ONC HTI-5 FINAL RULE

Executive Summary | October 28, 2026

HHS Office of the National Coordinator for Health Information Technology • 45 CFR Parts 170 and 172 • Federal Register Document 2026-21943

PAGE 1 — EXECUTIVE SUMMARY AND MAJOR CHANGES

Overview

The HTI-5 final rule substantially reduces federal certification obligations for electronic health record (EHR) products and other health IT. It removes 14 of the existing 60 certification criteria, revises seven, and retains 39 unchanged. ONC originally proposed eliminating 34 criteria, but adopted a narrower final approach. The stated goals are to reduce compliance burdens, modernize interoperability, and allow developers more flexibility.

The practical importance to hospitals is twofold: EHR vendors may face lower certification and testing expenses, while hospitals remain accountable for clinical safety, data exchange, privacy, and separate Medicare reporting obligations.

Five key takeaways

- 14 certification criteria eliminated; seven revised; 39 unchanged.
- Federal certification rules for predictive clinical decision-support tools are narrowed, including AI transparency and risk-management elements.
- ONC signals a transition toward modern FHIR-based interoperability while retaining selected older exchange criteria during a transition.
- Quality-measure and administrative certification requirements are streamlined, primarily benefiting health IT developers.
- Other hospital obligations, including HIPAA, information blocking and applicable CMS reporting, are not automatically removed.

Principal eliminated criteria (grouped by function)

Area	Certification functionality removed
Clinical and care coordination	Legacy clinical decision support; family health history; care plans; security tagging for care summaries.
Quality measurement	Clinical quality measure filtering; automated numerator recording; automated measure calculation.
Patient engagement	Patient health information capture.
Exchange and application access	Selected C-CDA creation-performance, application-access and Direct transport criteria.

Elimination of a certification criterion does not require a vendor to remove the underlying feature from its software. The rule also preserves certain privacy and security criteria that ONC had proposed eliminating.

Policy significance

The final rule moves away from prescribing some granular EHR capabilities and toward a more selective federal certification framework. Hospitals should evaluate which features their vendors will

retain voluntarily, which are contractually guaranteed, and which are required by separate law or CMS program rules.

IMPACT ON HOSPITAL OPERATIONS

1. Artificial intelligence and decision support

The final rule significantly narrows the Decision Support Interventions (DSI) certification criterion under 45 CFR § 170.315(b)(11). It removes specified source-attribute disclosures, access and modification functions, and risk-management requirements applicable to predictive decision-support interventions. Basic decision-support functionality remains within the certification framework.

Hospital implication: Hospitals using predictive algorithms for deterioration, readmissions, diagnostics, or care recommendations may need stronger contractual assurances about validation, intended use, bias, safety monitoring, and access to performance data. The rule does not prevent hospitals from imposing such requirements on EHR and AI vendors.

2. Interoperability and FHIR

ONC favors modern application programming interfaces using Fast Healthcare Interoperability Resources (FHIR). The final rule retires selected older exchange-related criteria but delays removal of specified C-CDA transitions-of-care certification requirements until January 1, 2030. This transition recognizes continuing dependence on legacy document exchange.

Hospital implication: Inventory interfaces with physician practices, skilled nursing facilities, behavioral health organizations, and rural partners. Avoid assuming that FHIR functionality is already available across all external trading partners; plan for parallel support during transition.

3. Quality measurement and CMS reporting

The rule eliminates selected certification criteria supporting automated quality-measure calculations and filtering and revises the clinical quality-measures reporting criterion. It does not, in itself, eliminate Medicare Promoting Interoperability, hospital quality reporting, or other CMS program requirements.

Hospital implication: Quality, compliance, and IT staff should independently validate CMS reporting specifications before retiring workflows or software components. ONC certification status and CMS participation obligations are distinct.

4. Patient access, privacy, and security

The final rule removes the patient health information capture criterion, revises aspects of patient view/download/transmit functionality, and eliminates certain security-tagging requirements associated with summaries of care. ONC did not finalize a broad repeal of existing privacy and security certification criteria.

Hospital implication: Continue HIPAA privacy/security compliance, information-blocking compliance, and required patient-access practices. Contractually preserve any critical patient-facing or data-segmentation functions that are no longer required by certification.

5. Testing and vendor accountability

Real-world testing and related developer reporting obligations are streamlined, along with parts of the ONC Insights program. This may reduce administrative expenses, although hospitals may receive less standardized certification-related information about some products.

Hospital implication: Seek clear vendor commitments on support, interoperability, downtime, safety issues, release testing and measurable product performance. Reduced federal certification obligations should not weaken service-level protections.

PAGE 3 — COSTS, IMPLEMENTATION AND RECOMMENDATIONS

Estimated economic impact

ONC estimates approximately $1.55 billion in present-value savings and about $108.1 million in annualized net savings (2024 dollars, 7% discount rate). These estimates are primarily reductions in developer certification and compliance costs—not established direct savings for hospitals. Effects on EHR subscription fees, maintenance costs, upgrades and hospital staffing remain uncertain.

Implementation dates

Date	Milestone
Oct. 28, 2026	Publication of final rule.
Dec. 28, 2026	General effective date for most provisions.
Jan. 1, 2027	Selected certification removals and related provisions become effective.
Jan. 1, 2030	Specified C-CDA transitions-of-care certification requirements phased out.

Five recommended hospital actions

Review vendor roadmaps. Obtain written commitments from Epic, Oracle or other vendors identifying affected criteria, retained functions, planned releases, and any new fees.

Strengthen AI oversight. Require documentation of validation, performance monitoring, bias assessment, clinical safety, and incident escalation for predictive tools.

Plan exchange modernization. Document use of C-CDA and Direct, prioritize FHIR capabilities, and ensure continuity with smaller community and post-acute partners.

Protect Medicare compliance. Cross-check CMS interoperability and quality-reporting requirements before changing any certified-technology workflow.

Revisit contracts and costs. Explore whether reduced vendor compliance expenses support lower fees, stronger service commitments, or added interoperability functions.

Issues for federal monitoring

Key questions include future FHIR-based certification proposals; how clinical AI transparency and safety will be addressed outside ONC certification; alignment of ONC and CMS standards; technology transition costs at rural and safety-net hospitals; and whether deregulation produces lower hospital EHR expenditures.

Overall assessment

HTI-5 is principally an EHR vendor deregulation initiative, not a direct hospital payment or compliance-relief rule. It offers an opportunity to simplify obsolete requirements and modernize information exchange, but shifts greater responsibility for certain safeguards onto purchasers and users of technology. Hospital leaders should protect patient safety, continuity of exchange, access to information, and vendor accountability while seeking a share of any realized cost reductions.

Primary source: HHS/ONC, “Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity,” Final Rule, Federal Register Document 2026-21943. https://public-inspection.federalregister.gov/2026-21943.pdf