

Comment on

HTI-5 Final Rule: Impact on Public Health

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Summary

The Office of the National Coordinator for Health IT (ONC) released the Health Data, Technology and Interoperability: ONC Deregulatory Actions to Unleash Prosperity (HTI-5) final rule on October 26, 2026 and the good news for public health is what HTI-5 did *not* do. It removes 14 of 60 certification criteria, revises 7 and leaves 20 untouched, and this is far short of the 34 removals it proposed last December. Every public health transmission criterion except antimicrobial use and resistance (AUR) survived as is.

Here is an overview of how public health related criteria fared in the final rule:

- **Electronic case reporting:** The proposal to turn (f)(5) into a "functional" criterion with no required standards was not finalized. The eICR and Reportability Response standards from HTI-1 stay in place.
- **Immunization:** (f)(1), including bidirectional query and response, is unchanged. However, the final rule removes both IIS Insights measures and Real World Testing for (f)(1), so there's no longer any national evidence that these interfaces are used or that they work. Jurisdictions and the AIRA community would need to continue to fill that gap..
- **Cancer registries and health care surveys:** Both were proposed for removal on January 1, 2027. Both were kept.
- **AUR:** (f)(6) is the one public health criterion that changed, effective 60 days after publication.
- **Broader exchange:** Both Direct Project criteria are gone. Direct is also phased out of transitions of care, effective January 1, 2030. The justification for removing the Direct Project criteria is to reduce the regulatory burden for a functionality widely relied on and supported in the healthcare industry. By removing these criteria we don't believe anyone would remove the support for Direct, but there is a risk that new health IT developers will not support the Direct Project specification in the future.
- **Information blocking and TEFCA:** These proposals were deferred, and HTI-6 is expected in November.

HLN's February comments argued that removing standards-based certification for eCR, cancer, AUR and surveys would add burden, not reduce it. On eCR, cancer and surveys, the final rule landed where HLN asked it to.

What changed for public health

This table compares the proposed rule with the final rule for each criterion that matters to public health reporting. Final-rule entries come from ONC's certification criteria fact sheet. Proposed entries come from the February 2026 overview.

Criterion	Proposed (Dec 2025)	Final (Oct 2026)	Effective
(f)(1) Immunization registries	No change	No change	—

Criterion	Proposed (Dec 2025)	Final (Oct 2026)	Effective
(f)(2) Syndromic surveillance	No change	No change	—
(f)(3) Reportable lab results (ELR)	No change	No change	—
(f)(4) Cancer registries	Remove	**Kept**	—
(f)(5) Electronic case reporting	Revise to functional, drop standards	**Kept**	—
(f)(6) Antimicrobial use and resistance	Revise to functional	Revise	60 days after publication
(f)(7) Health care surveys	Remove	**Kept**	—
(b)(1) Transitions of care	Revise	Revise: document-based and Direct requirements removed	Jan 1, 2030
(h)(1), (h)(2) Direct Project transport	Remove	Remove	60 days after publication
(g)(7), (g)(9) Legacy app access	Remove	Remove	Jan 1, 2027
(g)(10) Standardized FHIR API	Kept	Kept	—
(d)(1)–(d)(13) Privacy and security	Remove all	**Kept**	—
Insights condition (§ 170.407), due to begin 7/1/2027	Cut back	IIS submission and IIS history/forecast measures removed; FHIR apps and bulk data measures kept (bulk data delayed to July 2029)	60 days after publication
Information blocking, TEFCA manner exception	Revise; remove TEFCA exception	**Deferred**	—

Three other changes reach public health indirectly. Real World Testing was scaled back, including the testing plans, results and SVAP. That means a risk of less evidence that the interfaces in (f) criteria work. Insights reporting, due to begin 7/1/2027, was also reduced. Last, the Base EHR and CEHRT definitions now point to a shorter criteria list, which CMS has already reflected in its FY 2027 IPPS final rule.

