

# No Escaping FHIR: New ONC Regulations Mandate FHIR for EHRs and Create Opportunities for Growth

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Electronic Medical Record

Administration Information

Medical Information

Name

ID Card/Passport

Photo

Gender

Address

Date of Birth

e-mail

Marital

Occupation



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## Summary

To facilitate patient access and streamline the exchange of clinical and related data between disparate healthcare stakeholders, the ONC requires that Providers implement HL7<sup>®</sup> Fast Healthcare Interoperability Resources (FHIR<sup>®</sup>) APIs by December 31, 2022

The new FHIR mandates are included in the Final Rule § 170.315(*g*)(10), commonly referred to as *g*(10). Additional mandates—including the *Consolidated Appropriations Act 2021* (CAA) and the CMS Hospital Price Transparency Rule—are intended to accelerate adoption of FHIR and increase interoperability through pending legislation. Similar mandates on Payers, most notably the CMS Interoperability and Patient Access API “Final” and “Proposed” Rules, and Burden Reduction are designed and enforced in lockstep with *g*(10) with the overall goal to significantly reduce the administrative burden on Providers.

While *g*(10) requires EHR vendors to implement FHIR by year end, savvy EHR vendors can leverage FHIR’s myriad features to create competitive advantage. ONC and CMS have legislation on the books which will see FHIR-based Prior Authorization mandated under the aptly named “Burden Reduction” as the CAQH estimates this will save the average doctor \$66,000 per year. Other short-term mandates designed to bring about system efficiencies include price transparency via Good Faith Estimates, quality measures, risk adjustments, etc.

## Introduction: New Legislation Adds Significant Requirements for EHR Vendors

The healthcare industry is plagued by siloed data that obstructs communications and collaboration. Limited interoperability inhibits sharing of patient information, which hinders care and results in inefficient workflows, particularly burdensome for Prior Authorizations (PA), a leading cause of Provider frustration and burnout<sup>1</sup>. Furthermore, without access to our data, we as patients cannot make informed decisions and consequently remain passive participants in our healthcare journeys.

Electronic Health Records (EHRs) are intended to help the healthcare industry with digital transformation, to better protect and share patient information more easily, eliminate the need for paper records and ultimately improve the quality of patient care. The hope was EHRs would also solve the problems listed above. While they delivered on many promises, such as digital orders and clinical decision support, their full potential cannot be achieved without interoperability. All too often, patient information stays isolated within various health systems unable to be shared with any other organizations.

Greater health systems interoperability has been a siren call seemingly forever. Past efforts were stymied principally for three reasons: limited adoption of EHRs, little to no business incentive for Providers and competing/no *de facto* interoperability standards.

While deadlines addressing these are quickly approaching, many Providers and vendors are unaware of the new requirements and what methods they should use to achieve compliance. This paper explores how the impending mandates are designed to catalyze interoperability in the Provider space via carrots and sticks, respectively.

Electronic Health Records (EHRs) are intended to help the healthcare industry with digital transformation, to better protect and share patient information more easily, eliminate the need for paper records and ultimately improve the quality of patient care.

The paper also delves into other mechanisms regulators are introducing to further drive ubiquitous adoption of FHIR, including but not limited to transparent pricing, data blocking fines, common digital quality measures designed to recognize efficiency and consistency and burden reduction. Finally, it will examine how EHR vendors can position themselves for strategic advantage by enabling customer compliance through the provision of interoperability standards via a certified FHIR solution.

## Interoperability Mandates and Compliance through FHIR

Fast Healthcare Interoperability Resources (FHIR) is a standard plus myriad supporting tools for enabling efficient and reliable healthcare data exchange between disparate networks, servers, vendors and healthcare stakeholders. Recent legislations and final rules released by the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare and Medicaid Services (CMS) promote advancements to how healthcare information is shared between patients, Payers, Providers and the EHR vendors that support them. These regulations either require or are enhanced by the use of the FHIR standard.

In this paper, the focus is on the prominent new regulations - described in detail below:

- Final Rule § 170.315(g)(10) for enhanced interoperability - “g(10)”
- CMS Prior Authorization Rule - “Burden Reduction”
- The Consolidated Appropriation Act, 2021 - “CAA”
- CMS Hospital Price Transparency Rule
- Star Ratings and digital quality measures - “MIPS”

These mandates are intended to relieve administrative burdens on Providers while also increasing price transparency and accessibility to information for patients, their circle of care and the wider healthcare community. EHR vendors have a unique opportunity to increase customer retention and growth through the implementation of FHIR that can help their customers achieve compliance while simultaneously recognizing strategic value.

