



// WHITE PAPER · HEALTH INFORMATICS

Two standards, two cautionary tales.

*HL7 v3 and ICD-11 in the United States healthcare standards
landscape*

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ABSTRACT

HL7 v3 is widely considered a failure in its original messaging form, while ICD-11 — seven years after World Health Organization adoption — remains largely unimplemented in the United States. Both standards illustrate the same painful truth: in healthcare informatics, theoretical elegance loses to installed bases, implementation cost, and political will.

This white paper examines the parallel adoption trajectories of HL7 Version 3 and the eleventh revision of the International Classification of Diseases. Drawing on peer-reviewed literature, gray literature from standards bodies and consultancies, and policy guidance from the National Committee on Vital and Health Statistics, the analysis identifies four structural forces that govern healthcare-standard adoption in the United States: installed-base gravity, implementation complexity, business model and licensing, and regulatory leverage. The paper situates these forces against the Latin American regional context — particularly Chile’s interoperability framework under Ley 21.668 — and concludes with three signals that will determine ICD-11 adoption timing in the United States over the next twenty-four months.

1 Introduction: two standards in question

HL7 v3 survived only through its document-oriented offshoot, the Clinical Document Architecture (CDA), which was effectively mandated by the Office of the National Coordinator for Health Information Technology in 2014 and now underpins billions of clinical document exchanges (Health Level Seven International, n.d.-a). ICD-11, meanwhile, went into global effect on January 1, 2022, and more than 64 of 120 World Health Organization member states are actively implementing it (World Health Organization, n.d.). Yet the United States has no implementation date, no designated lead agency, and by expert estimate is ten to fifteen years away from morbidity coding adoption (National Committee on Vital and Health Statistics [NCVHS], 2024).

Together, these two stories define how modern healthcare data exchange evolved into today's reality of FHIR-plus-ICD-10 and clarify what United States payers, providers, and vendors should expect next.

1.1 HL7 Version 3 and the Clinical Document Architecture

HL7 Version 3 is a suite of XML-based messaging specifications published by Health Level Seven International, built on a single underlying Reference Information Model (RIM) that attempts to describe every clinical fact in a consistent, object-oriented vocabulary. It was developed across roughly a decade beginning in the late 1990s to correct the so-called optionality problem of HL7 v2, in which every hospital interface required custom mapping because the standard let vendors pick and choose fields (Health Level Seven International, n.d.-b). Its companion deliverable, the Clinical Document Architecture, uses the same RIM but packages information as human-readable, machine-parseable XML documents — discharge summaries, referrals, and continuity-of-care documents (Health Level Seven International, n.d.-a).

1.2 The eleventh revision of the International Classification of Diseases

ICD-11 is the World Health Organization's eleventh revision of the International Classification of Diseases, formally adopted at the 72nd World Health Assembly in May 2019 and in effect globally since January 1, 2022 (World Health Organization, 2019). Unlike ICD-10's flat alphanumeric structure, ICD-11 is built on a semantic foundation with a digital application programming interface, a post-coordination mechanism that combines stem codes with extension codes for specificity, and new chapters covering immune-system disease, sleep-wake disorders, sexual health, and traditional medicine (IFHIMA, n.d.). The new revision adds codes for antimicrobial resistance, patient safety events, and more clinically granular diabetes complications — content that ICD-10-CM, frozen by the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services

since the World Health Organization stopped updating ICD-10, increasingly lacks (Yan et al., 2024).

2 The HL7 v3 trajectory: collapse and survival

2.1 Why messaging failed in the United States

The short verdict from practitioners is blunt: HL7 v3 was largely considered a failure in the United States market, leading many integrators to revert to HL7 v2 (Medblocks, n.d.; PureLogics, n.d.). The rigorous consistency that the standards committee treated as a virtue became a liability because real healthcare institutions capture and exchange different data in different ways. The specification ran to thousands of pages; implementation required mastering the RIM plus data types, an XML implementation technology specification, message wrappers, and transport protocols; and the committee spent nearly a decade refining abstractions before real implementers tested them — a rewrite-by-committee pattern the software industry generally regards as doomed (Whitefox, n.d.).

