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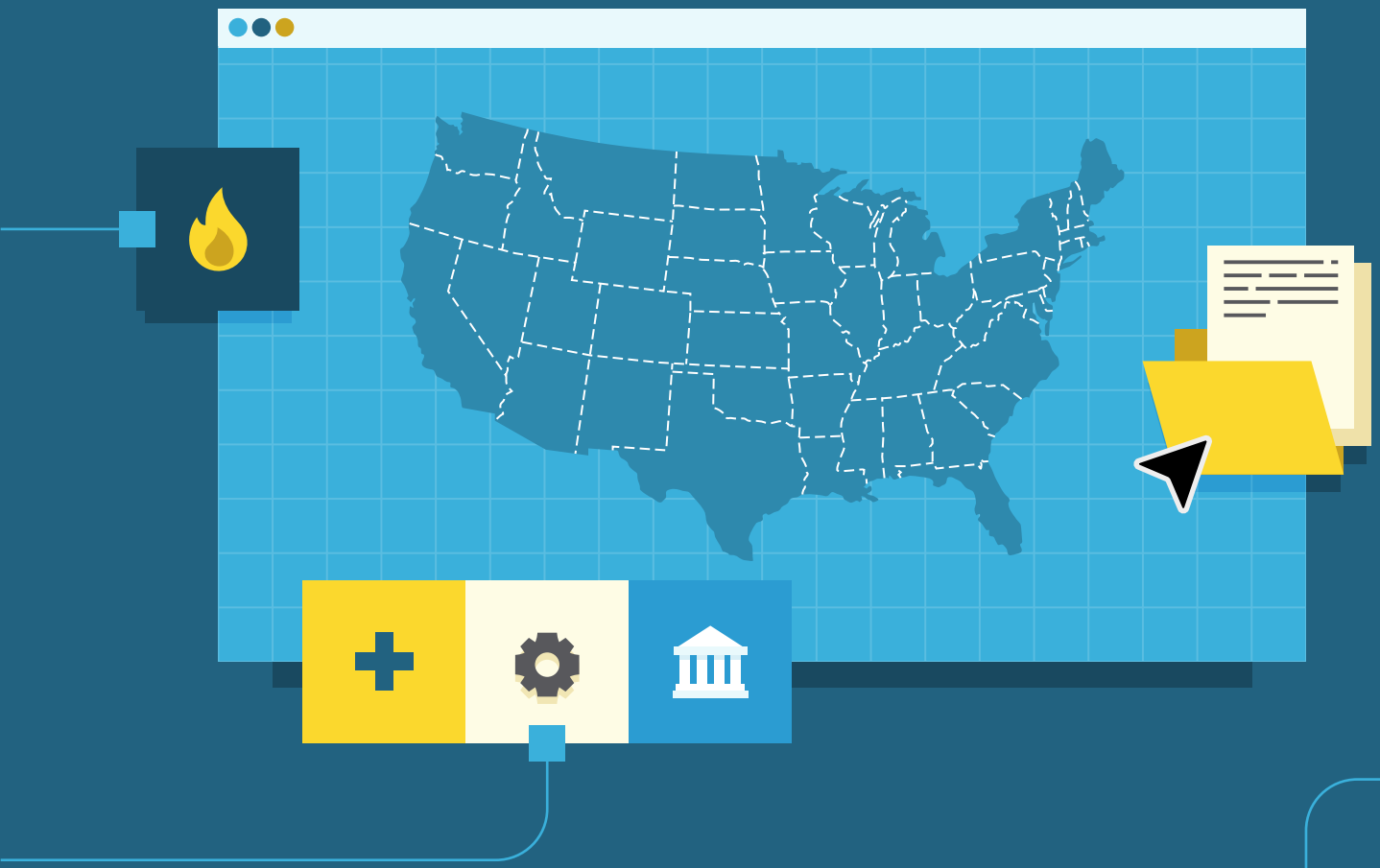


FHIR in US healthcare regulations

The ultimate guide

eBook

Table of contents

01 Intro

Healthcare IT is a dynamic environment in which digitization presentstransformational, technical, and commercial opportunities. The regulatory push to stimulate these developments is especially strong in the US, where both the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) has introduced a steady stream of new regulations, criteria, and deadlines in Health IT.

