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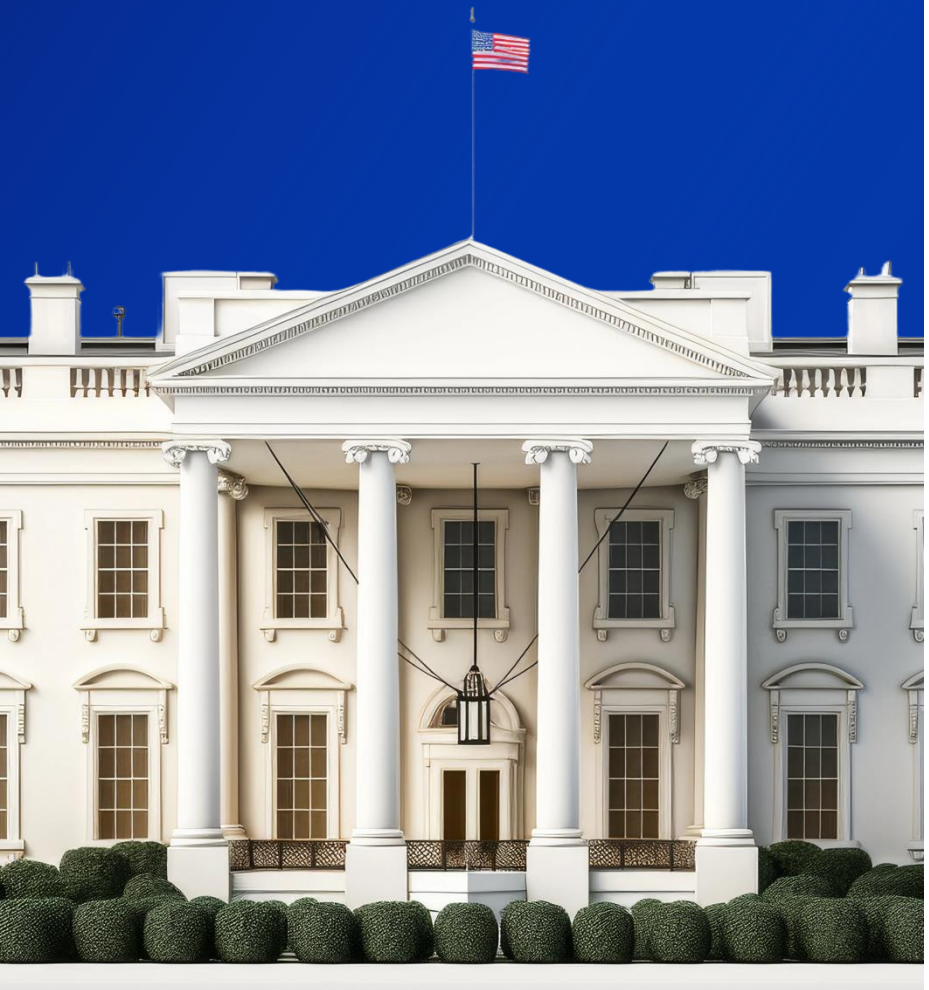

Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity (HTI-5) Final Rule

October 29, 2026

Disclaimers

- The materials contained in this presentation are based on the “Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity" (HTI-5) Final Rule. 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 provisions are contained in the final rule.

- This communication is produced and disseminated at U.S. taxpayer expense.

Reduce

Outdated and unnecessary certification requirements

Reset

The regulatory foundation for future FHIR-based interoperability

Improve electronic health information access, exchange, and use

ONC Health IT Certification Criteria

60 criteria as of October 29, 2026.

PROPOSED RULE ↓	FINAL RULE ↓		
	Removed	**Revised**	**No Changes**
34 proposed for removal	**14**	**2**	**18**
7 proposed for revision	—	**5**	**2**
	14	**7**	**20**

HTI-5: Proposed vs. Final Rule Certification Criteria

All references are to § 170.315. Unchanged = no changes to criterion.

Certification Criteria	Proposed	Final
(a)(5) Patient demographics and observations	Revise	Unchanged
(a)(9) Clinical decision support	Remove	Remove
(a)(12) Family health history	Remove	Remove
(a)(14) Implantable device list	Remove	Unchanged
(b)(1) Transitions of care	Revise	Revise
(b)(2) Clinical information reconciliation and incorporation	Remove	Revise
(b)(7) Security tags - summary of care - send	Remove	Remove
(b)(8) Security tags - summary of care - receive	Remove	Remove
(b)(9) Care plan	Remove	Remove
(b)(11) Decision support interventions	Revise	Revise
(c)(3) Clinical quality measures — report	Revise	Revise
(c)(4) Clinical quality measures — filter	Remove	Remove
(d)(1) Authentication, access control, authorization	Remove	Unchanged
(d)(2) Auditable events and tamper-resistance	Remove	Unchanged