2.2 International successes through national mandates

Where v3 did take root, the common thread was political homogeneity and the absence of a large installed base of v2 interfaces. The United Kingdom's National Health Service built specifications on the v3 RIM for its National Programme for IT; the Netherlands placed v3 messages at the core of its national medication and general-practice record infrastructure; Canada Health Infoway made v3 the foundation of its EHR Architectural Blueprint, with every province implementing v3 pharmacy messages; and the United States Centers for Disease Control and Prevention adopted v3 for the National Electronic Disease Surveillance System (Emorphis Health, n.d.). In each case, a single governmental authority could mandate adoption in a greenfield or near-greenfield environment. In the decentralized United States provider market, with tens of thousands of hospital interfaces already speaking HL7 v2, no such mandate was ever going to stick.

2.3 The CDA exception: regulation as accelerant

The document-oriented branch tells a different story. After the Office of the National Coordinator's 2014 certification rule named C-CDA Release 1.1 as a required exchange format, adoption expanded rapidly, and the current C-CDA Release 2.1 remains backward-compatible with that version (Health Level Seven International, n.d.-a). Billions of clinical documents now move in CDA format, even as the standard's thousand-plus-page specification plus Companion Guide routinely drive developers to so-called green CDA simplification projects (Emorphis Health, n.d.).

CDA succeeded because United States regulators attached it to a financial carrot — Meaningful Use — rather than asking the market to adopt it voluntarily. The v3 messaging side had no such lever and withered.

2.4 FHIR as the open-license successor

The industry’s real successor to v3 is FHIR, the Fast Healthcare Interoperability Resources specification, launched as a Grahame Grieve side project, adopted by HL7’s Fresh Look Task Force, and — critically — published under an open license rather than behind HL7’s paywall. FHIR’s REST-plus-JSON design explicitly rejects v3’s model-driven maximalism in favor of the so-called eighty-percent rule: standardize the resources everyone needs and let implementers extend the rest (Bender & Sartipi, 2013).

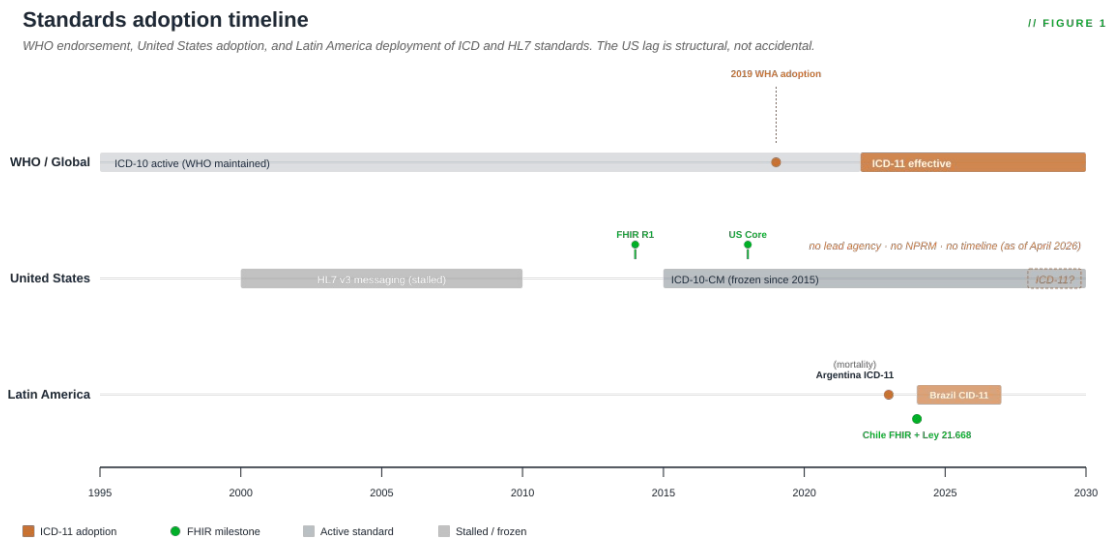


Figure 1. Adoption timelines for ICD-10, ICD-11, and the HL7 v3 / FHIR transition across WHO, the United States, and Latin America. The US lag in adopting ICD-11 is structural, not accidental — Latin American countries with smaller installed bases of ICD-10-CM are moving faster. Sources: WHO (2019, n.d.); NCVHS (2019, 2024); PAHO (2023); CFM (n.d.); Libman Education (n.d.).