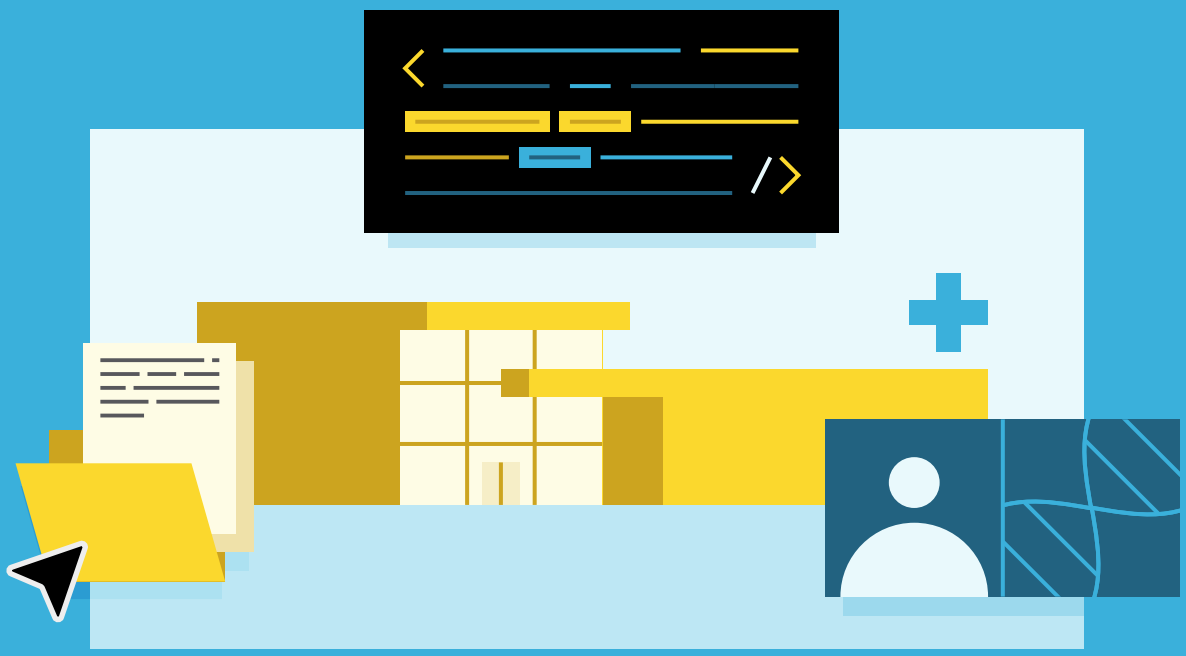
Thanks to this impetus, the US leads the world in the adoption of FHIR and Interoperability.
This presents an opportunity for growth, innovation, and progress. But it also presents challenges that make it hard to follow the big picture. The proliferation of regulations can be overwhelming. It's easy to lose track of what's coming down the road, and it’s hard to prioritize complex rules and meet certification deadlines when you’re dealing with customer projects at the same time.

As one of the initiators of FHIR, Firely keeps a close eye on all FHIR-related compliance requirements. We gather valuable information and insights as we work, and we believe this knowledge is helpful to the wider healthcare IT community. This eBook provides an overview of relevant FHIR-related US regulations, implementation guides, and technologies. It will help you understand their scope, decide what affects your use case, and make decisions about resources, hiring, and whether to buy or build solutions.

Our aim is to create a comprehensive overview of all relevant topics and to keep this eBook as up-to-date as possible. But please be aware that the regulations are subject to frequent changes and additions, and we may have missed a detail that affects your specific use case. We’re not legal experts, we don't claim to give legal advice, and we’re not responsible for business decisions that others make based on our information.

In short

This eBook provides an overview of relevant FHIR-related US regulations, implementation guides, and technologies. It will help you understand their scope, decide what affects your use case, and make decisions about resources, hiring, and whether to buy or build solutions.



02 Who's it for?

This eBook is written for anyone responsible for interoperability in US-based HealthTech companies, healthcare providers and payers that are working with FHIR and Regulations, including Product Managers, IT leads, and Solution Architects.

We'll walk you through the most important criteria such as §170.315(g)(10), §170.315(b)(10) and regulations like CMS-0057-F. We'll also tell you more about the technologies you'll encounter and the Implementation Guides you need to use to become compliant with regulations.

As the US government, specifically ONC and CMS, converges regulation and policy towards FHIR, who better to help you navigate the regulations and meet the deadlines than one of the initiators of FHIR itself.

Let's get started.

03 Who makes the rules?

In this eBook we explain the FHIR-related regulations created by two key US governmental agencies that administer the provisions of the ONC Cures Act Final Rule to the companies and organizations in the US healthcare sector.

The Office of the National Coordinator for Health Information Technology (ONC)

Centers for Medicare & Medicaid Services (CMS)

The Office of the National Coordinator for Health Information Technology (ONC) is a division of the U.S. Department of Health and Human Services (HHS). ONC is responsible for promoting the adoption of health information technology (IT) to improve healthcare delivery, coordination, and patient outcomes. ***Centers for Medicare & Medicaid Services (CMS)*** is a federal agency within HHS. Its primary mission is to administer and oversee crucial healthcare programs including Medicare and Medicaid. Both of these agencies have developed Final Rules based on the provisions of the ONC Cures Act of 2016.