Certification Criteria	Proposed	Final
(d)(3) Audit report(s)	Remove	Unchanged
(d)(4) Amendments	Remove	Unchanged
(d)(5) Automatic access time-out	Remove	Unchanged
(d)(6) Emergency access	Remove	Unchanged
(d)(7) End-user device encryption	Remove	Unchanged
(d)(8) Integrity	Remove	Unchanged
(d)(9) Trusted connection	Remove	Unchanged
(d)(10) Auditing actions on health information	Remove	Unchanged
(d)(11) Accounting of disclosures	Remove	Unchanged
(d)(12) Encrypt authentication credentials	Remove	Unchanged
(d)(13) Multi-factor authentication	Remove	Unchanged
(e)(1) View, download, and transmit to 3rd party	Revise	Revise
(e)(3) Patient health information capture	Remove	Remove
(f)(4) Transmission to cancer registries	Remove	Unchanged

Certification Criteria	Proposed	Final
(f)(5) Transmission to public health agencies — electronic case reporting	Revise	Unchanged
(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting	Revise	Revise
(f)(7) Transmission to public health agencies — health care surveys	Remove	Unchanged
(g)(1) Automated numerator recording	Remove	Remove
(g)(2) Automated measure calculation	Remove	Remove
(g)(3) Safety-enhanced design	Remove	Revise
(g)(4) Quality management system	Remove	Unchanged
(g)(5) Accessibility-centered design	Remove	Unchanged
(g)(6) Consolidated CDA creation performance	Remove	Remove
(g)(7) Application access — patient selection	Remove	Remove
(g)(9) Application access — all data request	Remove	Remove
(h)(1) Direct Project	Remove	Remove
(h)(2) Direct Project, Edge Protocol, and XDR/XDM	Remove	Remove

Certification Criteria Removals Not Finalized

We did not finalize the proposed removal of the following certification criteria:

Implantable device list (§ 170.315(a)(14))	• We retained the certification criterion in order to align our Certification Program requirements with the CMS Promoting Interoperability Program.
Transmission to cancer registries (§ 170.315(f)(4))	• We retained the certification criterion because of the continued value that it brings to cancer registry reporting. • We remain confident in the continued progression toward FHIR-based solutions for cancer reporting and will monitor advancements to inform future Certification Program requirements as appropriate.
Transmission to public health agencies — health care surveys (§ 170.315(f)(7))	• We retained the certification criterion due to the continued reliance on CDA-based standards for public health reporting in a number of settings, and because of the value the certification criterion continues to bring to supporting consistent, interoperable public health surveillance as the industry advances toward FHIR readiness. • We support continued movement toward FHIR-based reporting and will monitor and encourage advancements in FHIR-based standards for health care surveys going forward
Quality management system (QMS) (§ 170.315(g)(4))	• Retaining the certification criterion provides a consistent, market-wide baseline assurance of quality management practices, supporting safety, consistency for new entrants, and providing a meaningful signal for providers and purchasers of developer QMS practices. • Retention also keeps the Certification Program aligned with its broader commitment to transparency and public reporting on developers' QMS practices.
Accessibility-centered design (§ 170.315(g)(5))	• Widespread industry use of accessibility-centered design supports retaining this certification criterion, since it preserves a transparent, measurable baseline and guards against uneven adoption over time, including among new entrants, especially as accessibility practices continue to evolve. • Retention also keeps the Certification Program aligned with its broader transparency and public reporting approach.

Privacy & Security Certification Criteria/Certification Framework

Proposal

- We proposed to remove all the privacy and security (P&S) certification criteria and the associated Privacy and Security Certification Framework.
- In lieu of removing all of the P&S certification criteria and the P&S Certification Framework, we offered an alternative proposal to retain the “auditing” certification criteria only.

HTI-5 Final Rule

- The proposal focused primarily on a binary choice between removing all the P&S certification criteria and P&S Certification Framework (with a discrete alternative proposal) or not. We decided not to finalize either proposal.
- Commenters generally did **not** respond to our rationale for removal. Rather, they offered different rationales for keeping or updating the criteria.
- We will continue to consider the best regulatory approach for P&S certification in anticipation of future rulemaking.

Certification Criteria Revised, Not Removed

We retained and revised the following two certification criteria instead of finalizing their removal.

Clinical information reconciliation and incorporation (CIRI)
(§ 170.315(b)(2))
	• We reconsidered our proposed policy and retained the criterion as a **functional requirement**, with revisions that reduce certification burden and increase flexibility.
	  ○ Health IT can now demonstrate conformance with the criterion in a broader range of workflows instead of only upon receipt of a transition of care/referral summary.
	  ○ Removed references to specific content exchange standards and implementation specifications thus making it a functional criterion and giving developers flexibility to adopt FHIR-based solutions.
	  ○ Removed the requirement to simultaneously display the data from at least two sources in a manner that allows a user to view the data and their attributes, which will reduce burden and allow movement toward innovative, FHIR-based solutions.

