US

Questions from the Public Webinar Crowd

Q: Which Prior Auth certification criterion are included as a base EHR function? Any?

A: None of the ePrior Auth criteria are in the Base EHR definition; thus, adoption and use is driven by CMS requirements for providers (e.g., through MIPS and Promoting Interoperability)

Q: Would you please confirm the timeline for Prior auth and associated modular APIs?

A: Because the Certification Program is voluntary, there is not a specific deadline specified for ePA certification. However, many healthcare providers participating in the Medicare Promoting Interoperability program and the MIPS Promoting Interoperability performance category will be required to report on an electronic prior authorization measure beginning in 2027.

Q: By naming version 2.0.1 of the IG for CRD, DTR, and PAS, how will the 2.1 and 2.2 fixes of the IGs be incorporated into the Program?

A: ASTP/ONC uses the Standards Version Advancement Process (SVAP) to permit health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program to newer versions of adopted standards. For more info, visit: https://www.healthit.gov/topic/standards-version-advancement-process-svap.

Q: Do the new standards preempt state laws that might require different standards?

A: There is nothing in the requirements that preempt state laws. These requirements are specific to developers who voluntarily participate in the ONC Health IT Certification Program.

Resources Available on HealthIT.gov!

Visit https://healthIT.gov/HTI4 for more information.

- → HTI-4 Final Rule Blog
- → HTI-4 Final Rule Fact Sheet
- → URL to view the Final Rule at the Federal Register

2025 Standards Version Advancement Process (SVAP)

Shawn Spurlock, Certification & Testing

Standards Version Advancement Process (SVAP)

The SVAP allows health IT developers participating in ONC's Health IT Certification Program to voluntarily update their Health IT Modules to use newer versions of standards than are adopted in regulation so long as certain conditions are met.

Why Is This Important?

- Provides flexibility to approve newer versions of adopted standards without rulemaking.
- Institutes a predictable and timely approach within the Certification Program to keep pace with the industry's standards development efforts.
- Supports interoperability in the real world as updated versions of standards reflect insights gained from real-world implementation and use.

ONC established the voluntary SVAP flexibility as part of the "Real World Testing" Condition and Maintenance of Certification requirement of the 21st Century Cures Act.

SVAP and Certification

- Limited to standards adopted in the certification criteria to meet the Real World Testing Condition of Certification.
- Increased flexibility when seeking initial certification or to maintain certification of a Health IT Module.
- Ensures standards version updates are effectively implemented.
- Address standards version updates in annual Real World Testing plans and results.

SVAP Certification

https://www.healthit.gov/topic/standards-version-advancement-process-svap

The SVAP Cycle

- To keep pace with the industry's standards development efforts, the process to identify, approve, and make available newer versions of standards takes place on an annual cycle
- The cycle commences each with the opening of the Public Comment Period and concludes when the Approved SVAP Standards become effective.

Previously Approved SVAP Standards

- A version of an adopted standard approved for use during any SVAP cycle remains available for certification until a newer SVAP version of that standard is approved.
- If a newer SVAP version is approved, the previously approved SVAP version will be replaced and no longer available for use in the Certification Program.
  - Certified Health IT developers **do not** need to keep advancing to newer SVAP versions once they choose to use SVAP.
  - No new certifications can be made to the replaced SVAP version once the newer version goes into effect in the Certification Program.
  - Any certifications to the replaced SVAP version will still be valid.

Previously Approved SVAP Standards:
https://www.healthit.gov/topic/standards-version-advancement-process-svap

Approved Standards for 2025

- **United States Core Date for Interoperability (USCDI), Version 3.1, (June 2025)-**

  https://www.healthit.gov/isp/sites/isp/files/2024-07/USCDI-Version-3.1-July-2024-Final.pdf

- **United States Core Data for Interoperability (USCDI), Version 5, March 2025 Errata**

  https://www.healthit.gov/isp/sites/isp/files/2024-07/USCDI-Version-5-July-2024-Final.pdf