FHIR is a robust and rapidly expanding and evolving suite of tools.

At its core, FHIR is a data interoperability standard that includes the following features:

- Opinionated hierarchical schemas
- Terminology services with supporting operations
- Data access controls including protocols for security, authentication, authorization, SMART on FHIR applications, consent, data provenance, a powerful RESTful API protocol that’s a 4GL unto itself
- A bevy of additional tools such as CQL, CDS Hooks, FHIRPath, Implementation Guides, subscriptions, numerous RPC like operations including the ability to author custom operations etc. that will be discussed later in the paper.

For anyone who’s new to the world of FHIR, this can seem daunting. It is our intention to demystify much of this in the following pages.

### Interoperability

Historically, it has been difficult for healthcare systems and facilities to share patient information with external entities. It can be a cumbersome ordeal even within the same EHR system, resulting in reliance on outdated communication channels like faxes and EDI to share important information. Slow and incomplete/low-trust processes are particularly problematic in secondary care and emergency situations, when care teams are often tasked with providing treatment without reliable knowledge of patient medications, allergies, relevant history, previous diagnosis etc.

Having access to complete and trustworthy patient data is essential to delivering quality care and support for both Providers and Payers. Software systems and connected devices can elevate the quality of care, but require reliable and practical interoperability to enable the sending and receiving of patient information.

The ONC has finalized rule § 170.315(g)(10), commonly referred to as *g(10)*, which implements the interoperability provision of the *21<sup>st</sup> Century Cures Act*.<sup>2,3</sup> With enforcement beginning December 27, 2022, *g(10)* facilitates a near real-time data exchange between (initially) Providers, health plans and patients. Yes, you read that correctly; *g(10)* mandates that “the patient has the right to access their data”, which is recognized through significant “data blocking” fines.

The United States Core Data for Interoperability (USCDI) Implementation Guide (IG) will become the new standard in March 2022. Healthcare providers are expected to attest to *g(10)* compliance as of January 27, 2023. Health IT vendors who support Providers will need to update their systems to provide FHIR capabilities including USCDI by the close of calendar year 2022.

Conditions and maintenance of compliance certification include criteria in the following categories: <sup>4</sup>

- **Information blocking** - According to the definition used in 42 U.S. Code § 300jj-52, health IT developers cannot “interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information.”<sup>5</sup>
- **Assurances** - Health IT vendors must certify any product which stores electronic clinical information and ensure the unrestricted implementation of certification criteria.
- **Communications** - A health IT developer may not prohibit or restrict communication regarding its product’s usability, security, and interoperability.
- **APIs** - The scope is limited to USCDI. It must have a read-only focus and employ HL7 FHIR Release 4.0.1 as the base standard to support single-patient and population services.

- **Testing** - Interoperability capabilities must be tested in the types of settings for which they will be marketed.
- **Attestations** - Certified health IT developers must make biannual attestations of compliance with a 30-day window for submissions.
- **EHR Reporting** - These criteria are still being determined. Monitor the ONC website for details.

**Compliance is inheritable.** An EHR vendor can gain compliance through the implementation of FHIR capabilities, and that compliance is then transferable to EHR customers.

Compliance is inheritable. An EHR vendor can gain compliance through the implementation of FHIR capabilities, and that compliance is then transferable to EHR customers. Providers will link to their EHR vendor within their annual submission for certification renewal and EHRs can do the same, tracing their inheritable compliance to a FHIR vendor. While the *g(10)* requires EHR vendors to implement FHIR by year end, savvy EHR vendors can leverage FHIR’s numerous features to recognize immediate benefits, while charting a course aligned to both forthcoming regulations and providing their Provider customers with new and exciting capabilities to reduce burnout and enhance patient care.

### FHIR for Interoperability

FHIR can help organizations achieve compliance and elevate patient care by enabling a fast, secure data exchange between various facilities, regardless of location or system affiliation. For example, if a patient is admitted to the hospital for a cardiac



event, the attending physician can view previous lab work and cardiology tests from the general practitioner and specialty clinics.

Patient data can also be shared between Providers and Payers. As with the aforementioned PAs, FHIR allows clinicians to quickly access PA submission guidelines and documentation requirements without switching between various applications. The process is handled directly within the EHR platform, allowing for a cohesive workflow that can be executed at a fraction of the required time and resources. FHIR can also enable third-party access to patient information within customers' accounts while maintaining compliance with HIPAA and other federal and state data privacy requirements.

