smile CDR

FHIR for Payers

Achieving Sustainable Interoperability with a FHIR-based CDR

WHITE PAPER

Executive Summary

New rules from the CMS & ONC under HHS aim to get more payment and clinical data in the hands of patients when and where they need it.

Among other requirements, payers will need to share member information using open data standards, especially Fast Healthcare Interoperability Resources (FHIR).

To comply with regulatory milestones, payers operating plans under CMS authority must implement a system using FHIR based on three rules:

1. Patient Access APIs (the most technically demanding requirement)
2. Provider Directory
3. Payer-to-Payer Data Exchange

While the rules present a graduated approach to enforcement, achieving successful compliance in a timely and cost effective manner will be a challenge for most payers. Payers will face a host of largely unfamiliar challenges including:

- Patient matching: matching claims/EOB Blue Button data to correct clinical information/USCDI (including new incoming data in 2022) from multiple disparate systems. Suboptimal matching could result in a HIPAA violation or other potential associated risks.
- Authenticating users via OAuth2 and authorizing users via Open ID Connect protocols.
- Leveraging SMART on FHIR applications to manage multiple identities, define a digital- engagement competitive advantage, and anticipate future requirements.
- Consent management mechanisms to ensure only the right users view the right data to maintain patient privacy and consent.
- Data availability and scalability, including data migration options which provide alternatives for ensuring compliance with requirements that claims data be available through the Patient APIs within one (1) business day of adjudication.
- Exposing data assets to untrusted 3rd party applications.
- Mapping legacy enterprise systems which often use older (e.g. X12) and/or proprietary data models to FHIR.
- Allocating internal resources for compliance with regulations and providing ongoing business and technical maintenance to remain in compliance.

Executive Summary *continued*

Overcoming these challenges, however, can catalyze payers' strategic transformation into data- driven organizations. While compliance will be associated with upfront implementation costs, it should ultimately strengthen their competitive advantage and provide a favorable ROI. Navigated correctly, this implementation is a chance for payers to go beyond compliance and emerge with more actionable, analytics-driven insights and an enhanced ability to engage members with meaningful applications. In other words, to be better prepared for value-based care payment models and the future of healthcare delivery.

The bottom line is that payers need a solution that can match the complexity of this implementation, and an actionable plan to get production systems up and running by Q4 2020.

Key Takeaway:

Payers should be looking for FHIR solutions that address their near term requirement for compliance without compromising their ability to meet growing demands for data sharing and analysis.

By implementing an enterprise-class data platform, payers can meet CMS & ONC rules while realizing the full benefits of FHIR.

Executive Summary *continued*

In particular, this white paper recommends that payers consider the following in their implementation plans:

1. Select a robust FHIR server which both enables a flexible architectural design encapsulating the full FHIR specification in anticipation of future clarifications to/evolution of the final rules and also allows you to build out your data infrastructure vision.
    a. Consider where to implement FHIR-based data repositories versus FHIR facades, depending on what best fits your organization's architectural needs.
    b. Determine what FHIR server architecture best provides the enterprise-class performance needed for your organization and has features enabling scalability, concurrency, translations, streaming, subscription services, security, and consent management.
    c. Consider use of a FHIR repository to provide a quality assurance staging platform for strong patient matching of clinical data (USCDI) to claims data (Blue Button 2.0).
2. Anticipate growing demands from patients, providers and other payers by implementing FHIR at scale along with enterprise-class tooling such as industrial APIs and master data management.
3. Adopt tooling to accelerate implementation in areas such as mapping claims/EOB data and clinical data to FHIR.
4. Put in place the interfacing technologies between your existing systems and the new systems being implemented to meet the rules.
5. Extend the business case for compliance with the final rules by also implementing analytics and machine learning to support digital transformation initiatives and value-based care initiatives such as Healthcare Effectiveness Data and Information Set (HEDIS).
6. Consider vendor implementation experience: ask your prospective vendor if they've gone live with FHIR implementations at other payers.