The ONC Cures Act Final Rule relates to electronic health information (EHI) sharing and interoperability. It aims to improve the exchange of EHI among healthcare providers, patients, and other stakeholders while ensuring data privacy and security. It defines requirements for health information technology (HIT) developers, and healthcare providers, to support secure and interoperable health information exchange. ONC is the certifying authority for EHRs, so this is the Final Rule we read about most of the time.

The Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule CMS-0057-F mostly applies to payers, but providers are also affected. The CMS Interoperability and Prior Authorization Final Rulerequires health plans to make patient health information available to patients and their authorized clinicians via APIs. It aims to improve prior authorization processes and care coordination, reduce costs, and put patients at the center of their own healthcare.

04 Key factors

04.1 Implementation guides

Implementation guides (IGs) set out rules and documentation for using FHIR resources for specific purposes. FHIR IGs provide practical instructions, examples, and best practice for developers, healthcare organizations, and other stakeholders involved in implementing FHIR-based systems. They help ensure consistency and interoperability by defining common standards, data definitions and rules, protocols, and methodologies for using FHIR in different contexts.

04.2 The Standards Version Advancement Process (SVAP)

The Standards Version Advancement Process (SVAP) is part of ONC's "Real World Testing" Condition and Maintenance of Certification requirement. It allows health IT developers to voluntarily incorporate newer versions of standards and implementation specifications. More information is available here.

04.3 Data and data definitions

When we mention data definitions in relation to US Regulations and FHIR, we usually mean the United States Core Data for Interoperability (USCDI) or the FHIR representative format of the same, known as the US Core Implementation Guide.

United States Core Data for Interoperability (USCDI)

USCDI is a standardized set of health data elements that are essential for sharing health information between healthcare providers, organizations, and information systems promoting interoperability, care coordination, better decision making, and enhanced patient engagement.

i

USCDI V1 *laid the foundation for interoperability throughout the ONC Cures Act Final Rule, including §170.315(g)(10), and for FHIR and other interfaces to be interchangeable with each other. The standard evolves with new versions and updates.*

US Core FHIR implementation guide

US Core is a set of technical implementation specifications developed by ONC. It focuses on a subset of FHIR resources and data elements that are considered essential for interoperability and support common use cases. These specify the content, structure, and format of the data that should be exchanged to achieve interoperability and help align systems and implementations.

USCDI and US Core – how they relate

USCDI facilitates data exchange, US Core identifies how to achieve it, and as you can see from our versions table, they are closely related. The USCDI establishes standardized data representation using a common code set. The US Core Implementation Guide incorporates US Core profiles that reflect changes in the USCDI as new versions are released. This connects the standardized USCDI datasets to their representation in FHIR.

As more USCDI data element definitions become standardized and supported within EHR workflows and databases, the same data can be made interoperable by using the corresponding US Core version profiles. US Core versions used to be developed reactively, but with US Core 4.0.0, closer alignment with USCDI has been achieved.

Both USCDI and US Core are data definition standards, and EHR software still needs to map the actual data points from the USCDI data elements to the US Core FHIR profiles.

USCDI	US Core
V1	3.1.1*
V1	4.0.0*
V2	5.0.1**
V3	6.1.0

* Retired as of December 31, 2025

** Retired by HT-1 Final Rule as of December 31, 2023

USCDI+

The USCDI+ initiative facilitates the identification and creation of domain or program-specific data element lists as extensions to the existing USCDI. ONC provides this service to federal and industry partners to promote the adoption of interoperable data element lists that go beyond the core data in the USCDI and meet specific programmatic and use case requirements. ONC is actively advancing USCDI+ in two domain categories: Public Health and Quality Measurement.

05 Key terms and technologies

Technology mandates and recommendations issued by ONC and CMS are described and defined in Implementation Guides, criteria testing and certification guides, clarifications and factsheets, and the regulatory framework itself. The key terms and technologies to know about are:

The FHIR Restful API is the fundamental technological implementation of the FHIR standard for US Regulations.

SMART on FHIR is a foundational set of implementation guides that facilitate user authorization and authentication, application launching, and backend authorization.

Bulk Data Export (BDE) is the process of exporting a large amount of data in a single operation – typically in a structured format – for analysis, reporting, backup, or transferring between systems. It is used in IGs to facilitate bulk downloading or exchange of patient data.

EHI refers to electronic protected health information (ePHI) included in a designated record set.

