

2021 White Paper Setting Healthcare on FHIR

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Abstract

Trailing behind other industries, U.S. healthcare struggles with data sharing and interoperability. Exacerbated by the glacial pace of change, the result is a system that is at best, confusing to navigate, and at worst, deterring patients from receiving quality care.

With a long history of healthcare legislation and industry attempts at data sharing, in 2015, the government stepped in to address the problem. The 21st Century Cures Act was enacted to accelerate interoperability and promote data sharing. To do so, the Cures Act calls for uniformed use of FHIR (the Fast Healthcare Interoperability Resources). FHIR enables the industry to exchange more data and unstructured data and makes the implementation process more accessible, agile, and intuitive.

As FHIR continues to expand, it's expected to eventually impact all stakeholders in the U.S. healthcare industry. However, the brunt of the impact currently falls on payers with three distinct APIs: Patient Access API, Provider Directory API, and Payer-to-Payer API. While the future of FHIR is still being determined, it is certain that FHIR will play a pivotal role in the future of healthcare.

Introduction

In 1972, a group of banks in California sought a replacement for check-based payments with a mechanism to allow participating financial institutions to freely exchange customer information to transact banking business. Their work spawned the Automated Clearing House (ACH) technology which introduced a new level of financial interoperability that is the basis for how geographically distributed automated teller machines (ATMs) form a network to dispense cash to customers who have accounts located in different banks. This new technology provided access and convenience by breaking the bond between the customer and the local branch of their bank, an experience we all continue to enjoy today. This technology was introduced and adopted nearly 50 years ago.

The Problem: Why Healthcare Trails Behind

Today, the U.S. healthcare industry (and virtually all healthcare sectors around the world) trails in terms of data sharing and interoperability. The convenience that is now commonplace in the banking industry is foreign in healthcare and creates a web of impossible coordination when care settings expand beyond the confines of a hospital or integrated delivery network (IDN). Patients today find themselves in the middle of an intricate maze of caregivers, tests, results, documents, and care instructions that are nearly impossible to decipher, resulting in poor care management and a dreadful patient experience.

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Exacerbating this problem is the glacial pace of change in healthcare, driven by a variety of factors. Primarily, patients over the years have developed a fear (rational or irrational) of discrimination over chronic or existing conditions – or worse yet, a breach of this information resulting in perceived catastrophic consequences that limit their options, prohibit employment, mask insurability, or increase costs of healthcare premiums due to risks associated with their care. Second to this, the U.S. healthcare industry (until recent years) was largely paper-based, where paper-laden charts continued to dominate the documentation of patient care. EHRs (Electronic Health Records) were still in their infancy with adoption following the same glacial pace we had seen for years. Unfortunately, as health IT vendors gained traction and their data platforms evolved, they did so with an inward focus that contemplated the need to document the patient's experience within a single setting of care, that being the four walls of the hospital, often ignoring portability or the need to extend patient care to multiple care settings where a variety of health IT systems were in play.

Since then, these same health IT vendors have maintained this inward, nonsharable focus. And, they have amassed significant repositories of patient data and have treated this data as if it were their own, often developing systems and solutions that prohibit the free exchange of patient data. In many cases, health IT vendors have attempted to monetize access to this data under the banner of data and analytics or scorecards designed to improve clinical and operational performance. But because of this, the promise of portability and the convenience of technology advancements seen in other industries (e.g., the banking industry) have remained elusive in healthcare.

Bipartisan Legislation Advances the Industry

Left on its own, the U.S. healthcare industry has created an impossible web of non-shareable data, complex care pathways that often require geographically diverse care settings, and an intricate set of health IT solutions that are walled off from one another. If change in healthcare was going to happen, it was apparent it was not going to evolve on its own. So, in 2009, operating under the implication of eventual sharing of PHI (protected health information), the U.S. government introduced the Meaningful Use program as a part of the 2009 HITECH (Health Information Technology for Economic and Clinical Health) Act. Building on HIPAA (the Health Insurance Portability and Accountability Act of 1996), this act encouraged healthcare providers to acquire, implement, and demonstrate "meaningful use" of certified EHR technology to qualify for reimbursement through an economic stimulus. The program drove significant adoption of certified health IT, accomplishing nearly 97% adoption across care settings. However, the program did very little to promote the open exchange of EHI, leaving care isolated within care settings and systems, while perpetuating the problem for the patient at the center of the puzzle. This issue has remained for the past 20 years and has limited care coordination, complicated administration, and has limited favorable outcomes for patients.