Safety-enhanced design (§ 170.315(g)(3))	• We reassessed whether our proposal to completely remove the criterion was necessary to achieve our objective of reducing costs and burden. • We revised the criterion to establish an attestation-based certification requirement, reducing the testing/reporting requirements in paragraphs (ii), (iv), and (v). ○ An attestation-based approach reduces burden while preserving baseline assurances that developers apply user-centered design practices according to industry or Federal government standards. • We retained the criterion's application to condition-based certification (§ 170.550(g)(1)).

Certification Criterion Revisions Not Finalized

We did not finalize the proposed revisions to electronic case reporting (§ 170.315(f)(5)).

Transmission to public health agencies — electronic case reporting (eCR)

(§ 170.315(f)(5))

We did not finalize the proposal to revise § 170.315(f)(5) into a functional requirement at this time given the continued reliance on CDA-based standards and still-limited adoption of FHIR-based standards on both the sending and receiving ends.

We remain confident in FHIR's future trajectory for eCR, and retaining the option to certify to either CDA-based or FHIR-based standards provides a helpful glidepath that encourages continued progress toward a fully FHIR-based future.

Standards and Implementation Specifications for Health Information Technology

In instances where we removed or revised a certification criterion, we also **removed the standards** that were referenced by the certification criterion.

In some cases, we **removed a standard** consistent with a certification criterion transition period (until January 1, 2027).

We **removed standards from the Code of Federal Regulations (CFR)** that are outdated and no longer referenced in the Certification Program.

We **retained standards related to Direct** to support interoperability advancement under the HHS Health IT Alignment Program.

The Direct Project standards are widely utilized in various use cases and maintaining the standards will support interoperability.

Decision Support Interventions

FINALIZED CHANGES

Removes "model card" requirements

Ends required source attribute support, access, and modification.

Removes predictive DSI risk management requirements

Removes the transition-of-care trigger

Ends the required trigger when medications, allergies and intolerances, and problems enter from a care or referral summary.

Narrows the data scope

Limits applicability to specified data in (iii)(A), Clinical Notes, and Assessment and Plan of Treatment.

RATIONALE

Developers report limited clinician time and technical capacity to use source attributes during care.

There is no evidence of use or improved patient care from these requirements.

Developers of certified health IT have reported an inconsistent approach to oversight of other parties producing similar, health-based SI systems.

ONC expects reduced developer burden and more flexibility for innovation and monitoring by removing these requirements.

Conditions and Maintenance of Certification Requirements for Health IT Developers

Conforming Edits

We have finalized conforming edits for several Conditions and Maintenance of Certification requirements, including:

- *Assurances*
- *Application Programming Interfaces*
- *Attestations*
  - For example, a health IT developer must provide the Secretary an attestation of compliance with § 170.404, the API Conditions and Maintenance of Certification requirements, according to § 170.406(a)(4). Because we have removed § 170.315(g)(7) through (9), we also have removed the reference to § 170.315(g)(7) through (9) in § 170.406(a)(4).

Remove and Descope

Real World Testing

We have removed requirements and descoped "Real World Testing" Condition and Maintenance of Certification requirements with the following deregulatory actions:

- Removing the requirement to submit real world testing plans for all real world testing certification criteria (§ 170.405(b)(1));
- Limiting full real world testing results reporting (§ 170.405(b)(2)) to only Health IT Modules that are certified to the API certification criteria; and
- Permitting the use of the Standards Version Advancement Process (SVAP) for the remaining non-API real world testing certification criteria.

Insights

We have removed and descoped measures associated with the "Insights" Condition and Maintenance of Certification requirements to limit reporting requirements only to the:

- "use of FHIR in apps through certified health IT"; and
- "use of FHIR bulk data access through certified health IT".

Proposals Still Under Consideration

We have reviewed and responded to comments on a narrowed set of proposals from the Proposed Rule. Comments received in response to other Proposed Rule proposals not discussed in the final rule remain under review and consideration. The Proposed Rule proposals not discussed in the final rule may, in the future, be included in subsequent final rules or as revised proposals in subsequent proposed rules.

These include proposals related to:

Patient Demographics (§ 170.315(a)(5))

United States Core Data for Interoperability Version 3.1

Information Blocking

Resources Available on HealthIT.gov!

RESOURCES AVAILABLE

Visit https://healthIT.gov/HTI5 for more information.

- → HTI-5 Press Release
- → HTI-5 Final Rule Fact Sheet
- → HTI-5 Final Rule Information Session Recording
- → Final Rule at the Federal Register

Reach out via phone or web

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

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