Clinical Quality Language (CQL) is a special computer language designed to be understood by clinicians and non-developers. It is used to create quality measures and tools that help doctors make better choices. The specification includes the Expression Logical Model (ELM) which provides conversion from the readable language to a more direct computer language.

Terminology is the standardized set of codes, value sets, and other artifacts used in the FHIR specification to provide a common vocabulary and coding system.

06 The regulations

This eBook presents an exploration of FHIR-related regulations introduced by the ONC Cures Act Final Rule in 2020, and revised and implemented by Final and Proposed Rules devised by ONC and CMS. Throughout the eBook, the term "regulation" is used interchangeably with other related US Government directives words such as Act, Rule, and Law, for the sake of simplicity and clarity.

06.1 The ONC Cures Act Final Rule

The ONC Cures Act Final Rule is designed to give patients and their healthcare providers secure access to health information.

The four key provisions are:

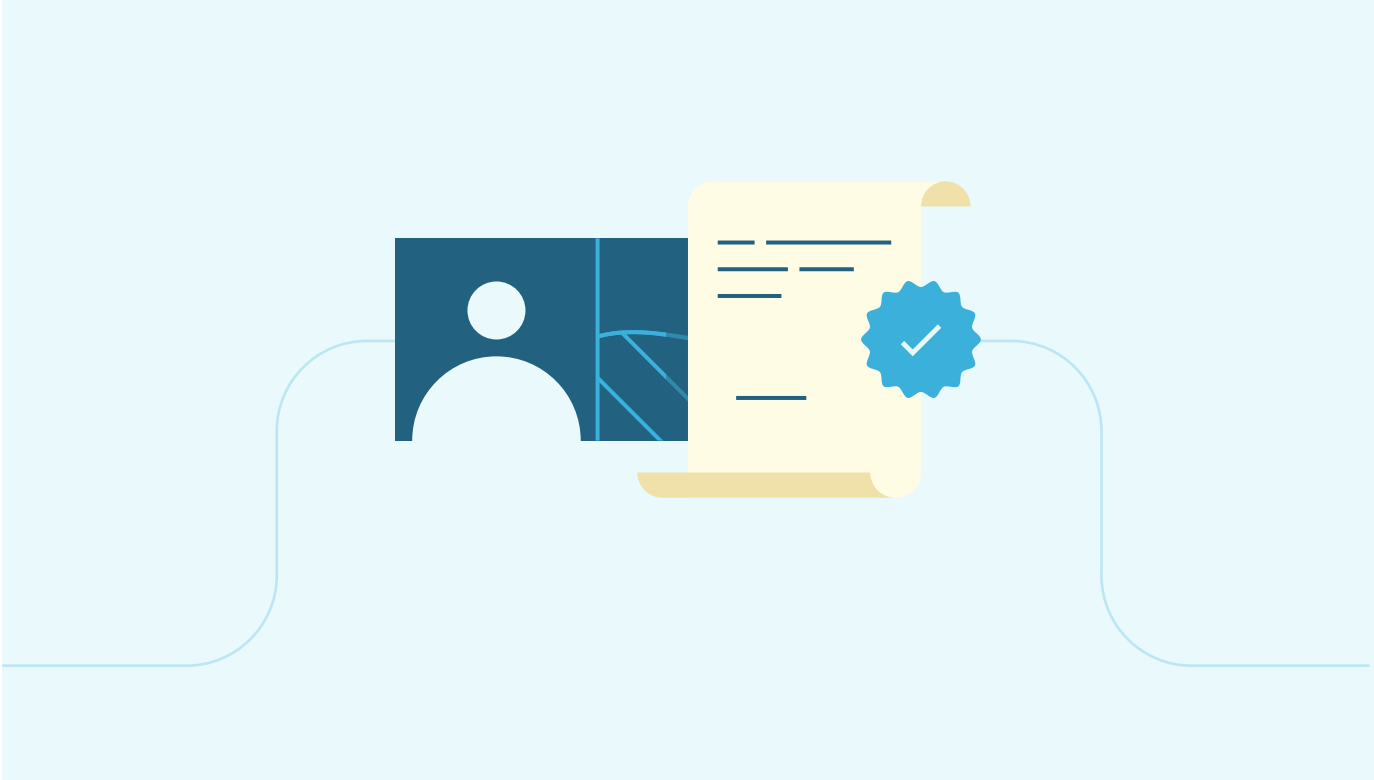
1. **Information Blocking -** Health IT developers and healthcare providers are prohibited from engaging in practices that prevent the sharing of Electronic Health Information (EHI) or make it difficult for patients to access their health information.
2. **Interoperability -** Health IT developers and healthcare providers must implement standardized data exchange protocols to ensure seamless and secure sharing of EHI across different systems and platforms.
3. **API functionality -** Health IT developers must implement APIs that allow patients to access and exchange their health information through third-party applications.
4. **Certification -** Health IT developers must certify their products to ensure they meet the technical and functional requirements outlined in the rule.

