The 2026 ISA: ONC Drops a Catalog, Founders Should Read It Like a Term Sheet

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Abstract

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What it is: The Interoperability Standards Advisory (ISA) is ONC's annual catalc health data interoperability standards and implementation specs. The 2026 Refe Edition is the stable annual snapshot of that catalog, published alongside a wave other major policy outputs in Q1 2026.

Key concurrent developments driving the relevance of this edition:

- Draft USCDI v7 released Jan 29, 2026, adding 30 proposed data elements (29 ne plus one major revision), bringing the total proposed element count to 156

- HTI-5 proposed rule (Dec 15, 2025): major deregulatory rewrite of ONC certification, going FHIR-first

- Diagnostic Imaging Interoperability RFI (Jan 30, 2026): ONC asking industry w do with DICOM and imaging standards

- USCDI v3 became required as of Jan 1, 2026 (94 data elements mandatory for certified HIT)

- SVAP 2025 approved standards include USCDI v5 (156 total elements), availabl voluntarily as of Aug 29, 2025

- Comment deadlines: USCDI v7 closes April 13, 2026; HTI-5 closed Feb 27; Ima RFI closed March 16

Why it matters: This edition lands at an inflection point where ONC is simultan raising the data floor (USCDI v3 required), sketching a higher ceiling (USCDI v7 draft), deregulating the compliance box-checking (HTI-5), and openly asking wh do about 30+ years of DICOM files sitting in siloed PACS systems. For entrepren building on health data and investors placing bets in that space, Q1 2026 is a pol burst that reshapes the data infrastructure layer.

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What the ISA Actually Is and Why It Ge Ignored

Most people in health tech either pretend the ISA doesn't exist or treat it as background noise in a compliance email from their legal team. That's understan The document is basically a giant table of acronyms mapping interoperability us cases to standards. USCDI, FHIR, HL7 v2, C-CDA, SNOMED, LOINC, RxNorm, NCPDP SCRIPT, DICOM, and about sixty other things you've either heard of or

actively tried to forget. ONC breaks the catalog into more than sixty subsections organized by use case: clinical care, lab, imaging, public health, pharmacy, admi patient demographics, and so on. Each entry gets a maturity rating and an adopt level, which is ONC's honest attempt to tell you whether a given standard is something real people use or just something a standards development organizati published to a mailing list in 2009.

Here's the thing though: the ISA is effectively the regulatory substrate for healt infrastructure investment. It's not a mandate in itself. ONC is explicit that being listed in the ISA does not require implementation. But what the ISA does is defi vocabulary, signal ONC's directional intent, and anchor everything from certific criteria to payer rules to TEFCA participation requirements. When CMS's Prior Authorization final rule (CMS-0057-F) says payers must expose data via FHIR A it's the ISA-adjacent standards stack that defines what "FHIR" means operationa When a developer wants to get ONC-certified, the standards in the ISA are the s standards that end up in certification criteria. The ISA is not just documentatio the genome of what the health data layer is supposed to look like.

The 2026 Reference Edition drops at a genuinely busy policy moment. Three ma overlapping ONC outputs landed within about six weeks: the HTI-5 proposed ru December 15, 2025, Draft USCDI v7 on January 29, 2026, and the diagnostic ima RFI on January 30. The 2026 ISA is the stable reference snapshot that industry p can point to in contracts, grant applications, and vendor agreements while all th activity is in flight. So even if the document itself reads like an encyclopedia of t letter acronyms, it matters as the settled floor of what is real and expected right

The Standards Stack Right Now, Hones

Let's briefly ground the conversation in where things actually stand. As of Janua 2026, USCDI v3 became the required baseline for certified health IT under the H final rule. That means EHRs and certified health IT modules have to be able to exchange 94 data elements, structured according to FHIR US Core profiles versi 6.1.0 and C-CDA Companion Guide Release 4.1. The 94-element threshold soun

big, but coming from USCDI v1's 52 elements (which was the law since the 21st Century Cures Act), the delta is meaningful in specific categories. USCDI v3 adc health insurance information, clinical tests (including non-imaging, non-lab clin assessments), pediatric vital sign refinements, and a handful of other additions t had been stuck in the pipeline for years.

