

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

December 2025

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AGENDA

- Overview
- ONC Health IT Certification Program
 - ONC Certification Criteria for Health IT
 - Standards and Implementation Specifications for Health Information Technology
 - Terms and Definitions
 - Condition and Maintenance of Certification Requirements
 - ONC Health IT Certification Program Administrative Requirements
- Information Blocking

HTI-5 Proposed Rule

URL: [HealthIT.gov/Proposedrule](https://www.healthit.gov/proposedrule)

Purpose of the HTI-5 Proposed Rule



Implementing the 21st Century Cures Act

- Application Programming Interfaces (APIs) that allow electronic health information (EHI) from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards
- Reasonable and necessary activities that do not constitute information blocking



Achieving the Goals of the Trump Administration Executive Orders

- Executive Order (EO) 14192 "Unleashing Prosperity Through Deregulation"
- EO 14267 "Reducing Anti-Competitive Regulatory Barriers"
- EO 14179 "Removing Barriers to American Leadership in Artificial Intelligence"



Leveraging Health IT and Advancing Interoperability

- HITECH Act
- Interoperability Advancement – transition to Fast Healthcare Interoperability Resources (FHIR®) – based APIs
- ONC Health IT Certification Program



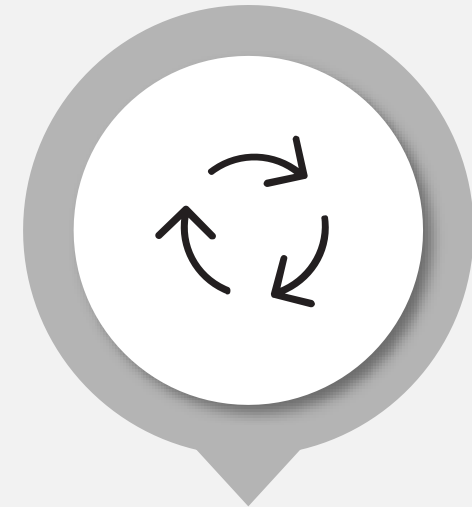
Reduce

Outdated and redundant
certification requirements



Reset

The regulatory foundation for future
FHIR-based interoperability



Refine

The ONC Health IT Certification
Program and the Information
Blocking Regulations

Improve electronic health information access, exchange, and use

Goals of the HTI-5 Proposed Rule

The HTI-5 Proposed Rule has three core goals:

1. Reducing burden on health IT developers by streamlining the ONC Health IT Certification Program (Certification Program) by removing redundant requirements;
2. Updating the information blocking regulations to better promote EHI access, exchange, and use so that patients' access to their data is not blocked; and
3. Advancing a new foundation of Fast Healthcare Interoperability Resources (FHIR®)-based application programming interfaces (APIs) that promote AI-enabled interoperability solutions through modernized standards and certification.

Cost Savings:

- \$1.53 billion, including \$650 million over the next 5 years for health IT developers, providers, and other stakeholders
- The proposed deregulatory actions reduce the effort of developers of certified health IT to meet ongoing Certification Program requirements and reduce entry barriers for new Certification Program participants.
 - The proposed revisions and removal of certification criteria from the Certification Program are estimated to save certified health IT developers more than 1.4 million compliance hours in their first year (an average savings of 4,000 hours per developer) – giving developers new capacity to deliver innovative solutions for their customers.