3 The ICD-11 trajectory in the United States

3.1 The WHO timeline and the US adoption gap

The World Health Organization’s timeline makes clear how slow United States transitions run. The country implemented ICD-10 for mortality reporting in 1999 and for morbidity in 2015 — twenty-five years after WHO endorsement — and only after a protracted regulatory fight in which, by NCVHS’s own postmortem, inadequate communication with industry

stakeholders led to decisions that resulted in increased cost and burden (NCVHS, 2019). ICD-11 is tracking for a similar or worse fate despite its clear clinical advantages (Reed, 2023).

3.2 NCVHS and the lead-agency problem

The National Committee on Vital and Health Statistics, statutory advisor to the Department of Health and Human Services on HIPAA code sets, first recommended preparation for ICD-11 in 2019. When those recommendations went unheeded during the COVID pandemic, NCVHS reissued them in September 2021. In 2022 it stood up a dedicated ICD-11 Workgroup on Timely and Strategic Action because, as its May 2024 letter to the Secretary put it, there is an urgent need for a central coordinating entity for planning and adopting ICD-11 — language that itself reveals no such entity exists (NCVHS, 2024).

The Centers for Disease Control and Prevention’s National Center for Health Statistics issued a Request for Information in January 2024; responses from the American Hospital Association, AHIP, the American Clinical Laboratory Association, and the American College of Obstetricians and Gynecologists broadly supported transition but demanded side-by-side dual-coded case scenarios before any final recommendation. None of the formal prerequisites for a HIPAA rulemaking — Notice of Proposed Rulemaking, Final Rule, industry testing — have been triggered. Industry consultancy projections range from an optimistic 2025 to 2027 window (SPRY, n.d.) to a realistic at least ten years, probably closer to fifteen (Libman Education, n.d.).

3.3 Structural barriers to a drop-in transition

The structural problem is that ICD-11 is not a drop-in replacement. ICD-10-CM uses fully-specified four-to-seven character codes; ICD-11 uses stem codes plus post-coordinated extensions, meaning a single clinical concept can be expressed many ways. Any ICD-10-to-ICD-11 mapping tool has to be probabilistic, not deterministic (Yan et al., 2024). Every payer reimbursement edit, every CMS DRG grouper, every quality measure specification, and every clinical decision support rule tied to specific ICD-10-CM codes would need rebuilding (Medwave, 2024). The CDC and CMS continue maintaining ICD-10-CM and ICD-10-PCS independently of the World Health Organization, which reduces the pain of not moving but widens the gap with international data (Healthicity, n.d.).

4 Regional perspective: Latin America and Chile

4.1 PAHO-supported transitions in Argentina and Brazil

Latin America occupies a middle ground. Argentina, working with technical support from the Pan American Health Organization, began preparing the national mortality system for CIE-11 processing in 2023 (Pan American Health Organization, 2023). Brazil’s Ministério da Saúde

published a revised CID-11 implementation timetable extending rollout across epidemiological and hospital systems through 2027 (Conselho Federal de Medicina, n.d.). In both cases, adoption follows the pattern v3 succeeded by abroad: a central health authority that can coordinate taxonomy migration across public hospital networks without having to negotiate with thousands of independent payers.

4.2 The Chilean opportunity under Ley 21.668

For Chile, the relevant parallel is interoperability rather than classification per se. Ley 21.668 and the Chile Core Release 4 FHIR profiles reflect a deliberate choice to leapfrog the v3 messaging era entirely, building on FHIR and international terminologies from the start. The Latin American ecosystem — well documented by informatics groups at Hospital Italiano de Buenos Aires and peer institutions — has long emphasized FHIR-native, RESTful architectures over v3 messaging, which positions the region to adopt ICD-11 as an API-consumed terminology rather than as a flat code set (Hospital Italiano de Buenos Aires, n.d.).

5 Where the two stories converge

Both cases expose the same four structural forces that govern healthcare-standard adoption in the United States, each of them weighing against ambitious redesigns. Table 1 summarizes the parallel pressures; the prose that follows develops each force in turn. Figure 2 then plots the major standards in this analysis on a two-by-two matrix of complexity and regulatory mandate, making visible why HL7 v3 messaging and ICD-11 occupy the same danger quadrant.