In 2015, the U.S. federal government, under the direction of the ONC (Office of the National Coordinator), published a NPRM (Notice of Proposed Rule Making) under the banner of the 21st Century Cures Act (Cures Act). Following a comment period and numerous negotiations both in the House and the Senate, the Cures Act moved even closer to becoming law. Then, late in 2016, in the

closing days of his presidency, President Barack Obama signed the Cures Act into law, setting the pace for a host of impactful regulations aimed at promoting interoperability in healthcare.

As one of the greatest demonstrations of bipartisan legislation in modern times, the new administration under President Donald Trump picked up where the Obama administration left off and pushed the Cures Act to final rule. And, in May of 2020, the Cures Act was entered into the Federal Register and became the law of the land with definitions and compliance dates for information blocking as well as interoperability. This new legislation was designed to start an evolutionary process in the U.S. healthcare industry aimed at the free exchange of EHI (electronic health information) to provide better access, visibility, and coordination of health focused on the consumer/patient, and wellness. With this legislation, many agree the U.S. healthcare industry is at the beginning of a monumental change that will impact how patient information is shared across systems and settings of care.

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Fast Healthcare Interoperability Resources - FHIR

Healthcare's Previous Attempts at Data Sharing

Healthcare standards are certainly not new and span a 25-year history across many facets of the healthcare domain, arguably starting in 1996 with the passage of HIPAA. During this time, our industry has seen many attempts to create standards for the sharing of data in healthcare, all with varying levels of success and adoption. For example, one of the most successful was DICOM (Digital Imaging and Communications in Medicine) in medical imaging. It has become the standard structure for medical imaging because of its standardized patient-data-header and common imaging file format. DICOM promoted the free exchange of medical images regardless of modality, greatly improving the ability to share information between radiologists and the ability to transmit, store, retrieve, print, process and display medical images. In many ways, DICOM paved the way for future conversations on healthcare interoperability and proved that standards, if properly shared, implemented, and followed can have incredible impacts on data sharing and interoperability.

Other standards operate in contrast and have not achieved such widespread adoption and use. An example is the HIE (Health Information Exchange), which has seen its share of headwinds and is far less of an adopted standard. This is largely attributed to limited participation within the provider community (presumably attributed to the lack of a mandate), minimizing the effectiveness and value of the standard.

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HL7 & Health Information Exchange Today

In recent years, however, information exchange has evolved. With the evolution of the IHE (Integrating the Healthcare Enterprise), we have seen a more pronounced adoption of standards such as HL7 (Health Level Seven) which defined a standard for health information exchange, integration, sharing, and retrieval.

First introduced in 1987, HL7 has evolved to become a cornerstone for system-to-system integration and interface, with flexibility and adaptability to serve a variety of applications and uses. This flexibility, however, has also been a limiting factor for HL7 and has led to inconsistency in adoption, application, and enforcement – introducing variability that makes HL7 less of a ubiquitous standard, in many cases.

Today, healthcare interoperability is once again evolving, largely due to governmental regulations and standards created by the ONC specifically targeting interoperability and the Cures Act. In this legislation, interoperability calls for the uniform use of FHIR (the Fast Healthcare Interoperability Resources). FHIR was introduced nearly 5 years ago by the HL7 workgroup as a draft standard focused on leveraging existing web-based development concepts (e.g., REST) with an emphasis on supporting clinical data exchange. It empowers organizations to leverage agreed-upon and consistent data elements and formats (known as resources) to build APIs (Application Programming Interfaces) to power data exchange across systems. According to the HL7 workgroup, the philosophy behind FHIR is to build a base set of resources that operate independently or in concert to satisfy a majority of common clinical use cases. FHIR resources aim to define the information content and structure for the core information set that is shared by most healthcare implementations. This information can be metadata (data about data, or demographics), text, or bundled data that together create clinical documents similar to a C-CDA (Consolidated Clinical Document Architecture).