Industry Challenge

Complying with these final rules raises a number of concerns for payers who need to transition from claims and administrative data to the complex world of clinical data and consent between multiple participants in the ecosystem.

CMS Interoperability and Patient Access Milestones

Public reporting Info Blocking

Providers self-assess. Those possibly info Blocking are made public. Promote patient choice.

Digital Contact Information

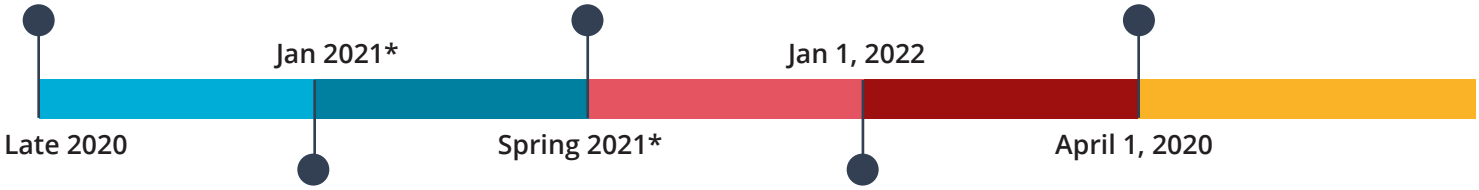
Providers update their contact infor in a national digital registry. Promote patient choice.

ADT Event Notifications

Hospitals to electronically send ADT events to downstream facility/ provider.

Dually Eligible Experience

States to exchange enrollee data for indiviuals eligible for both Medicare and Medicaid.



Patient Access API

Payers: Patients to easily access claims and encounter (clinical) data via 3rd party apps of their choice.

Provider Directory API

Payers: Make provider directory publically available to 3rd party apps.

Payer-to-Payer Data Exchange

Payers to send data to patient's request to another payer via USCDI.

*Rules call for readiness by January 2021 for Patient Access and Provider Directory APIs and Spring 2021 for ADT event notifications, with enforcement dates revised to July 2021 and Fall 2021 respectively (due to COVID19 outbreak).

No new data needs to be collected in 2021, but existing data must be converted to FHIR resources to meet the rules:

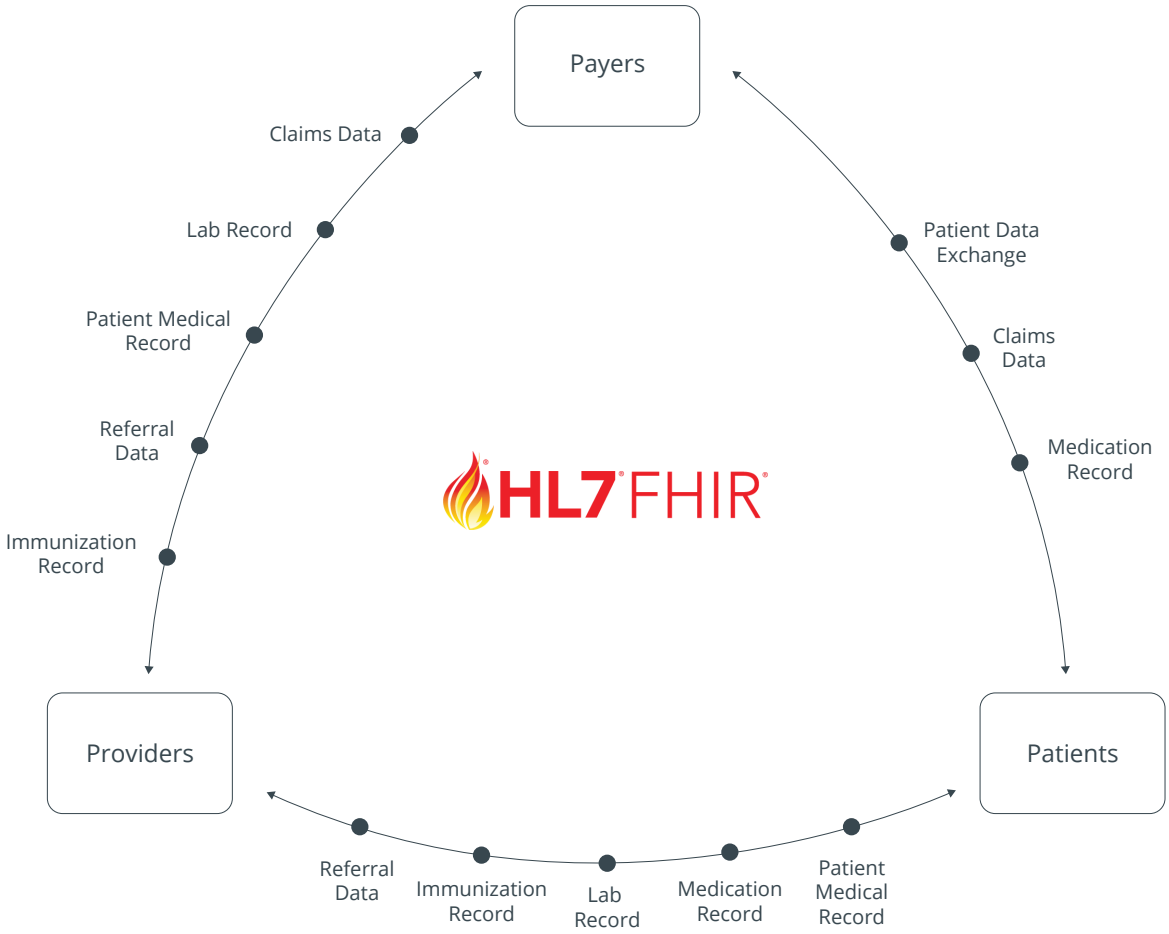
- EOB/Claims® FHIR CARIN Alliance Project Blue Button® 2.0 Spec (BB 2.0)
- Maintained Clinical Data → FHIR United States Core Data for Interoperability (USCDI)

The final rules require that payers use FHIR to deliver claims/EOB based data with the Blue Button 2.0 Patient Access API by 2021 while also capturing and delivering a full set of USCDI-defined clinical data—which is beyond that contained in most payer's systems —by 2022.

Industry Challenge *continued*

Implementing FHIR APIs is a more complex task than it may seem, given that most legacy enterprise systems use proprietary data models which will need to be mapped to FHIR. On top of that, the lack of consistency in how clinical data is made available adds yet another level of complexity to exchanging and storing this data. From the various terminologies—SNOMED, ICD, LOINC—to the different messaging standards (HL7 v 2, HL7 v3, CDA), the clinical data world is fraught with inconsistent use of standards, which ultimately led to the creation of FHIR as a standard for interoperability.

Most payers have never had the need to collect this detail of clinical data. As such, meeting the compliance requirements will necessitate rapidly introducing new technologies, products and expertise into the enterprise to manage and share this USCDI-defined clinical data with third-party FHIR consumers and producers.



There will be a need to support complex interactions between each stakeholder that go beyond the 1-1 relationships illustrated by some of the related Da Vinci use cases.

Industry Challenge *continued*

Delivering this data to patients also means exposing payer systems to the outside world via third-party SMART on FHIR applications and leveraging OAuth2 and Open ID Connect for security, authentication and authorization. This will further challenge these new systems to properly handle patient access and patient identity, along with the security and performance implications of accepting API calls from third-party applications.

Payers also need to consider the way these rules will impact their value proposition and how they will maintain their competitive edge in an environment of increasing data transparency. Increased data flows are an opportunity for payers to create differentiation by building more seamless digital customer experiences, drive improvements in care management, and control the cost of care delivery.