Certification

Health IT developers certify their products through a program administered by an ONC-Authorized Certification Body (ONC-ACB). The testing and evaluation process checks that the products meet thetechnical and functional requirements of the Rule and helps ensure they are interoperable.

Criteria

The ONC Cures Act Final Rule sets out essential criteria that Health IT Companies must meet to achieve compliance and obtain certification. The most far-reaching of these are §170.315(g)(10) - Standardized API for patient and population services, and §170.315(b)(10) - Electronic Health Information export.



In short

The ONC Cures Act Final Rule sets out essential criteria that Health IT Companies must meet to achieve compliance and obtain certification. The most far-reaching of these are §170.315(g)(10) - Standardized API for patient and population services, and §170.315(b)(10) - Electronic Health Information export.

§170.315(g)(10) - Standardized API for Patient and Population services

This criterion focuses on the requirement for electronic health record (EHR) systems to provide a standardized API for patients and authorized third-party applications to securely access patient health information and population-level data. Essentially this provision is the adoption of FHIR by the US healthcare industry. This, in turn, encourages the development of innovative applications and services that leverage patient data to improve healthcare outcomes.

Implementation guides

The three main implementation guides mandated within the regulation remain operational, but SVAP allows health IT developers to incorporate newer versions of standards, adopt USCDI updates, and upgrade implementation specifications. Developers who opt for SVAP must notify clients and the ONC-ACB in advance and ensure their testing plans and certified health modules use the updated standards.

SVAP is voluntary, therefore the Regulatory Standard Version remains valid for certification until future rulemaking retires a standard, such as the adoption of HTI-1 (see below). For §170.315(g)(10) these standards focus on specific FHIR IGs and any related USCDI changes.

The current and emerging standards relating to FHIR and criteria §170.315(g)(10) are:

Regulatory Standard Version	SVAP Version
1. US Core IG 3.1.1 (USCDI V1) Retired December 2025	1. US Core IG 4.0.0 (USCDI V1) Retired December 2023
2. Bulk Data Export IG 1.0.0 Retired December 2025	2. US Core IG 5.0.1 (USCDI V2) Retired December 2023
3. SMART Application Launch Framework IG 1.0.0 Retired December 2025	3. US Core IG 6.1.0 (USCDI V3)
	4. Bulk Data Export IG 2.0.0
	5. SMART Application Launch Framework IG 2.0.0

§170.315(b)(10) - Electronic Health Information export

Under section §170.315(b)(10), health IT systems must be able to export individual and multiple patient data-sets, including structured and unstructured information. This goes beyond USCDI/US Core data to encompass all data relevant to a patient's EHI record. EHI refers to electronic protected health information (ePHI) included in a designated record set as defined in 45 CFR 164.501.

The regulation does not specify an output format or export method, so vendors can implement their preferred technologies. But it does mandate that all patient data must be exportable, regardless of multi-product interactions or connected databases: if a patient's data is stored in a FHIR server and other EHR-related databases, all that data must be exportable.

> *The ONC's EHI Export Fact Sheet offers valuable insights into this aspect of the regulations.*

Implementation guides

The FHIR community recognized the importance of standardizing (b)(10) in FHIR and independently created the EHI Export API IG. Firely has adopted the output format outlined in this IG and expects it to become a regulatory standard. We will be monitoring future developments.

Data

§170.315(b)(10) is not based on USCDI, but data plays an important role since failing to export Electronic Health Information (EHI) can hinder compliance with Information Blocking rules. The ruling provides a clear definition of EHI, and supporting documents such as *'Understanding EHI'* help to ensure that all of a patient's records are included in the export.