Structural force	HL7 v3 (US experience)	ICD-11 (US experience)
Installed-base gravity	Tens of thousands of v2 interfaces already deployed; no authority to force coordinated migration.	ICD-10-CM embedded in every claims system, payer contract, DRG grouper, and quality measure.
Complexity at implementation	RIM abstraction required multi-year training; thousands of spec pages; years before implementer testing.	Post-coordination breaks deterministic code matching; mapping must be probabilistic, not 1:1.
Business model and licensing	Behind HL7 paywall for most of its life; FHIR succeeded partly by going open.	WHO-free, but US-specific tooling, education, and modifier frameworks are unfunded.
Regulatory lever	Messaging side: never mandated,	No NPRM, no Final Rule, no

Structural force	HL7 v3 (US experience)	ICD-11 (US experience)
	withered. CDA side: ONC Meaningful Use mandate, adoption exploded.	designated lead agency (as of April 2026).
Successful pathway	Document-based (CDA) and open successor (FHIR) displaced the original messaging intent.	Likely FHIR-wrapped, API-consumed ICD-11 through TEFCA networks before formal HIPAA adoption.

Table 1. Structural forces shaping United States adoption of HL7 v3 and ICD-11. Both standards face the same headwinds; the differences lie in which mitigation pathways have so far succeeded.

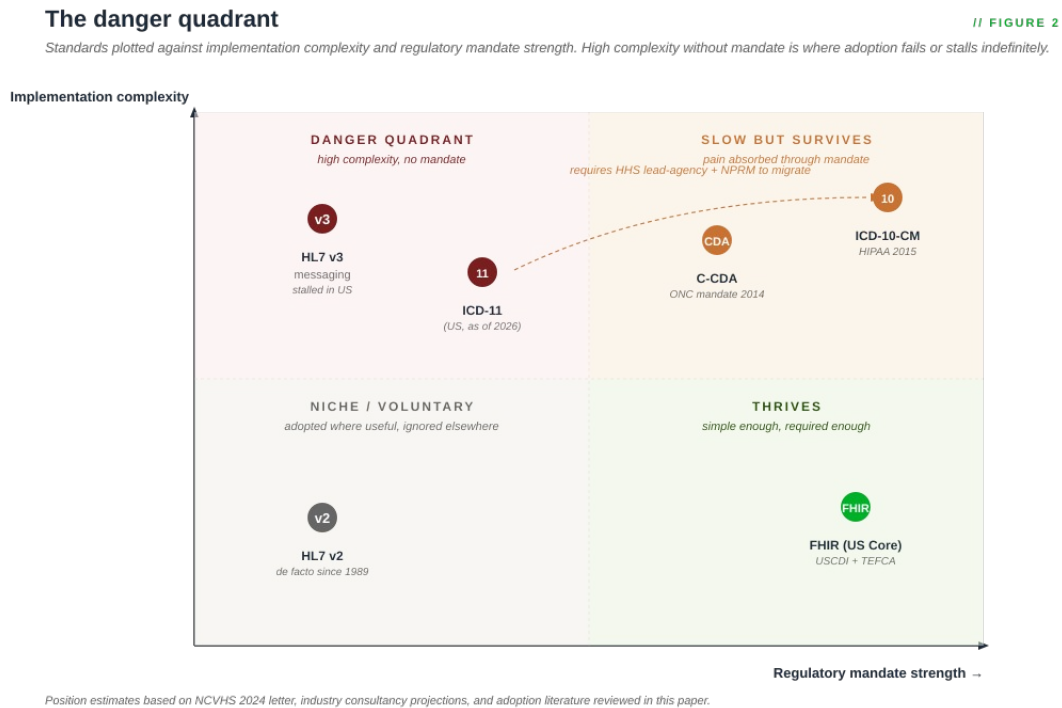


Figure 2. Strategic positioning of major United States healthcare data standards along axes of implementation complexity and regulatory mandate strength. HL7 v3 messaging and ICD-11 occupy the same upper-left danger quadrant — high complexity, no mandate — which is structurally where standards stall. ICD-10-CM and C-CDA sit in the upper right because regulatory mandates absorbed their complexity; FHIR thrives because it is simple enough to deploy without one.