1. **Jan. 2021***
   a. Meet **Payer-to-Patient** information sharing requirements by providing claims data which includes the encounter data provided in Explanation of Benefits [EOBs] along with any clinical data that the payer's systems may possess.
      i. The specifications for project Blue Button Common Payer Consumer Data Set (CPCDS) provide a roadmap to help map common claims and EOB data.
      ii. If a payer has clinical data then they should provide it, which implies implementing an integrated delivery mechanism based on USCDI. Plans impacted by these rules must deliver in 2021 any customer data via FHIR using the project Blue Button 2.0 spec. and deliver via USCDI spec. any clinical data currently maintained by the payer.
      iii. Use SMART IG/OAuth 2.0 and OpenID Connect
   b. Provide FHIR-based **Provider Directories**.
      i. The rules make suggestions for compliance but set no specific architecture. Health plans must make information about their provider networks available through a Provider Directory API in a standardized format:
         1. Argonaut Provider Directory Implementation Guide
         2. Da Vinci Payer Data Exchange Implementation Guide
2. **Jan. 2022**
   a. **Payer-To-Payer Data Exchange** is the ability for patients to make sure their clinical data moves with them if they change health plans using USCDI. The rule states that the patient will have the right to request such a transfer. However, payers do not have to provide data they have not received, so many view this as an on-ramp to meeting the expected clinical data requirements of 2023. CMS has stated that more rules are pending to further clarify this requirement.
3. **April 2022** - State programs to provide daily updates on all dual eligibles activity.

**Enforcement deferred until July 2021.*

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The Opportunity

Digital transformation is underway across many industries in their efforts to stay competitive, and US payers are no exception.

According to a 2019 survey by McKinsey and Company, while payers were initially slow to digitize and lagged behind other industries in their use of artificial intelligence and automation, as well as in customer satisfaction, they're now starting to catch up.

Payers who invested in human-centric digital transformation are beginning to see value, including material changes in member satisfaction and trust, increased revenue from digital branding and improved sales tools, and double-digit reductions in administrative costs. An indicative breakdown of where they are experiencing some of these "wins" is provided below:

Typical Breakdown of Value Generated through Digital Transformation

Potential Areas of Impact	Example Capabilities
Administrative Cost Savings	• Self-service tools (member/provider) • Paperless communications • Sales support process automation
Medical Cost Savings	• Analytics-driven provider pricing • Provider contract standardization • Guided care/pharmacy selection
Revenue Growth	• Decision support tools for age-in conversions • Unified CRM solutions enabling better lead management and cross sell/up-sell

Source: McKinsey Digital Health Practice

The Opportunity *continued*

The next wave of digital innovation at payers will lean heavily on member and clinical data to inform innovation, develop new products and applications in order to drive continued growth and competitiveness. Data will provide insights to enable better operational efficiencies and reduced costs, while analytics and machine learning will lead to improved customer engagement and acquisition, increasing revenues.