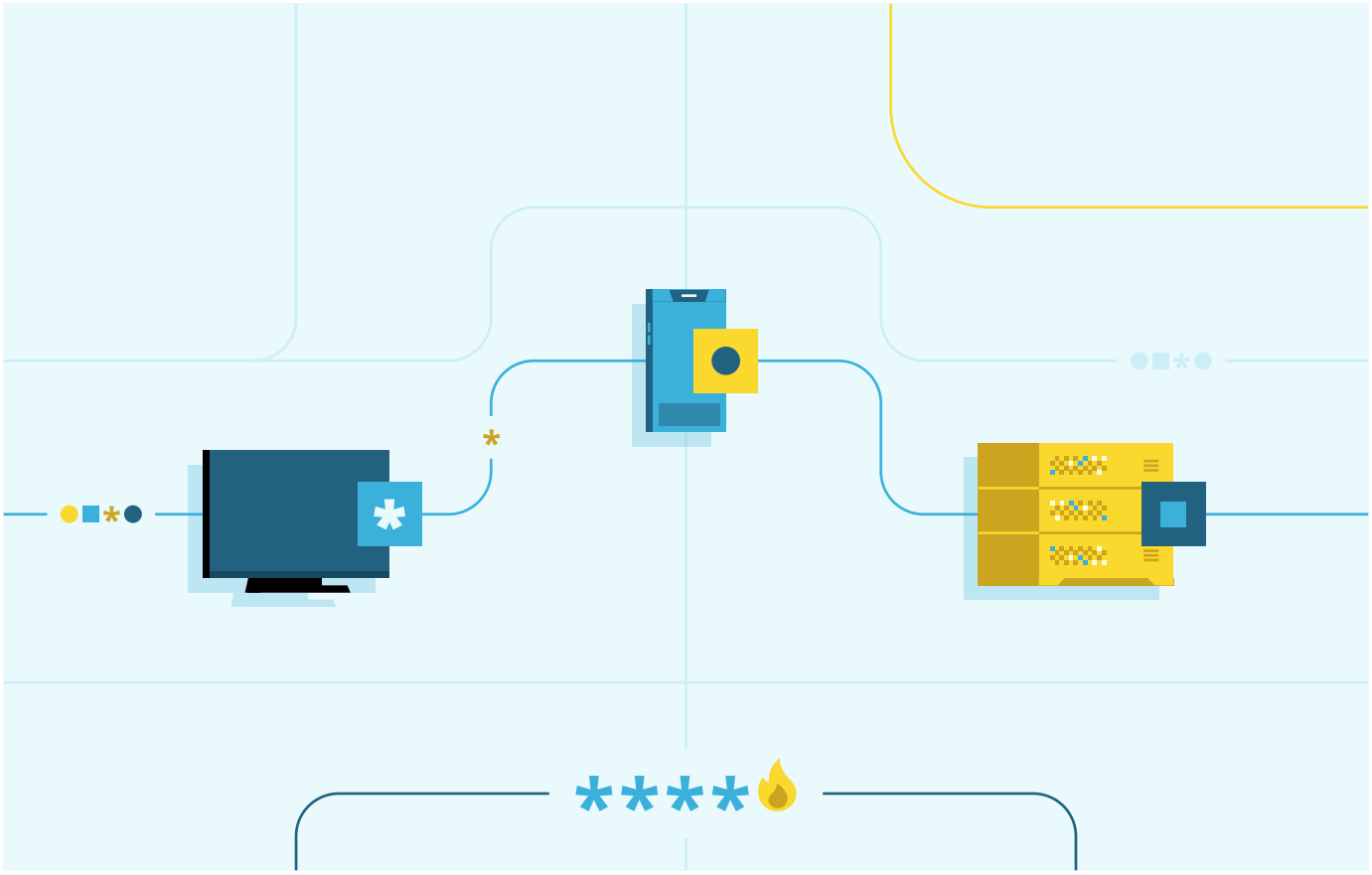
Metric Collection

As part of the Conditions of Maintenance requirements, metrics must be collected on the usage of FHIR APIs by the certified vendor. This is known as Real World Testing (RWT) and is a mandatory aspect of Certification. It requires demonstrating interoperability and functionality in real-world production settings, not just in controlled test environments. Certified developers must submit detailed plans outlining how they will conduct Real World Testing to ensure their certified health IT products continue to perform as intended, measuring observations of interoperability and data exchange.

Other Criteria

As part of the base ONC HealthIT certification requirements, HealthTech vendors are also responsible for attesting or certifying to the following criteria:

1. §170.315(d)(1) Authentication, Access Control, Authorization
2. §170.315(d)(9) Trusted Connection
3. §170.315(d)(10) Auditing Actions on Health Information (Cures Update)
4. §170.315(d)(12) Encrypt Authentication Credentials (Cures Update)
5. §170.315(d)(13) Multi-Factor Authentication (Cures Update)
6. §170.315(g)(4) Quality Management System
7. §170.315(g)(5) Accessibility-Center Design



06.2 HTI-1 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule

HTI-1 builds upon the ONC Cures Act Final Rule, ushering in a comprehensive set of improvements. These encompass a wide range of areas, including health information transmission methods, new data standards for information flow, electronic case reporting, and enhanced algorithm transparency. Furthermore, HTI-1 extends its influence by incorporating Trusted Exchange Framework/Common Agreement (TEFCA) elements to update ONC information blocking regulations, adds additional API provisions for information security, and implements updated standards and certification criteria.

