

Policy Brief

HTI-5 Final Rule

On October 28, ONC published the HTI-5 Final Rule in the Federal Register. HTI-5 is part of the Administration's broader deregulatory agenda and is intended to reduce the cost and burden of the ONC Health IT Certification Program for health IT developers while resetting the program around FHIR-based APIs. In its December 2025 proposal, ONC called for removing more than half of the 60 certification requirements then in effect, including all privacy and security requirements, several public health reporting requirements, and many requirements tied to document-based exchange, along with changes to the information blocking rules.

The proposal drew substantial public comment, much of it raising concerns that FHIR-based alternatives are not yet mature or widely adopted, that public health agencies and smaller, rural, and under-resourced providers are not ready to make the transition, and that removing certification requirements would shift costs and responsibilities to providers, public health, and health information networks. In response, ONC finalized a considerably narrower rule, removing fewer than half of the certification requirements it had proposed to eliminate, keeping requirements for widely used exchange standards in place through 2030, and setting aside its proposed changes to the information blocking rules for future consideration.

What the Final Rule Does

- **A smaller, streamlined certification program:** ONC scaled back its proposal considerably, removing just 14 of the 34 certification requirements it had proposed to eliminate. It kept many requirements that commenters said were still needed, including all privacy and security protections and several public health reporting capabilities. ONC also reduced the testing and reporting that developers must do to keep their products certified, and it dropped the requirement that developers share information about how AI-based decision support tools were built and tested.
- **A shift toward FHIR, with time to transition:** ONC describes the rule as a reset that prepares for future requirements built around FHIR-based APIs, which it plans to address in a separate rule. In the meantime, ONC kept the requirements for document-based exchange and Direct secure messaging in place through January 1, 2030, to give the industry time to move to newer standards.
- **Information blocking changes deferred:** ONC did not finalize any of its proposed changes to the information blocking rules. Those proposals remain under consideration for a future rule.

Most changes take effect December 27, 2026, 60 days after publication, while others take effect January 1, 2027.

Comparison with Civitas Comments

Civitas's comments on the proposed rule centered on a key concern: as certification requirements are reduced, responsibility for keeping exchange reliable, public health reporting timely, and patient data protected does not disappear but shifts to providers, public health agencies, and the networks that connect them. The final rule addresses much of that concern for the near term by



keeping in place the exchange standards and safeguards our members rely on while the industry moves to FHIR. It leaves the larger questions about oversight, real-world performance, and the information blocking framework unresolved, and those are the areas where continued engagement will matter most.

Issue	Civitas Recommendation	Final Rule
Exchange standards during the FHIR transition	Keep certification requirements for widely used standards, such as document-based exchange and Direct secure messaging, during a defined transition period	Kept document exchange and Direct secure messaging requirements in place through January 1, 2030, and kept the Direct standard in federal regulation. ONC also kept the requirement to reconcile incoming patient data, with more flexibility in how developers meet it, and removed the stand-alone Direct transport certification as proposed.
Public health reporting	Avoid disrupting public health reporting while public health agencies move to FHIR	Kept the cancer registry and health care survey reporting requirements it had proposed to remove, and kept case reporting tied to established standards. Antimicrobial use reporting became a functional requirement to better align with CDC's reporting system.
Oversight of capabilities no longer certified	Explain how these capabilities will be overseen, and consider alternatives such as attestation or third-party testing	Said these alternatives were outside the scope of this rule. ONC moved one design requirement to an attestation model and clarified that states can still set their own requirements.
Privacy, security, and transparency safeguards	Preserve core safeguards, including security protections and transparency for decision support tools	Kept all privacy and security requirements. Removed the transparency requirements for AI-based decision support tools and the criteria for tagging sensitive data in exchanged documents.
Real-world testing	Emphasize real-world interoperability testing	Eliminated developers' annual testing plans and limited reporting of results to API capabilities.



Issue	Civitas Recommendation	Final Rule
Information blocking	Protect good-faith actors, clarify that standardized participation agreements used by exchange networks are not contracts of adhesion, and set clear expectations for verifying and auditing automated access	Did not finalize any changes to the information blocking rules. Our comments remain under consideration for a future rule.

What Comes Next

The final rule buys time more than it settles direction. The 2030 date for document exchange and Direct secure messaging gives providers, public health agencies, and networks a defined transition period, but ONC has not yet said what FHIR-based requirements will replace them, and its next rulemaking will determine whether that transition is workable for organizations with fewer resources. ONC kept the privacy and security requirements but said it may revisit them, so the baseline that many smaller providers rely on when buying health IT is secure for now but remains open. The information blocking proposals carry the most direct consequences for health information networks, including how participation agreements and automated access would be treated, and they remain pending with no timeline for final action.

As ONC moves toward FHIR-based requirements, Civitas will continue to advocate for federal policy that builds on the exchange infrastructure already in place, including the local and regional networks that work alongside national networks to support exchange across clinical care, public health, and communities. These networks bring governance, consent management, and trusted relationships with providers and public health agencies that new requirements can draw on rather than recreate. Civitas will continue to engage with ONC on these issues on behalf of our members.

Additional Resources

- ONC's HTI-5 Final Rule page, with an overview fact sheet and a list of removed and revised requirements
- Healthcare Dive, a summary of the final rule
- Fierce Healthcare, on the deferred information blocking proposals