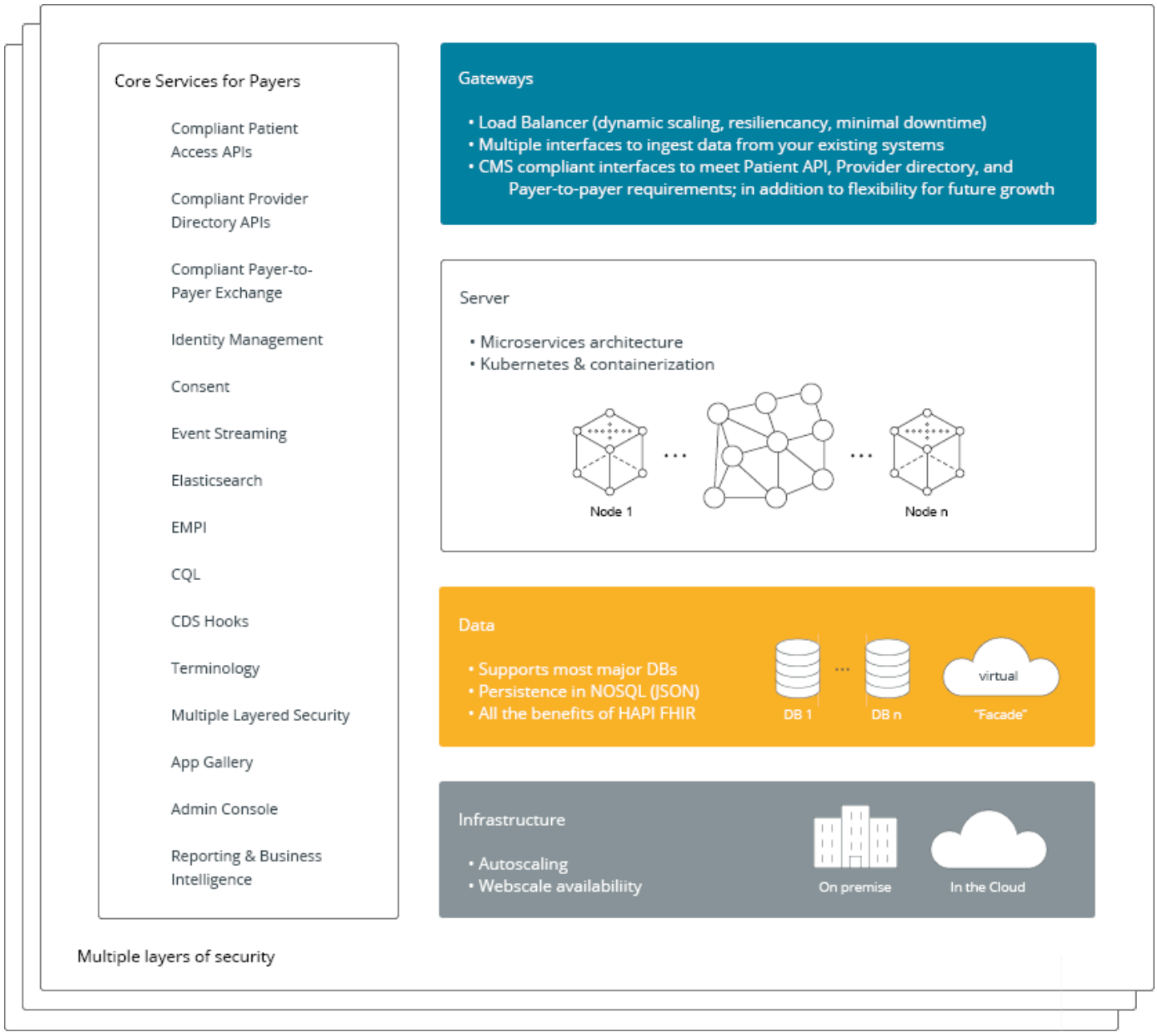
The ONC and CMS final rules provide an impetus and means for payers to gather much more member and clinical data, and thereby accelerate their digital transformation. By implementing a platform that allows data to be exchanged and consumed easily, payers have the opportunity to tap into this information flow, and spur innovation by rapidly developing new applications and microservices for their stakeholders —both internally and externally.

The choice of implementation strategies, however, will be determined by payer ambition. If the goal is restricted to complying with the final rules by making incremental changes, then payers will realize much less value from digital transformation. Forward thinking payers who commit to digital transformation will recognize the final rules as an opportunity to spur the implementation of data platforms that transform them into information factories. In turn, these platforms will become the foundation for payers to drive their next wave of digital innovation and realize the full benefits of their digital transformation journey, particularly an enhanced ability to participate in value-based care schemes.

Suggested Solution Characteristics

Payers need a secure solution that will scale and won't degrade performance. FHIR APIs allow for the construct of simple to very complex queries, returned in a consistent way.

Given that the final rules require that patients must be able to read and write their data via an "app of their choice", the architecture supporting the FHIR APIs must be designed to withstand heavy payloads and scale accordingly as more and more stakeholders are implemented.