- **HL7® FHIR® US Core Implementation Guide STU 8.0.0, (June 2025)**

  https://hl7.org/fhir/us/core/STU8/

- **HL7 CDA® R2 Implementation Guide: Consolidated -CDA Templates for Clinical Notes Edition 4.0 – US Realm (June 2025)**

  https://hl7.org/cda/us/ccda/4.0.0/

- **2025 CMS QRDA I Implementation Guide for Hospital Quality Reporting (Updated May 2024)**

  https://ecqi.healthit.gov/sites/default/files/QRDA-HQR-2025-v1.1.pdf

- **2025 CMS QRDA III Implementation Guide for Eligible Clinicians (Updated December 2024)**

  https://ecqi.healthit.gov/sites/default/files/2025-CMS-QRDA-III-EC-IG-v1.1.pdf

SVAP Resources

- **2025 SVAP Fact Sheet: https://www.healthit.gov/sites/default/files/2025-06/2025_SVAP_Fact_Sheet_508.pdf**
- **SVAP Certification Page**: **https://www.healthit.gov/topic/standards-version-advancement-process-svap**
  - Obtain the list of approved SVAP versions and operational information for certification
- **SVAP Process Page**: **https://www.healthit.gov/svap**
  - View information on the annual process, including the list of eligible standards and their versions for consideration
- **ASTP Standards Bulletin**: **https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin**
  - View and sign up for healthcare stakeholder alerts that include updates about ONC health IT standards initiatives such as the SVAP
- **Certification Program Resources**: **https://www.healthit.gov/topic/certification-ehrs/certification-resources**
  - Access reference documents and other resources related to ONC's Health IT Certification Program

CMS EHR Certification ID Update

Papia Paul, Certification & Testing

CMS EHR Certification ID
What's New

CMS EHR Certification ID

- Generated by the Certified Health IT Product List (CHPL) for CMS reporting
- Represents product(s) certified to 100% of the Base EHR Definition

Why Now?

- Previously tied to editions, but Certification Program is now edition-less
- Need identifiers to stay current as certification criteria evolve

What's Changing?

- **Year-based syntax:** "2025C" replaced "15C" as of Sept. 1, 2025
- New identifier each Sept. 1 (e.g., "2026C" next year)

CMS EHR Certification ID
Developer Takeaways

Impacts

- No change to CMS ID generation process in CHPL
- New CMS ID required annually, even if product(s) do not change
- Certification criteria required to meet the Base definition (CY2025)

Resources

- Base EHR Definition (requirements)

  https://www.healthit.gov/topic/certification-ehrs/base-electronic-health-record-definition

- CHPL Public User Guide (instructions)
  - **Direct: https://www.healthit.gov/sites/default/files/policy/chpl_public_user_guide.pdf**
  - **CHPL: https://chpl.healthit.gov/ > CHPL Resources > CHPL Public User Guide**

Insights Condition Information Session

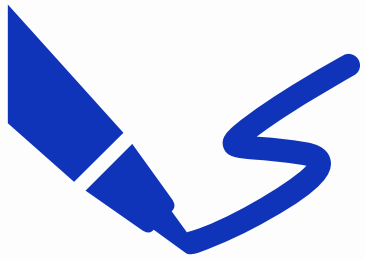
Meghan Gabriel, Technical Strategy & Analysis

Insights Condition Information Session

September 25th, 2025 at 2pm EST

Please join ASTP to learn more about the Insights Condition and Maintenance of Certification requirements for developers participating in the ONC Health IT Certification Program.

Visit ASTP's Events Page to register



This session will provide the latest updates on developer responsibilities, including key considerations ahead of the 2026 reporting period and an overview of the “Use of FHIR in Apps” measure.

Who Is Required to Submit Insights Responses?

➢ CONDITION OF CERTIFICATION

A Certified Health IT developer **must submit** one of the following annually **for each applicable measure**:

Measure responses including: •Product-level aggregated data •Data sources and methodology •Percentage of customers represented	**OR**	**Attestation** that they: •Do not have at least 50 hospital sites or 500 clinician users across their certified health IT •Do not have certified technology for a measure •Do not have users for that certified functionality

➢ MAINTENANCE OF CERTIFICATION

Developers must submit responses (data or attestation) **annually**

- **First data collection starts:** January 1, 2026
- **First response window opens:** July 1, 2027

Thank You!

Please submit questions, concerns, or feedback to https://inquiry.healthit.gov/