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Why Use FHIR?

Throughout history, healthcare standards have focused primarily on the exchange of patient data in a structured format, or data that adheres more readily to a structured interface format, like HL7. FHIR is a new and evolving standard that expands a set of published resources that deliver the capability to exchange more than data and includes an ability to transmit unstructured content or documents as well. This differentiator broadens the types of information that can be shared and improves upon the applications of interoperability between systems.

FHIR also improves upon the transport mechanism and the methods for data calls. Prior to FHIR, HL7v2 relied heavily on a socket protocol-based standard. HL7v3 relied on SOAP (Simple Access Object Protocol) and the use of an XML (Extensible Markup Language) file structure. Unfortunately, both models made these interfaces difficult to understand, implement, and maintain.

As FHIR has evolved, so has the simplicity of the new transport protocol known as REST (Representational State Transfer) and JSON (JavaScript Object Notation) where interface parameters are more easily constructed and passed as non-apparent elements of URLs (Uniform Resource Locators, or web-addresses). REST APIs with FHIR are less cumbersome, more agile, and intuitive than the socket-protocol of SOAP and prior versions of HL7, which makes them easier to implement, extend, and scale. In addition, the use of REST is far more amenable to developers with experience in web development and mobile applications, skill sets that are more commonplace in today's technology industry.





FHIR Releases Include Continued Improvements

In January 2019, FHIR took a major step forward with Release 4 (R4). With a "normative" designation, R4 now provides resources that determine how to use terminologies, how to build APIs, and data formats that define how to recognize patients. This normative designation indicates that all future changes to FHIR will be backward compatible, meaning applications that implement the normative sections of R4 will stay conformant irrespective of future versions of FHIR.

HL7 has already noted that Release 5 (R5) will build upon the core tenants of R4 to expand normative content, enhance publishing implementation guidelines and improve support for apps that use multiple versions of FHIR.

HL7 Workgroups Expand APIs

In addition, several HL7 workgroups have emerged, focused on the use of FHIR and JSON and the advancement of the Cures Act APIs. These groups are focused on an evolutionary expansion of the APIs, their definitions, and their use in healthcare. The following are examples of HL7 workgroups:

- Argonaut Project focused on furthering the expansion of the Patient Access API.
- **CARIN Alliance** focused on payer data exchange.
- **CodeX** focused on data modeling for oncology.
- Da Vinci focused on value-based care.
- Gravity Project focused on SDoH.
- Vulcan Accelerator focused on clinical research
- FHIR Accelerator Confluence Space focused on the evolution of HL7

Who Must Comply with FHIR?

Arguably still in its infancy, the implications of FHIR are somewhat limited. But as an element defined in the Cures Act, FHIR is expected to expand as a standard that will eventually impact all stakeholders in the U.S. healthcare industry with its scope and application already expanding rapidly.

Today, FHIR is widely adopted and supported by the main EHR vendors who are submitting EHI to Medicare, Medicaid and on-exchange ACA health plans. Nearly all main EHR vendors have developed compliant interfaces through the use of FHIR and are sharing EHI as mandated.

The Impact on Payers

Many would suggest that stricter standards for the open sharing of patient EHI should fall on the provider community and the outward sharing of EHI by hospitals, health systems, and other providers. And, stricter standards are on their way. But with the diverse settings of care required to treat most conditions (chronic or otherwise), the commonality across the patient's journey (today) is the payer or the place where claims are aggregated from a health plan/insurability/reimbursement perspective. So, the focus of the Cures Act follows this logic pattern and directs compliance on the health plans and payers far more directly as a means to create a more comprehensive view of data reflecting a patient's journey.

Today, the payer community is wrestling with tight timelines that call for compliance with mandates for publishing outward-facing APIs that provide the free exchange of EHI to patients. Specifically, the Cures Act calls for three distinct APIs focused on three specific problems.