Electronic case reporting (eCR)

For eCR, the result is stability. The standards-based version of (f)(5) took full effect on January 1, 2026, and stays in place. Certified EHRs must still produce:

- An eICR, using either HL7 CDA eICR STU 3.1 or the eICR profile of the HL7 FHIR eCR IG 2.1.0.
- Triggering based on the Reportable Conditions Trigger Codes (RCTC) value set.

Certified EHRs must still consume and process:

- A matching Reportability Response (CDA RR STU 1.1 or the FHIR RR profile).

The proposed rule would have dropped these standards and made eCR "functional," so any developer-defined method of sending case data would count. HLN warned that this would lead to fragmented, jurisdiction-specific reporting. The final rule didn’t change the eCR standards, so that risk is off the table for now.

What this means for PHAs and the eCR ecosystem

- The APHL AIMS and RCKMS pipeline keeps a predictable, standardized input from certified EHRs.
- Jurisdictions that have built RR and eICR processing for CDA keep their investment. FHIR eCR remains an allowed path, so FHIR readiness can keep moving at each agency's own pace.
- CMS still requires eCR for the Promoting Interoperability Public Health and Clinical Data Exchange objective..

What to watch

- Transport. eCR is often routed through HISPs or HIEs, sometimes over Direct, and the (h) transport criteria are gone. The eCR content stays certified, but how it moves is now up to the market.
- HTI-6. ONC's stated path is toward FHIR-based APIs and fewer non-FHIR criteria. A future proposal to move (f)(5) to FHIR-only, or to make it functional again, is plausible.

Immunization data exchange

The certification criterion for IIS exchange is unchanged. HTI-5 never proposed changes to (f)(1), which still requires:

- VXU submission using the HL7 v2.5.1 Immunization Messaging IG, Release 1.5, with its 2015 addendum.
- Queries to IIS (QBP Z44) that requests, accesses and displays a patient's evaluated history and forecast.
- CVX and NDC code sets, updated as of the December 31, 2025 deadline.

HTI-5 does affect immunization in one way that's less visible: the Insights condition. HTI-1 added two IIS measures to Insights. One counts immunizations submitted to an IIS, starting July 2027. The other counts

history and forecast queries, starting July 2028. ONC says the final rule "reduced" Insights but kept the FHIR bulk data measure. HLN, and others in the public health community, opposed dropping them in our comments to the proposed rule.

With these measures not included, IIS programs lose a free, national, vendor-reported view of how much bidirectional query is actually in use. Jurisdictions and the AIRA community would need to continue to fill that gap from IIS-side data.

One other point for IIS: HTI-5 doesn't move IIS exchange toward FHIR. ONC's longer-term FHIR-first direction makes it worth keeping an eye on the HL7 FHIR immunization work and HLN will continue to stay at the forefront of this work. Nothing changes for HL7 v2 interfaces today.

Broader data exchange: HIEs, HDUs, TEFCA and APIs

For HIEs and health data utilities (HDUs), Direct is being moved out of certification. The Direct transport standard stays in regulation, and ONC says it recognizes how widely Direct is still used. If this change will actually have an impact on the use of Direct is uncertain, and from our perspective unlikely.

What this means for HIEs and HDUs acting for public health

- Many HIEs and HDUs route eCR, ELR, syndromic, immunization and admit/discharge feeds to PHAs, and some of those routes use Direct or XDR. Those routes keep working, but certification no longer guarantees vendors will maintain them..
- C-CDA isn't going away. (b)(1) and (b)(2) are revised, not removed, and summary-of-care measures continue. CMS removes the referral loop measures starting in CY 2029, which lines up with the 2030 (b)(1) change. HDUs that build on C-CDA have about three years to plan a move to FHIR.
- The FHIR API criterion (g)(10) and the bulk data Insights measure are kept, so the FHIR foundation HDUs use for population-level and public health queries is stable. Legacy app access, (g)(7) and (g)(9), goes away on January 1, 2027.
- Security tags for summary of care, (b)(7) and (b)(8), are removed. That matters for HDUs that handle sensitive data flows, such as 42 CFR Part 2 data and reproductive health data. Segmentation will rely more on policy and HDU-level controls.