5.1 Installed-base gravity dominates everything else

HL7 v2 is embedded in roughly ninety-five percent of United States hospitals’ admission, discharge, and transfer flows; ICD-10-CM sits inside every claims system, payer contract,

and quality program in the country. Replacing either requires simultaneous coordinated change across thousands of independent organizations with no single authority to force the move. Countries that successfully deployed v3 had that authority; the United States does not (Emorphis Health, n.d.). NCVHS explicitly frames its ICD-11 challenge as avoiding the ICD-10 transition's polarization of positions resulting in a failure to achieve industry consensus (NCVHS, 2019).

5.2 Complexity compounds at implementation, not specification

V3's RIM was elegant on paper but required years of training to use; ICD-11's post-coordination provides flexibility but breaks every deterministic code-matching system downstream (Yan et al., 2024). A standard that is theoretically superior but practically burdensome tends to lose to a good-enough incumbent — the classic perfect-as-enemy-of-good pattern, applied to informatics.

5.3 Business model and licensing shape uptake more than technical merit

HL7 v3 and CDA sat behind HL7's paywall for most of their history; FHIR is free. ICD-10-CM is freely available from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services; ICD-11 is free from the World Health Organization but requires United States-specific tooling, education, and modifier frameworks that no agency has been funded to build. NCVHS's core 2024 ask — name a lead agency — is really a request for budgeted ownership (NCVHS, 2024).

5.4 Regulatory levers work; voluntary adoption rarely does

Meaningful Use mandated C-CDA and adoption exploded. HIPAA code-set rules mandated ICD-10-CM and, after years of delay, adoption happened. Absent such a mandate, HL7 v3 messaging languished and ICD-11 is languishing. The lesson for any future standard — FHIR US Core, USCDI, TEFCA — is that federal certification and reimbursement hooks are not accelerants; they are prerequisites (YES HIM Consulting, n.d.).

6 Outlook: what to watch over the next twenty-four months

The United States healthcare data stack as of April 2026 is effectively a hybrid: HL7 v2 for real-time event messaging, C-CDA for document exchange, FHIR for modern application programming interfaces and patient access, and ICD-10-CM and ICD-10-PCS for billing and statistics. HL7 v3 messaging persists mainly in CDC public-health feeds and in the Commonwealth and European national programs that committed to it before FHIR existed. ICD-11 is being implemented abroad — more than half of World Health Organization

member states are in transition — and the longer the United States waits, the greater the divergence in international comparability of mortality and morbidity data (World Health Organization, n.d.; Dx Revision Watch, 2019).

Three concrete signals will determine timing over the next twenty-four months. The first is whether the Department of Health and Human Services designates a lead agency for ICD-11 in response to the 2024 NCVHS letter; without that, no Notice of Proposed Rulemaking is possible. The second is whether the CDC and the National Center for Health Statistics publish the side-by-side dual-coded case scenarios that the American Hospital Association and other stakeholders have made a precondition for endorsement. The third is whether FHIR-based exchange of ICD-11-coded data through TEFCAs-qualified Health Information Networks creates a de facto pathway that precedes formal HIPAA adoption — a pattern that would mirror how FHIR itself became dominant before any single rule mandated it (Bender & Sartipi, 2013).

7 Conclusions

Ambitious, model-driven healthcare standards succeed only where a coordinating authority can compel adoption and fund the transition. They fail or stall where the market is asked to migrate voluntarily.

HL7 v3 messaging died in the United States and survived abroad because other countries had national health authorities that v3's complexity did not overwhelm. CDA lived because the Office of the National Coordinator turned it into a regulatory requirement. ICD-11 will likely follow the ICD-10 pattern — a decade-plus delay, pressure from international divergence, eventual HIPAA rulemaking, and a painful multi-year dual-coding transition — unless the Department of Health and Human Services names an owner soon.

For stakeholders planning interoperability roadmaps now, the practical implication is to invest in FHIR-first architectures with code-set abstraction layers that can swap ICD-10-CM for ICD-11 when, not if, the mandate arrives. For Latin American implementers, and particularly in Chile's Ley 21.668 context, the lesson is the inverse: the absence of a large v2 and ICD-10-CM installed base is a structural advantage, and FHIR-native, ICD-11-ready architectures should be the default assumption rather than an aspirational target.

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