- 1. Patient Access API
- 2. Provider Directory API
- 3. Payer-to-Payer API





These APIs operate to expose EHI to application developers who are focused on providing patients with a customized experience for directing their healthcare.

Patient Access API

Exposes over 25 resources focused on providing detailed information about a patient, their care, and their history to enhance the ability to share information amongst providers.

Provider Directory API

Helps patients who are searching for providers who are within a local geography, have a specific specialty, and are covered under health plans.

Payer-to-Payer API

Designed to create greater portability between insurers as patients move from one health plan to another. The Cures Act calls for the data contained within these APIs to be easy to obtain and to be free of charge, greatly expanding the ability for application developers to gain access to data and improve the patient's experience in healthcare.

The Future of FHIR

However, while FHIR represents a defined standard that operates on the promise of greater capability, tighter standardization to remove variability, and a wider range of applications, it remains a relatively new standard. And, providers and payers alike are struggling to find and develop talent with knowledge and expertise with FHIR. In order for the industry to rapidly adopt this new standard, significant investments in human capital are required where knowledge, expertise, and applicability of the standards become commonplace.

How KMS Technology Embraces FHIR

At KMS, we believe that healthcare is at a pivotal point where the patient is finally the focus of regulations. Specifically, it is the patient experience and the use of EHI in a practical sense that will enhance a patient's healthcare experience. We believe this will lead to improved and more complete diagnoses, a more precise treatment plan, a shorter length of stay, improved adherence to post-discharge instructions, a reduction in hospital readmissions, improved outcomes, and a greater ability for patients to manage chronic conditions. We also believe the use of FHIR has enormous implications and greatly expands the art-of-the-possible when it comes to developing new applications in healthcare.

Our History in Healthcare

For the past twelve years, KMS-Technology has been developing applications for the healthcare industry. We specialize in the development of server-based solutions, web applications, to mobile apps designed to solve some of healthcare's most challenging problems. We have witnessed much of the evolution in healthcare interoperability and continue to do so. Our deep expertise with HL7, FHIR, and SMART on FHIR applications is leveraged daily in the development of commercially hardened solutions in the healthcare space. Our engineering team has deep training and certification in the use of FHIR. We have developed FHIR Server architectures and have expertise in Flat FHIR and big data utilizing the protocol. In addition, we have developed an internally leveraged FHIR Lab for the ongoing training, ideation, and incubation of solutions focused on the development of healthcare integrations.

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KMS-Technology is heavily invested in healthcare and the requisite knowledge-base and skill sets required to embrace this new era of change. We see the industry growing, evolving, and improving toward interoperability. We see a future with a free exchange of EHI where patients have greater control over their healthcare needs and consumption. We see a patient, informed via consumerism and transparency, who is helping to shape their path forward, working in concert with care providers, not at their mercy. We see technology as a core component of this evolution. As a result, our investments are significant and continue to grow in this space.

Ultimately, we believe we are at a defining point in history that will shape future generations in healthcare. Perhaps, 50 years from now, as we utilize the technology of the day, we will all look back on these days as the turning point in healthcare that defined an entirely new experience where data and data sharing are as commonplace as an ATM machine.

About KMS Technology

KMS Technology is a leading provider of Healthcare technology software development, quality assurance, and consulting services. Our Healthcare technology solutions ensure our customers stay ahead of evolving industry demands, regulatory compliance, and data-driven requirements.

We understand healthcare's most complex and challenging business problems and have harnessed technology to solve them. KMS provides innovative solutions to providers, payers, and the medical technology vendors who are deploying technology to create today's most innovative health solutions.



Meet the Author: Patrick Gardner



Currently serving as KMS's Senior Vice President of Healthcare, Patrick Gardner has nearly 30 years of experience working with Healthcare Technology and a long history of bringing enterprise products and solutions to market.

He leads KMS Technology's Healthcare Practice. When not serving clients, you might find him watching his son's hockey game or spending time with family on Lake Lanier.

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