For anyone who's been building a data integration product or an analytics layer c of EHR FHIR APIs, the practical reality is that EHRs rolled out USCDI v3 suppc unevenly throughout 2025. Epic did it on a site-by-site basis depending on when individual health systems applied the update. Oracle Health (Cerner) had its owı rollout cadence. The market is not uniform. There's a meaningful variance in wh structured data is actually accessible from any given FHIR endpoint right now, v is a real problem for companies building products that assume a consistent data That gap is both a risk for founders and an opportunity.

The Standards Version Advancement Process, or SVAP, is the mechanism ONC u let developers get ahead of required versions without waiting for the full regulat cycle. The 2025 SVAP approved standards, published in May 2025 and available voluntary adoption starting August 29, 2025, include USCDI v5 (which has 126 required data elements plus the 30 proposed v7 additions that would bring the t 156 if finalized), updated FHIR US Core support, and revisions to QRDA I and I quality reporting. This is how the more sophisticated vendors signal technical leadership: early SVAP adoption lets them credibly say to health system clients t they're already ahead of the next required standard. For founders pitching enter health systems, understanding which USCDI version your platform natively sup is table stakes in 2026.

USCDI v7 Draft Breakdown and What It Signals

The draft USCDI v7, published January 29, 2026, proposes 30 additions: 29 new elements and one major revision. The revision is to Tobacco Use, which replaces simpler Smoking Status element that's been in USCDI since v1. That change ma

because it signals a broader conceptual shift toward capturing behavioral health related social context in structured, interoperable form rather than the clinical shorthand of a checkbox.

The 30 proposed additions span three major clusters. The first cluster is adverse health and safety events, which includes Adverse Event (capturing unintended e of clinical interventions like medication or vaccine reactions) and Adverse Event Outcome (the patient's clinical result from that event, including hospitalized, recovered, or deceased). The fact that these are going into USCDI is significant f patient safety infrastructure companies and pharmacovigilance tooling. If advers events become a standard interoperable data element, that unlocks federated sig detection across care settings in a way that's currently very hard to do at scale be the data isn't structured the same way everywhere. There are real companies to b on top of that, and investors should be paying attention.

The second cluster involves care coordination and patient context. This is where USCDI is starting to look more like a longitudinal care record rather than just a clinical document summary. Elements related to functional status, nutrition-rela data, and health insurance administrative information are pulling into the stand The nutrition-related additions are tied explicitly to the Make America Healthy federal health agenda, which is worth noting: federal priorities do influence wha ONC proposes in USCDI. That's not a bug, it's the feature. USCDI is a policy instrument as much as a technical one.

The third cluster is clinical care, which includes imaging reference data, clinical findings, and other structured clinical observations. The imaging reference addi important and connects directly to the imaging RFI discussed in the next sectior "diagnostic imaging reference" data element in USCDI v7 is defined as the information needed to access a diagnostic imaging study: the imaging study end weblink, unique identifiers, and contextual metadata. It's not the image itself. It pointer. Think of it as a structured URL with provenance attached. But getting t pointer into the standard data exchange layer is a necessary precondition for bui anything useful on top of imaging data at scale.

The USCDI v7 comment period runs through April 13, 2026. Final version is exp in July 2026. The current proposal has already drawn comments from the AMA (is specifically requesting that ONC provide implementer-ready code system guic for each proposed element to prevent the usual scenario where the element exist nobody actually encodes it the same way), ACLA (which is pushing for continuec v2 and CDA support alongside FHIR rather than forced FHIR migration), and N (which has specific requests around quality measurement data element alignmen Those comment patterns are informative because they tell you where the real fri is. Labs are worried about FHIR transition costs. Physicians are worried about encoding consistency. Quality organizations are worried about measure alignme three of those pain points are startup opportunities.

HTI-5 Changes the Game for Developer

The Health Data, Technology, and Interoperability proposed rule known as HTI· published December 15, 2025, is a deliberate deregulatory rewrite of ONC's certification program. The comment period closed February 27, 2026. The rule reflects a fairly sharp pivot: ONC is effectively saying that a decade of compliand box-checking has produced a lot of certified health IT that checks boxes without advancing actual interoperability, and the better path is to strip out the non-FH functionality-based certification criteria and re-anchor on API-first standards.