TEFCA and information blocking

None of the information blocking proposals were finalized. These included removing the TEFCA manner exception, tightening the infeasibility and manner exceptions, and treating autonomous AI as "access and use." Current rules stay in effect, and HHS says it is still reviewing comments. TEFCA's Public Health Exchange Purpose is still the national route for query-based public health access. For now, actors can still use the TEFCA manner exception to steer requesters, PHAs included, toward TEFCA.

The 2026 Unified Agenda lists HTI-6, expected in November, covering expanded APIs, information blocking and targeted conditions of certification. That rule is where the TEFCA and public health access questions will most likely be settled.

Mandates and deadlines

The main mandate behind public health reporting, CMS Promoting Interoperability, didn't lose any public health measures. Hospitals and CAHs still have to report eCR, immunization, syndromic surveillance and ELR under the Public Health and Clinical Data Exchange objective. They also still have the certified technology to do it. The FY 2027 IPPS final rule already updated CEHRT to match HTI-5 and added one measure to that objective.

Date	What happens	Who it affects
Oct 28, 2026	HTI-5 published in the Federal Register	All
Dec 28, 2026 (60-days after publication)	Most HTI-5 changes take effect (60 days): Direct (h) criteria removed, (f)(6) AUR revised	Developers, HIEs/HDUs, NHSN AUR reporters
Jan 1, 2027	Family history, patient health information capture, automated measure criteria, (g)(7) and (g)(9) removed from certification and CEHRT	Developers, hospitals
CY 2027	New PI measure: Unique Device Identifiers for implantable devices, added to the Public Health and Clinical Data Exchange objective	Hospitals, CAHs
CY 2027 / 2028	Electronic prior authorization: optional bonus in 2027, required in 2028	Hospitals
July 2027 / July 2028	Insights IIS measures were set to begin. Removed with HTI-5.	Developers, IIS
CY 2029	CMS removes the referral loop (send and receive) measures	Hospitals, HIEs
Jan 1, 2030	(b)(1) transitions of care: document-based and Direct requirements end	Developers, HIEs/HDUs

Other public health reporting

- Syndromic surveillance (f)(2) and ELR (f)(3) are unchanged and still use HL7 v2.5.1.
- Cancer registry reporting (f)(4) was kept. That protects the certified path that state central cancer registries depend on, and the PI registry measure stays meaningful.
- AUR (f)(6) is the one public health criterion revised. It ties to the NHSN AUR measure that CMS has required of hospitals since CY 2024.
- Health care surveys (f)(7) was kept, so CDC's NCHS ambulatory and hospital surveys keep a certified source.

Recommendations for the Public Health Community

The takeaway for clients is that HTI-5 is a reprieve, not a resolution. The standards public health depends on survived this round. The pressure toward FHIR-only, API-first certification moves to HTI-6.

1. eCR, IIS, ELR, syndromic, cancer and survey criteria are all intact. PHAs don't need to change onboarding or validation processes because of HTI-5.
2. Plan for a 2030 C-CDA transition. HDUs that ingest C-CDA for public health purposes should map out a move to FHIR, such as bulk data and the FHIR eCR IG, on a three-year timeline.
3. Get ready for HTI-6 in November 2026. Expect proposals on FHIR APIs, information blocking, possibly the TEFCA manner exception, and public health access. HLN's HTI-5 comments are a strong base. Update them with real data on eCR adoption, IIS query volume and PHA FHIR readiness.

Sources

The full final rule text (Federal Register 2026-21943).

- ONC: HTI-5 Final Rule
- ONC: HTI-5 Final Rule removals or revisions of certification criteria (fact sheet)
- ONC: HTI-5 Final Rule overview fact sheet
- HHS press release, Oct 26, 2026
- Health System CIO: HTI-5 final rule coverage
- Becker's: HHS finalizes health IT rule
- ONC: HTI-5 Proposed Rule overview presentation (Feb 2026)
- HLN: HTI-5 proposed rule public comments
- McDermott: HTI-5 proposed rule analysis
- ONC test method: (f)(5) electronic case reporting
- ONC test method: (f)(1) immunization registries
- CMS: FY 2027 IPPS final rule fact sheet
- Acmeware: 2027 IPPS final rule summary