ONC's revisions to §170.315(g)(10) under HTI-1 include:

1. Adopts USCDI version 3 and US Core 6.1.0 as the baseline standard as of January 1, 2026.
   - Retires USCDI v1 and US Core 3.11/4.0.0 as of January 1, 2026.
   - Retires USCDI v2 and US Core 5.01 for SVAP as of December 31, 2023.
2. Adopts the upgraded standards for authentication, authorization, and token introspection, leveraging SMART version 2.0.0 as of December 31, 2025.
3. Clarifies that patient authorization revocation should happen within one hour of a request.
4. Standardizes the criteria regarding API Maintenance Service Base URL criteria by requiring implementations to use the FHIR "Endpoint" resource as of December 31, 2024.
5. Creates new "Insights Condition" criteria which adopts metrics for measuring FHIR server, client, and bulk data usage reportable to ONC. Data collection and reporting starts in 2026 and increments in metric complexity each year through 2029.

Metric Collection

The Cures Act mandated ONC to establish the EHR Reporting Program for transparent reporting on certified health IT in various categories including interoperability. The HTI-1 final rule introduced the Insights Condition in the Certification Program, addressing information gaps, providing insights on specific functionalities, and offering data about certified functionalities' end-user use. Some FHIR related metrics include; unique individuals who access their EHI, FHIR client application volumes, and bulk data access requests completed. Metric collection starts January 1, 2026 and increments in metric complexity each year through 2029.

For health IT developers, the Insights Condition requires reporting if they have at least 50 hospital sites or 500 individual clinician users, health IT certified to specified criteria, and users actively using the certified health IT. Those not meeting these criteria submit an attestation indicating non-qualification for reporting.

06.3 Advancing Interoperability and Improving Prior Authorization Processes Final Rule CMS-0057-F

This rule formally withdraws the December 2020 CMS Interoperability and Prior Authorization proposed rule (85 FR 82586), in the light of valuable feedback from public commenters.

Prior authorization is the administrative process that enables providers to request approval from payers to provide items or services. The final rule builds upon the technology foundation established in the May 2020 CMS Interoperability and Patient Access final rule (85 FR 25510) and has a pivotal role in increasing efficiency, reducing the burden for payers and providers, and improving patient access to health information through FHIR APIs.

There are three APIs with a set of Implementation Guides (IGs) that have interconnected relationships across them. These APIs are the Patient Access and Provider Access API, the Payer to Payer API, and the Prior Authorization Requirements, Documentation, and Decision (PARDD) API. These APIs and their associated IGs work collaboratively to facilitate data exchange and streamline processes related to patient access, provider access, payer-to-payer interactions, and prior authorization requirements. Compliance for APIs is generally listed for January 1, 2027, however some API related requirements, such as metric collecting, start as early as January 1, 2026.

Implementation guides

Within the framework of CMS-0057-F, numerous Implementation Guides (IGs) are categorized based on their relation to specific APIs. Some IGs have broader relevance across all areas, while others fall into the dependent category. It is important to refer to the final rule and SVAP for the release versions of implementation guides, as they are subject to change over time.

Base Implementation Guides

1. *The US Core Implementation Guide*
2. *The SMART on FHIR specification*, describing authorization and authentication based on OAuth2
3. The *Bulk Data IG* for asynchronous downloads of large amounts of data

API-Specific Implementation Guides

a *Patient Access*

- *CARIN for Blue Button* enhances US Core with additional resources and profile constraints to exchange payer and pharmacy claims data.
- *PDex Payer-to-Payer Exchange* IG describes how plans/payers can exchange the clinical information (USCDI) of a single member.
- *PDex US Drug Formulary* describes medications and plan coverage, including a patient's existing meds.

b *Provider Access API & Payer to Payer API*

- *CARIN for Blue Button*
- *PDex Payer-to-Payer Exchange*
- *SMART App Launch IS* specifically addes to support backend communication services.
- *SMART App Launch IG* was specifically added to support backend communication services.

c *Prior Authorization Requirements, Documentation and Decision (PARDD) API*

- *Da Vinci Coverage Requirements Discovery (CRD)* describes the workflow to allow payers to provide coverage requirements information through healthcare provider systems when treatment decisions are being made.
- *Da Vinci Documentation Templates and Rules (DTR)* specifies the documentation payers use to process authorization requests and claims submissions.
- *Da Vinci Prior Authorization Support (PAS)* describes direct submission of prior authorization requests from EHR systems using FHIR, and conversion between X12 and FHIR – collecting information from CRD and DTR and submitting it to payers.

d *Provider Directory API*

- *Da Vinci Payer Data Exchange–Plan Net* provides a standard approach for requesting and receiving provider information based on a patient's insurance plan. It uses a subset of profiles from the *VHDir implementation guide.*

Dependent Implementation Guides

(Referenced in other IGs)

1. *Da Vinci Health Record Exchange (HRex)* is a use-case independent meta-IG for Da Vinci IGs. It contains the definition for the member-match operation used in PDEX and other IGs to help match patients across health plans.