## Burden Reduction

Prior authorizations (PAs) are intended to facilitate care by pre-approving services and treatment for reimbursement before patients receive them. While this enables Payers to reduce reimbursement spending and processing costs on items and services not covered under a patient's health plan, Providers struggle with inefficient workflows that require an exorbitant amount of time and resources to complete.

Currently, PAs are one the highest costs for Providers, averaging nearly \$11 US per manual authorization and between \$2-\$4US for fully and partially electronic submissions, respectively. Estimates show that fully-electronic PA submissions could save Providers \$355 million US annually. Despite the potential cost savings, electronic submission rates are sluggish, increasing by only one percent from 2018 to 2019.<sup>6,7</sup>

The CMS has instituted the Prior Authorization Rule, intended to reduce Providers' burden in determining which items and services need prior authorization and what documentation is required to submit the request.<sup>8</sup> Payers benefit

from receiving fewer incomplete or incorrect submissions that result in denials and appeals. The Prior Authorization Rule does not change the medical necessity or documentation requirements. Instead, its purpose is to accelerate speed to care by making the process more efficient for both Providers and Payers.

Beginning January 1, 2023, the Prior Authorization Rule requires Payers to provide patients with a clear understanding of the PA process and its impact on their care by sharing information about pending and active authorization decisions.

However, the rate of adoption will likely rise in the coming years. Beginning January 1, 2023, the Prior Authorization Rule requires Payers to provide patients with a clear understanding of the PA process and its impact on their care by sharing information about pending and active authorization decisions. Payers must verify that third-party applications adhere to specific privacy policy provisions and submit quarterly metrics reports to determine the API's impact on patients.

## FHIR for Prior Authorizations

The mandates included in the Prior Authorization Rule, along with the cost-saving incentives of fully-electronic submissions, are likely to direct Providers toward enhanced interoperability through FHIR. In fact, the Prior Authorization Rule explicitly encourages organizations to implement FHIR capabilities to achieve compliance. In doing so, Providers gain quick access to PA submission requirements for Medicare fee-for-service (FFS). Payers can address Medicare claim issues sooner and provide assurances of payment for items

and services that receive provisional affirmation decisions. This rule also encourages Payers to implement and maintain a FHIR-based prior authorization Documentation and Requirement Lookup Service (DRLS) API that can be integrated within a Provider's EHR workflow while maintaining HIPAA standards.

### Price Transparency

Rising costs in healthcare combined with the general lack of price transparency have caused crippling surprise medical bills for patients in the US. Surprise bills arise when patients receive care from an out-of-network (OON), non-participating Provider or facility and are, therefore, responsible for paying the OON rates. Medical bills, including unforeseen costs, have become one of the leading reasons for financial bankruptcy, an issue that has caught the attention of lawmakers on both sides of the aisle.<sup>9,10</sup>

To address these issues and protect patients from surprise bills, legislators enacted several new rules and legislation to promote price transparency in healthcare, each with its own caveats and requirements. Two that are relevant to this paper include:

- *The No Surprises Act* (Title I of the *Consolidated Appropriations Act, 2021*); and
- The CMS Hospital Price Transparency Rule

These mandates are intended to provide comprehensive federal guidance, replacing a patchwork of inconsistent state laws that were not enforceable nationwide.

#### [The Consolidated Appropriations Act, 2021](#)

The *Consolidated Appropriations Act of 2021* (CAA), signed into law on December 27, 2020, is a massive omnibus spending bill (\$2.3 trillion US) that touches upon a wide variety of sectors, including healthcare.<sup>11</sup> Title I of Division BB of the CAA, titled *The No Surprises Act* (NSA) addresses the cost of

healthcare specifically. Provisions within the NSA require actions from both Payers and Providers to be more transparent with the cost of healthcare services, as well as making this information readily available to patients in a timely manner.