ONC Health IT Certification Program

HTI-5 Proposed Rule | Proposed Removals or Revisions of Certification Criteria

Certification Criteria	Reference	Remove/Revise	Timing
Patient demographics and observations	§ 170.315(a)(5)	Revise	Effective date of final rule
Clinical decision support	§ 170.315(a)(9)	Remove	Effective date of final rule
Family health history	§ 170.315(a)(12)	Remove	Effective January 1, 2027
Implantable device list	§ 170.315(a)(14)	Remove	Effective date of final rule
Transitions of care	§ 170.315(b)(1)	Revise	Effective January 1, 2027
Clinical information reconciliation and incorporation	§ 170.315(b)(2)	Remove	Effective January 1, 2027
Security tags - summary of care - send	§ 170.315(b)(7)	Remove	Effective date of final rule
Security tags - summary of care - receive	§ 170.315(b)(8)	Remove	Effective date of final rule
Care plan	§ 170.315(b)(9)	Remove	Effective date of final rule
Decision support interventions	§ 170.315(b)(11)	Revise	Effective date of final rule
Clinical quality measures — report	§ 170.315(c)(3)	Revise	Effective date of final rule
Clinical quality measures — filter	§ 170.315(c)(4)	Remove	Effective January 1, 2027
Authentication, access control, authorization	§ 170.315(d)(1)	Remove	Effective date of final rule
Auditable events and tamper-resistance	§ 170.315(d)(2)	Remove	Effective date of final rule
Audit report(s)	§ 170.315(d)(3)	Remove	Effective date of final rule
Amendments	§ 170.315(d)(4)	Remove	Effective date of final rule
Automatic access time-out	§ 170.315(d)(5)	Remove	Effective date of final rule
Emergency access	§ 170.315(d)(6)	Remove	Effective date of final rule
End-user device encryption	§ 170.315(d)(7)	Remove	Effective date of final rule
Integrity	§ 170.315(d)(8)	Remove	Effective date of final rule
Trusted connection	§ 170.315(d)(9)	Remove	Effective date of final rule

HTI-5 Proposed Rule | Proposed Removals or Revisions of Certification Criteria *(continued)*

Certification Criteria	Reference	Remove/Revise	Timing
Auditing actions on health information	§ 170.315(d)(10)	Remove	Effective date of final rule
Accounting of disclosures	§ 170.315(d)(11)	Remove	Effective date of final rule
Encrypt authentication credentials	§ 170.315(d)(12)	Remove	Effective date of final rule
Multi-factor authentication	§ 170.315(d)(13)	Remove	Effective date of final rule
View, download, and transmit to 3rd party	§ 170.315(e)(1)	Revise	Effective date of final rule
Patient health information capture	§ 170.315(e)(3)	Remove	Effective January 1, 2027
Transmission to cancer registries	§ 170.315(f)(4)	Remove	Effective January 1, 2027
Transmission to public health agencies — electronic case reporting	§ 170.315(f)(5)	Revise	Effective date of final rule
Transmission to public health agencies — antimicrobial use and resistance reporting	§ 170.315(f)(6)	Revise	Effective date of final rule
Transmission to public health agencies — health care surveys	§ 170.315(f)(7)	Remove	Effective January 1, 2027
Automated numerator recording	§ 170.315(g)(1)	Remove	Effective January 1, 2027
Automated measure calculation	§ 170.315(g)(2)	Remove	Effective January 1, 2027
Safety-enhanced design	§ 170.315(g)(3)	Remove	Effective date of final rule
Quality management system	§ 170.315(g)(4)	Remove	Effective date of final rule
Accessibility-centered design	§ 170.315(g)(5)	Remove	Effective date of final rule
Consolidated CDA creation performance	§ 170.315(g)(6)	Remove	Effective date of final rule
Application access — patient selection	§ 170.315(g)(7)	Remove	Effective January 1, 2027
Application access — all data request	§ 170.315(g)(9)	Remove	Effective January 1, 2027
Direct Project	§ 170.315(h)(1)	Remove	Effective date of final rule
Direct Project, Edge Protocol, and XDR/XDM	§ 170.315(h)(2)	Remove	Effective date of final rule

Privacy and Security Certification Criteria

- Future State: We intend to prioritize the adoption of privacy and security capabilities that are fit for purpose, use case specific, and deliver much needed technical consistency in the market when paired with specific conformance requirements.
 - For example, as we pursue more API-focused certification criteria, if the standards and implementation guides adopted for them do not specify or leave optional specific security requirements, we may look to add further constraints (e.g., multi-factor authentication support).
 - But in all cases, we intend to make security capability conformance a built-in part of a certification criterion's conformance and not the separate and stand-alone conformance assessment that it is today.
- Deregulatory Proposed Rule: Despite the Certification Program providing various certification flexibilities and approaches to accommodate the privacy and security certification criteria (i.e., different approaches for the 2011, 2014 and 2015 Editions), the costs and burden of these requirements far exceed their intended purpose and benefits.
 - Proposal: Remove all the privacy and security certification criteria in § 170.315(d) and the associated Privacy and Security Certification Framework under § 170.550(h) as of the effective date of a subsequent final rule.
 - Alternative Proposal: Retain certain certification criteria related to audits that may serve to help identify fraud and abuse.