2. *Subscriptions R5 Backport* is used in PAS to help monitor the status of a claim if additional data points are needed to complete the decision process.

3. The *Structured Data Capture (SDC)* IG is a mechanism for capturing data consistently using the Questionnaire resource for forms and the QuestionnaireResponse resource for completed forms. CQL can be used in a Questionaire to support Prior Auth processes. It also provides guidance and technology to determine how forms are displayed.

4. *Clinical Decision Support Hooks (CDS Hooks)* provide a technology standard and framework for integrating clinical decision support systems with electronic health record (EHR) systems and enabling real-time, context-sensitive interventions.

5. *The Da Vinci Clinical Data Exchange (CDEX)* facilitates the exchange of unstructured and FHIR resources. Although not mandated by CMS, CDEX is referenced in HL7 workflow guidelines for the Patient Access API and Prior Authorization API. CMS does not impose restrictions or endorsements in the final rule but acknowledges that it may consider CDEX for future rulemaking as the CDEX IG evolves.

Metric Collection

CMS has built upon the previously mentioned Real World Testing and HTI-1 Insights Conditions ideas to specify that metric collection and reporting are required for each of the APIs starting as early as January, 1 2026. This means that in some cases, such as Prior Authorization, metric collection will be required even before the FHIR APIs are fully deployed to production.

06.4 Advancing to Digital Quality Measurement and the use of FHIR in Quality Programs

The CMS Digital Quality Measures (dQMs) initiative aims to use FHIR to transition to a fully digital and standards-based approach that will enhance quality measurement while providing a framework for integrating other CMS programs reliant on quality measures. The new methodology will promote interoperability and uniformity by replacing electronic clinical quality measures (eCQMs) with a FHIR-based representation of the same measures. It has already been incorporated for feedback through rulemaking in three key Medicare payment systems, with proposed incorporation in 2025:

Hospital Quality Programs
Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System

Physician Quality Programs
Physician Fee Schedule

Implementation guides

1. *Digital Quality Measures,* HEDIS, and the related *CQF Measure IG* define the measurement specifications, related implementation guides, workflows, use-cases, technologies such as CQL, and terminology.

2. *Da Vinci Data Exchange for Quality Measures (DEQM)* describes procedures for value-based care data exchange.

3. *Quality Improvement Core (QI-Core)* is an extension of the US Core FHIR profiles specifically for quality measures.

Data

Digital Quality Measures require additional data elements, over and above the foundational elements included in USCDI. The USCDI+ Quality initiative focuses on identifying priority data needs for quality measurement while staying aligned with data standards and priorities. The FHIR representation of USCDI+ Quality is the QI-Core Implementation Guide.

Technology

Clinical Quality Language (CQL) is the foundational language for Quality Measures.

07 What's Next?

There's a lot happening in the world of US healthcare regulations, with some elements mandated and other protocols awaiting final resolution. Simply monitoring the situation can take a serious amount of time: time that could be better spent developing and refining your products and services. And yet, you can't afford not to be prepared for compliance.

Navigating the ever-evolving landscape of US healthcare regulations is a time-consuming endeavor. Time that, let's face it, could be put to much better use, like building innovative products and services.
Yet, staying compliant is a priority and non-negotiable.

So, how can you strike a balance to ensure your HealthTech venture remains future proof? Imagine having a dedicated resource track regulatory developments for you; enabling you to discern their relevance for your specific situation. Consider the dilemma of choosing between adopting an out-of-the-box solution such as Firely Server or embarking on your own development path. To help address these challenges, we offer you our *Buy vs Build Guide and calculator* to help you make informed decisions about your HealthTech journey.

08 About Firely

Firely provides all the software, training, and expertise to bring FHIR to life.

We are one of the initiators of FHIR. The Firely team has been involved in FHIR since the beginning and is continuously contributing to the standard. Our 100% FHIR-based solutions enable compliance and innovation in one go. Our flagship products are Firely Server, Simplifier.net, and the open-source .NET SDK. Our software powers FHIR APIs and systems around the world. Governments, hospitals, payers, and HealthTech companies rely on our solutions for their FHIR capabilities.

Besides software products, we offer training and consulting services to support our customers with their FHIR implementation. We play a prominent role in the FHIR Community and are the driving force behind FHIR DevDays, the world's foremost FHIR event.

09 Get in touch

More information on our solutions, services, and education can be found on our *website*. We welcome your feedback on everything we do, and our experts are ready and willing to help. Please send your comments and questions to *info@fire.ly* or via our *contact page*.

Thanks for reading!

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