Suggested Solution Characteristics *continued*

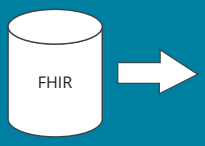
Payers need a secure solution that will scale and won't degrade performance. FHIR APIs allow for the construct of simple to very complex queries, returned in a consistent way.

A key characteristic of your FHIR platform is its ability to accommodate multiple data storage and delivery models, providing both enterprise-class FHIR repository and FHIR facade options.

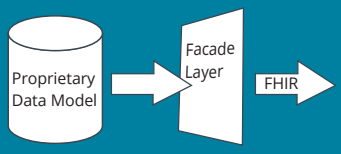
For the Patient Access API the FHIR data could reside in a new FHIR specific repository outside of the enterprise's internal firewalls, providing an important layer of additional security, filtering and mitigating the impact to existing systems. A FHIR facade could enable the data to be retrieved and translated into FHIR on-the-fly from the organization's underlying source systems.

Both models can be used in conjunction within the same application.

Regardless of which model you deploy, the right platform should be able to support all the necessary core features like subscriptions, elastic search, consent etc.



A **FHIR-based CDR** is a database that stores data as FHIR resources that align with the FHIR standard. It has the capacity to unify a rich and diverse set of Provider and Payer data as well as making the data accessible through FHIR APIs.



A **FHIR facade** uses a gateway technology that transforms the data into FHIR when requested. The data itself is stored in a database with different or often proprietary format.

Suggested Solution Characteristics *continued*

	Repository	Facade
Pros	Native FHIR repositories support most FHIR features out of the box e.g. new search parameters, includes, chaining, etc. A FHIR repository often instantly becomes a valuable enterprise asset	Leverages existing investments in SOA / microservices A single source of truth
Cons	Converting data up-front takes non-trivial effort as it has a higher threshold for "getting it right the first time" Duplicating large volumes of data has storage implications	Performance: Often times existing sources are not (and can not be) tuned for arbitrary online transactions Existing systems need to support additional performance load from third parties Can be hard to support "bare minimum" FHIR features, very difficult (possibly prohibitively so)for more advanced FHIR features Exposes corporate assets to potentially untrustworthy third party apps

In line with the digital transformation opportunity where payers gradually transform into information factories in order to leverage digital strategies to become more competitive, payers not only need to store and persist data in a reliable way, but also must facilitate the easy movement of data using data streaming strategies such as Kafka. This will enable payers to undertake strategies such as analyzing data in-stream (as data is flowing), all the way to creating data lakes for machine learning purposes.

Last but not least, payers need tools that provide integration and translation from their existing systems to operate seamlessly and accelerate implementations.

Ultimately, the challenges of meeting these requirements safely and effectively necessitates a comprehensive approach: using FHIR to provide data to the outside world on demand—especially for patients who will use the "app of their choice"—must be balanced with strong data security, data integrity, and system performance protections.

Smile CDR: Your Partner in Compliance and Beyond

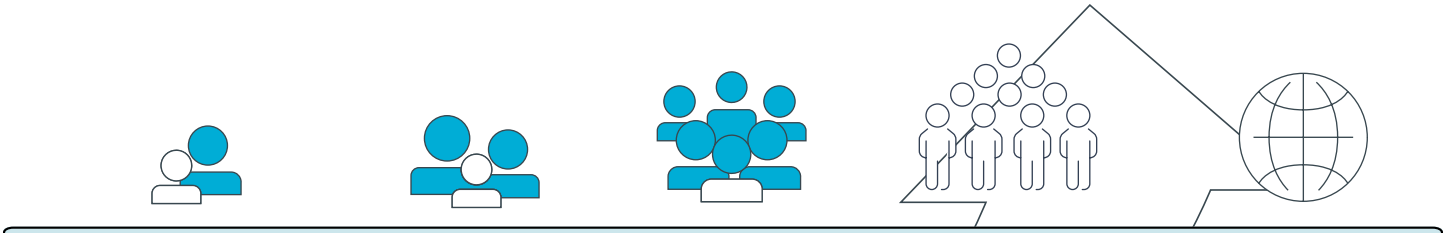
Smile CDR has a proven, enterprise-ready FHIR data platform.