Concretely, HTI-5 proposes to eliminate fourteen privacy and security certificati criteria on the basis that practices like multi-factor authentication, encryption, a audit logging are now standard practice in software development broadly and dc need to be certification requirements. It proposes to retire the legacy Clinical Decision Support criterion at 170.315(a)(9) in favor of the more modern Decision Support Interventions criterion. It proposes to remove the AI "model card" transparency requirements that were introduced in HTI-1, citing lack of demonstrated clinical utility and alignment with the current administration's deregulatory posture on AI. It reduces Real World Testing reporting to focus ma on FHIR API criteria. And it proposes to adopt USCDI v3.1 (the version from wl

certain data elements were removed following Executive Order 14168 in early 20
related to gender identity fields) rather than the original USCDI v3.

For health IT developers, the net impact of HTI-5, if finalized roughly as propos
lighter compliance overhead, a clearer FHIR-first certification architecture, and
prescriptive transparency requirements around AI-powered decision support. Fo
founders, this is interesting for a few reasons. The reduction in AI transparency
certification overhead theoretically lowers the cost of deploying AI-powered DSI
features within certified health IT. The information blocking rule revisions in H
are also significant: the proposed rule explicitly clarifies that "access" and "use"
electronic health information include automated means, including autonomous A
systems. That's a big deal for interoperability companies building agentic data
pipelines. It closes a potential loophole where a vendor could argue that an auto
data access request doesn't qualify as protected access under the information blo
rules.

The HTI-5 deregulatory posture is not without risk. Removing privacy and secur
certification criteria works on the assumption that market forces and existing la
(HIPAA, state privacy laws) are sufficient to maintain security standards without
ONC's certification layer. That's a legitimate debate. In a market where many ce
health IT vendors are operating legacy infrastructure, the removal of certificatio
level security requirements could create downstream liability exposure for healt
systems that rely on those certifications as a proxy for vendor security maturity.
Founders building cybersecurity and compliance tooling for healthcare should
absolutely be modeling the market implications of this shift.

Imaging Is the Next Frontier and It Is Wide Open

The diagnostic imaging RFI from January 30, 2026, is one of the more openly
acknowledged gaps in the entire health data interoperability project. ONC has b
dancing around imaging since at least 2015, when it removed imaging results as
certification criterion in the 2015 Edition Final Rule. HTI-2, published in Augus

2024, tried to reintroduce imaging interoperability requirements. HTI-2 was the withdrawn on December 29, 2025. Now ONC is asking the public what to do, wh the regulatory equivalent of admitting the problem is harder than it looks.

The core tension is between DICOM, which is the dominant standard for storing transmitting medical images and has been in production at hospitals globally for thirty years, and FHIR-based approaches like DICOMweb and FHIR ImagingStu resources that enable more modern API-driven access patterns. These aren't necessarily competing; DICOMweb is essentially DICOM accessed via RESTful and FHIR ImagingStudy resources can carry references to DICOMweb endpoint the gap between what exists in theory and what is actually deployed in productio PACS systems across a fragmented hospital market is enormous. A community hospital running a PACS vendor from 2012 does not have FHIR-native imaging exchange. Full stop.

The imaging RFI is asking questions that span standards, certification, workflow secondary use. Can imaging study metadata travel via FHIR without requiring fu DICOM payload transfer? What are the viable pilot designs for testing FHIR-ba imaging exchange across unaffiliated systems? How should ONC think about the relationship between DICOM-SR (structured reporting), FHIR DiagnosticRepor resources, and the USCDI v7 imaging reference data element? These are real tec questions with real infrastructure investment implications. The imaging data lay U.S. healthcare is enormous in volume terms, clinical significance, and AI model training value. Radiology AI has been one of the hotter categories in health tech investment for the past several years, but most of it depends on direct data acces agreements with individual health systems rather than any standardized interoperability layer. An ONC certification requirement for FHIR-based imagin exchange would change that market structure substantially.

The Epstein Becker Green analysis of the imaging RFI makes a useful point: the longitudinal data persistence problem is fundamentally what ONC is trying to s here. Most patients' imaging history is fragmented across systems that don't sha common access layer. A patient who had a chest CT at one health system and a f up at another two years later has two disconnected imaging records. Radiologist

oncologists, and primary care physicians all work around this by having patients physically carry CDs (yes, CDs) or by maintaining referral relationships with spe imaging centers. The infrastructure fix here is not trivial, but the regulatory sign from ONC is that imaging interoperability is coming into scope for federal stand requirements. That's a green light for founders and a directional signal for inves

Investment Implications and Where the Bets Are

Pulling this together into a framework that's actually useful for allocation decisi requires thinking about the ISA ecosystem in terms of infrastructure layers versu application layers, and distinguishing between what the regulatory push makes inevitable versus what it merely enables.