Standards and Implementation Specifications for Health Information Technology

- In instances where we propose to remove or revise a certain certification criterion, we also propose to remove the standards that are referenced by the certification criterion.
- In some cases, we propose to remove a standard consistent with a certification criterion transition period until January 1, 2027.
- In very limited circumstances, we retain a standard referenced by a certification criterion proposed for removal. We do this to support interoperability advancement under the HHS Health IT Alignment Program.
 - For example, we do not propose to remove the Direct Project transport standard in § 170.202(a)(2). The Direct Project standards are widely utilized in various use cases and maintaining the standard will support interoperability.
- We propose to remove standards from the Code of Federal Regulations (CFR) that are outdated and no longer referenced in the Certification Program.



Terms and Definitions - § 170.102

- Because of the proposed removal of certain certification criteria, we propose to make conforming edits to the terms and definitions in § 170.102.
 - Revise the “Base EHR” definition
 - Remove references to certification criteria that we have proposed to remove from the CFR
 - Remove “Common Clinical Data Set,” “Global Unique Device Identification Database (GUDID),” and “Production Identifier”
 - These terms are no longer referenced in 45 CFR part 170

Conditions and Maintenance of Certification Requirements for Health IT Developers

- We propose to **make 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 propose to remove § 170.315(g)(7) through (9), we also propose to remove the reference to § 170.315(g)(7) through (9) in § 170.406(a)(4).
- We also propose to **descope** “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 with minimal reporting requirements.
- We propose to **remove** and **descope** 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” measure.

ONC Health IT Certification Program Administrative Requirements

- We propose to make conforming edits, in subpart E of 45 CFR part 170, to remove references to certification criteria that we propose to remove in this proposed rule.
 - Specifically, in:
 - § 170.523,
 - § 170.550,
 - § 170.555, and
 - § 170.570.
 - We propose to make conforming revisions to the Principles of Proper Conduct for ONC-ACBs in § 170.523 by removing cross-references to certain certification criteria that we propose to remove.
 - For example, we propose to remove and reserve § 170.523(f)(1)(ix) through (xi) which reference the “privacy and security” certification criteria (§ 170.315(d)), the “quality management system” certification criterion (§ 170.315(g)(4)), and the “accessibility-centered design” certification criterion (§ 170.315(g)(5)).

Information Blocking

Current Definitions - § 171.102

Proposal: Revise the “access” and “use” definitions in § 171.102 to emphasize that the definitions include automated means of access, exchange, or use of EHI — including, without limitation, autonomous AI systems.

Alternative Proposal: In addition to updating the “access” and “use” definitions, potentially similarly revise the “exchange” definition.

Infeasibility Exception - § 171.204

- *Third party seeking modification use condition* - § 171.204(a)(3)

Proposal: Remove.

- *Manner exception exhausted condition* - § 171.204(a)(4)

- Proposal: Revise to:

- Require all three “alternative” manners from the Manner Exception alternative manner condition be offered
- Replace “The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requestor”

with

“The actor does not provide analogous access, exchange, or use of the requested electronic health information to any other individual or entity”

- Replace “same” with “analogous”
- Alternative Proposal: Remove the condition.

Manner Exception - § 171.301

Manner requested condition - § 171.301(a)

- Proposal:
 - Add text explicitly stating that any contract or agreement under which the actor and requestor agree to fulfill a request for access, exchange, or use of EHI, and any license from the actor of interoperability elements used in fulfilling the request in the manner requested:
 - is not at market rate;
 - is a contract of adhesion; or
 - that contains unconscionable terms.
 - Add definitions to § 171.102 for market rate, contract of adhesion, and unconscionable terms
- Alternative Proposal:

Apply the conditions of both the Fees Exception and Licensing Exception to any agreement an actor makes with a requestor related to fulfilling the request for access, exchange, or use of EHI in any manner requested.

Trusted Exchange Framework and Common Agreement (TEFCA) Manner Exception - § 171.403

Proposal: Remove the TEFCA Manner Exception (§ 171.403) and associated definitions.

Comment period: Dec. 29, 2025 – Feb. 27, 2026.
URL: HealthIT.gov/Proposedrule

Resources Available on HealthIT.gov!

RESOURCES AVAILABLE

Visit <https://healthIT.gov/Proposedrule> for more information.

- HTI-5 Press release
- HTI-5 Proposed Rule Fact Sheet
- URL to view proposed rule at the Federal Register



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