#### [No Surprises Act](#)

The *No Surprises Act* establishes new protections at the federal level against surprise medical bills—including both OON cost-sharing and balance billing amounts—for individuals covered by group and individual health plans when they receive:

- emergency services
- services from out-of-network air ambulance service Providers
- non-emergency services from out-of-network Providers at in-network facilities.<sup>12</sup>

In non-emergency situations, like when a patient schedules a service, there are several provisions that require Providers and Payers to be upfront about the cost of the patient's healthcare services. The provisions that are specific to Providers include (but are not limited to):

- Section 104 - **The Notice and Consent Provision**
- Section 116 - **The Maintenance of the Provider Directory**
- Section 112 - **The Good Faith Estimate.**

For the scope of this paper, sections 104 and 116 will only be discussed briefly; the remainder of this section will be devoted to unpacking the Good Faith Estimate (GFE) due to the particular relevance of its use of the FHIR standard for sending and receiving data.

### Notice and Consent Documents

If a patient chooses to have healthcare services provided by an OON facility or Provider, the Provider must submit a Notice of Consent



document stating that the patient agreed to pay the OON cost. However, Notice and Consent documents may not be used for emergency and ancillary services or care delivered during an urgent medical need arising from a procedure for which a Notice and Consent form was received.

### Maintenance of the Provider Directory

Providers are responsible for maintaining the Provider Directory by ensuring that they have processes to notify the group health plan when the Provider:

- begins a network agreement with a health plan
- terminates their contract with a health plan or
- makes any material changes to their contract.

### Good Faith Estimate

In non-emergency situations, Providers must inquire if the patient has group health insurance they want to use before providing services to a patient. If the patient is uninsured or chooses to pay for the services out of pocket, the Provider must submit a Good Faith Estimate (GFE)—a well-educated cost approximation of each service—directly to the patient.

However, if the patient is insured and chooses to use their group health plan coverage for the services, the Provider must directly submit a GFE to the insurer. If the service is scheduled for less than 10 business days, the Provider has one day to create and send the GFE. If the service is scheduled for more than 10 business days from that time, the Provider has three business days to create and submit a GFE to the patient's group health plan.

In a situation, such as a complex surgery, where the patient has multiple Providers involved in their care, the physician who schedules the service (the "convening Provider") is responsible for gathering the GFE's from each physician and sending them as a bundle to the Payer.

### CMS Hospital Price Transparency Final Rule

As of January 1, 2021, hospitals are required to maintain an annually-updated, public list of standard charges for their items and services, including descriptions and applicable codes for each.<sup>13</sup>

These lists must be made available free of charge, without requiring any Personally-Identifying Information (PII), and using two specified formats:

1. single machine-readable file (e.g., .XML, .JSON, .CSV)
2. A printable list of standard charges for a limited set of "shoppable services," including 70 CMS-specified services and 230 selected by each hospital.

According to this rule, all standard charges included in the lists are defined as follows:

- **A Gross charge** is the price for an individual item or service before any discounts.
- **Discounted cash price** is the cost for individuals who pay cash (or cash equivalent) for an item or service.
- **Payer-specific negotiated charges** are the prices a hospital negotiates with a third-party Payer.
- **De-identified minimum and maximum negotiated charges** are the lowest and highest price a hospital has agreed to with any third-party Payer for an item or service.

### FHIR for Price Transparency

FHIR allows for accurate, individualized costs for a patient's healthcare, and enables both Payers and Providers to comply with the various mandates intended to help patients avoid surprise bills and the potential for subsequent financial tribulations. While FHIR is beneficial for many of the regulations that fall under Price Transparency, it is instrumental, if not a necessity, for complying with the sending

and receiving of GFEs (as well as Advanced Explanation of Benefits). In these situations, FHIR can access the correct pricing information quickly to expedite the completion of a GFE and submit it to the Payer within the time window of one or three days. The Payer can also quickly receive and process the GFE and deliver the AEOB to patients within the time allotted. Additionally, Provider directories can be easily shared with Payers, who can quickly access any necessary data or make changes as needed.

## Quality Assessments

Many patients in need of receiving in-patient care struggle to make informed decisions on which facility would be best for them. With limited information on the quality of care offered, or the previous experiences others had with a particular Provider or facility, patients and their families have very little on which to base their decisions. Standardized assessment tools are necessary to fill the informational void and help consumers choose the right Providers and facilities capable of meeting their care needs. The assessments described below include interoperability and communication as substantial components of the rating criteria.

### Merit-Based Incentive Payment System (MIPS)

MIPS helps determine Medicare reimbursements adjustments by using a 100-point scale to grade Providers' Composite Performance Score (CPS), with higher scores resulting in larger payments and penalties issued for organizations scoring below 45. Those that achieve scores of 85 or higher can increase their Medicare reimbursements by up to nine percent.

