

HLB's Digital Health Blog

Insights

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HHS Finalizes HTI-5 Deregulatory Rule

On October 26, 2026, the Department of Health and Human Services (HHS) and the Office of the National Coordinator for Health Information Technology (ONC) released the long-awaited [HTI-5 Final Rule](#). The rule implements updates to the health information technology certification criteria in a significantly narrower form than proposed, removing 14 certification criteria and revising 7 out of 60 total criteria rather than the 34 proposed for elimination by ONC at the end of 2025. Among the changes, the rule eliminates annual Real World Testing plan submissions, reduces Insights Condition reporting metrics, and removes “model card” source attribute transparency and risk management mandates under the Decision Support Interventions criterion. On the removal of transparency requirements for decision support interventions, ONC took this action despite a “large majority of commenters” disfavoring the proposal, citing to concerns about it leading to a shift in “evaluation, governance, and liability burdens to providers and health systems and undermine patient safety, clinician trust, and the ability to evaluate bias, performance, and appropriateness.” The agency did elect to retain all privacy and security certification criteria, Quality Management System standards, and Accessibility-centered Design requirements in response to public feedback, however, while extending the deadline for removing document-based transitions of care requirements to January 1, 2030, to provide stakeholders a gradual transition toward Fast Healthcare Interoperability Resources-based API data exchange. Notably as well, the information blocking proposals were all omitted from this release and remain under consideration for future rulemaking (likely in a forthcoming HTI-6).

For more information about ONC’s finalized changes and regulatory timelines, review the [ONC HTI-5 Final Rule Overview Fact Sheet](#) and the [HTI-5 Criteria Removals and Revisions Fact Sheet](#). In addition, ONC will hold an information session on the Final Rule on October 29, for which you can register [here](#).

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