The data element expansion trend in USCDI is relentless. From 52 elements in v 94 required in v3 to a proposed 156 in v7, the floor is rising. Every additional mandatory data element is a certification cost for EHR vendors and a potential v unlock for applications built on top of richer structured data. Companies that h built data normalization and quality scoring infrastructure on top of FHIR endp mapping LOINC codes to clinical concepts and reconciling SNOMED hierarchie become more valuable as the mandated data surface expands. This is not a new insight, but the magnitude of the USCDI v3 to v7 jump is bigger than past cycles Founders building clinical data aggregation, normalization, and enrichment pro are sitting in a good spot structurally.

The adverse event data elements in USCDI v7 are an underappreciated signal. If Adverse Event and Adverse Event Outcome become required structured data in national interoperability standard, that creates a federated signal detection subs that doesn't currently exist at scale. Pharmacovigilance, post-market safety surveillance, and clinical quality improvement all depend on aggregating adverse event data across care settings, which right now requires either expensive manua abstraction or proprietary data access deals. A standards-mandated interoperabl

adverse event data layer would be one of the more interesting structural changes how safety signal detection works in the U.S. There are companies to build here.

The HTI-5 deregulatory move, specifically the clarification that automated AI ag are covered under information blocking protections, is probably the most overlo provision in the entire Q1 2026 policy burst. Agentic health data pipelines, prod that autonomously traverse FHIR APIs to pull patient data for care coordination analytics, now have explicit regulatory backing for the claim that EHRs and HIE cannot block that access. This matters enormously for companies building AI-na care coordination products, payer-provider data exchange layers, and anything t involves automated clinical data retrieval. The fight over whether a vendor can r limit or technically obstruct agentic API access just got a lot clearer in favor of t access side.

On imaging, the investment thesis is contingent on a regulatory development tha hasn't happened yet. ONC withdrew HTI-2's imaging requirements and is curre RFI mode. There is no finalized rule requiring FHIR-based imaging exchange. B direction of travel is unmistakable, and the USCDI v7 imaging reference data el is a meaningful signal that at a minimum, a structured pointer to imaging studie going to become a required interoperability element. Companies building on FH ImagingStudy resources, DICOMweb integration, and PACS-to-FHIR translatio middleware are ahead of a wave. Radiology AI companies that have been entirely dependent on bilateral data agreements should be building their FHIR integrati strategy now rather than waiting for a final rule that will almost certainly come the next two to three rulemaking cycles.

The SVAP dynamic is also worth calling out from an enterprise sales perspective Voluntary early adoption of SVAP standards is how differentiated vendors signal technical leadership to health system buyers. A certified EHR or data platform t has already adopted USCDI v5 via SVAP can walk into a health system CIO conversation with a credible story about being ahead of the regulatory curve. Fo founders building platform products that depend on ONC-certified data source understanding the SVAP trajectory matters for timing API integration features a structuring data access agreements with vendor partners.

One last thing worth naming: the ISA is not just a U.S. policy document. The glc context is relevant because international healthcare data standards convergence accelerating. The UK, Ireland, Australia, and several EU member states are all running parallel FHIR adoption programs with their own national core datasets. Companies building on FHIR US Core today should be tracking the FHIR R5 adoption timeline and the convergence between USCDI and international equiva like the International Patient Summary (IPS). The ISA and USCDI are U.S.-speci implementations of a global standards direction. For founders with ambitions be domestic markets, that convergence is a feature, not a compliance tax.

The 2026 ISA Reference Edition is, frankly, not fun to read. It's a catalog docum But read in context with USCDI v7, HTI-5, and the imaging RFI, it maps the ter for the next several years of health data infrastructure development more clearly most industry analyst reports. The floor is rising, the FHIR mandate is deepenin native data access just got regulatory backing, and imaging is next in line for standardization. If that doesn't produce a readable term sheet for where to build invest in health data, nothing will.

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