The criteria for organizational performance is split into four categories:

- Quality (40%)
- Promoting Interoperability (25%)

- Improvement Activities (15%)
- Cost (20%)

Weighted as one quarter of the total score, interoperability is a crucial component of the MIPS assessment. It has the potential to help organizations receive increased Medicare reimbursements or avoid financial penalties.

### Five-Star Quality Rating System

Similar to MIPS, the Five-Star Quality Rating System is a CMS tool designed to help consumers compare and select skilled nursing care centers. It relies on a variety of data from Health Care Surveys, Quality Measures and Staffing. Interoperability is included in this data as an indicator of an organization's communication and care coordination and has a direct effect on the CMS star rating. Users are empowered to use the ratings to make informed healthcare decisions with helpful resources and information about specific Providers and facilities.

Originally intended to serve only consumers, the star ratings' relevance has expanded to state regulators, insurers, lenders and investors. This elevates the influence ratings have over public perception of a care facility and can substantially impact its reputation in the marketplace.

### National Impact Assessment of CMS Quality Measures

The CMS National Impact Assessment is an annual report that categorizes 153 quality measures into 62 key indicators, specifically detailing the gap in interoperability across many facets of the US healthcare system including acute care, long-term care, accountable care organizations and managed care.<sup>14</sup> It is worth noting that interoperability is directly associated with Communication and Care Coordination, which is one of the six healthcare priorities established by CMS and used for this report.

These priorities are:

- Patient Safety
- Person and Family Engagement
- Communication and Care Coordination
- Effective Prevention and Treatment
- Working with Communities
- Affordable Care.

### FHIR for Quality Assessments

When FHIR capabilities are implemented within EHR platforms, Providers gain almost immediate access to patient data, regardless of facility location, health plan, network affiliation or the location of previous Providers. This interoperability is necessary for facilities to accelerate clinical communication and elevate the quality of care throughout the care continuum, thereby potentially raising scores on various assessments and increasing Medicare reimbursement percentages. By facilitating these capabilities and helping Providers increase revenue, EHR platforms create an opportunity for business development and growth through customer retention and acquisition.

## Conclusion

Despite the issues around poor communication and insufficient data sharing that has plagued the healthcare industry, US Payers and Providers are turning the corner on delivering on the promise of interoperability driven by need and through legislation of the FHIR standard. Interoperability, Burden Reduction, Price Transparency and quality ratings are opportunities (in addition to regulations) to access and share information in a way that brings sustained improvements to quality care and efficient organizational operations. Long-standing problems drive costs upward for all stakeholders, including patients, and have inspired reform from constituents and policymakers across the political spectrum.

The ONC *g(10)* rule recognizes the interoperability provision of the *21<sup>st</sup> Century Cures Act*, facilitating a near real-time data exchange between Providers, health plans, health IT vendors and patients. By standardizing information sharing with mandates that specify FHIR, care is administered with increased knowledge of a patient's medical history, allowing for improved patient outcomes and automation of historically burdensome tasks. Similarly, third-party connected apps are enabled to contribute toward the quality of patient care and practice management.

FHIR also enables the processes and tools required to comply with new and pending mandates for BR. Almost all of the manual and tedious efforts associated with prior authorizations are automated through Burden Reduction. Providers will rejoice in outsourcing their PA requirements to automation.

Pulling information into various quality assessments and submitting to the appropriate agencies is automated with FHIR.

By standardizing information sharing with mandates that specify FHIR, care is administered with increased knowledge of a patient's medical history, allowing for improved patient outcomes and automation of historically burdensome tasks.

## Implementing with a Certified FHIR-Based Platform

As we come out of the COVID-19 pandemic, many providers will discover of late the looming new *g(10)* regulations. Certified FHIR-based platforms, like Smile Digital Health, provide immediate compliance with proven rapid ROI, particularly when maintenance and forthcoming regulations are weighed against short-term/custom approaches. EHR vendors can offer inheritable compliance at a fraction of the time and cost of alternative approaches.

Smile Digital Health is an enterprise FHIR platform and Data Fabric that extends on our open-source code in HAPI-FHIR with a myriad of additional capabilities. FHIR, and particularly Smile Digital Health recognize the clinical and administrative objectives of Providers in the 21<sup>st</sup> Century.

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Learn more about how implementing interoperability with Smile Digital Health can reduce the time and resources required for EHR vendors to capitalize on the opportunities presented by the impending regulations and gain a competitive advantage in the marketplace. [Contact us](#) or [request a demonstration](#).

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