Our product set provides tooling needed for payers to comply with the rules and to benefit from the recognized business value of sharing, aggregating and analyzing healthcare data, along with the resulting optimized digital transformation pathway. Smile CDR provides an enterprise-ready compliance toolkit for payers to meet CMS and ONC's fast-approaching mandates.

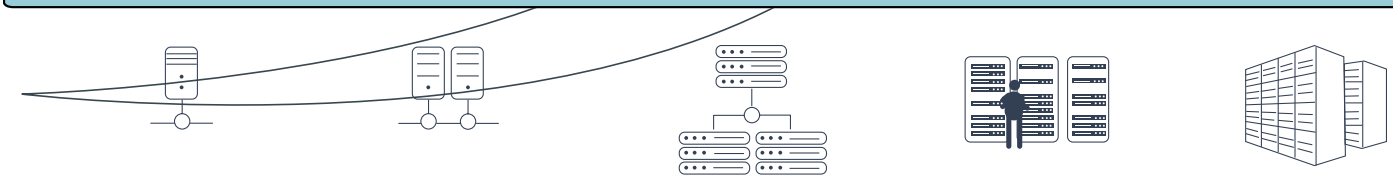
Smile CDR's industry-leading FHIR expertise embedded in an enterprise-class FHIR server will enable payers to build out fully scalable FHIR-based repositories, FHIR APIs and facades.

As a solution that is implemented in clinical settings, Smile is optimized to ingest and store clinical data. Smile's proven provider- side experience means payers have a solution that can be a bridge to Electronic Medical Records (EMRs) and other provider systems.

Grow with Smile



Growth	Plan and build internal users.	Add another node (automatically through the admin console) to ensure resiliency and support tons to hundreds of thousands of members.	As growth demands, continue to auto-scale. Smile performance grows with you.	Federate and/or grow geographically. Smile's ready to support your DRP & BCP (Disaster Recovery & Business Continuity Planning.)	Keep on growing and support billions of members (yes, we scale that target).
Use Cases	Start with a PoT (Proof-of-Technology).	Meet CMS & ONC requirements i.e. Patient Access APIs, Provider Directory APIs, Payer-to_Payer exchange.	Build a distributed data network to protect and limit interactions / aoid adverse impact on core operational systems.	BI and analytics on provier data, ML training for process automation and improved member engagement.	Consolidated all corporate data platform. Transformation to a data-driven organization by implementing new innovations/applications.



Smile is Your Platform Partner

Such an architecture should provide state of the art integration, master data management, translation, and industrial API hosting with an enterprise-class HL7 FHIR server and comprehensive FHIR APIs. The entire architecture needs to be efficient, personalized, scalable and agile.

Given the time constraints, this is not the time to fund and develop a vendor solution from scratch. As a mature solution that is already deployed and used globally by both payers and providers, Smile lets payers hit the ground running from day one.

To ensure they are ready to meet CMS and ONC interoperability deadlines while maintaining high levels of security and performance, payers can benefit from capabilities offered by Smile CDR:

Payers need a data architecture which will meet CMS rules by January 2021, and also evolve with them well into the future.

Capabilities	Description
Support for complete HL7 FHIR standard	Smile CDR is built around HAPI FHIR, the reference open source implementation of the FHIR specification in Java. Smile CDR is also the maintainer of HAPI FHIR which sees more than 20,000 downloads monthly. Smile CDR supports all FHIR resources and is at the forefront of incorporating the latest updates to the FHIR specification i.e. R5, R6, etc., as well as maintaining past versions to accommodate varying FHIR implementations and end points. Payers that stay at the forefront of FHIR development will be better equipped to interact with the dynamic and rapidly evolving FHIR information model, future Blue Button and USCDI changes, and the broader healthcare community.

Smile is Your Platform Partner *continued*

Capabilities	Description
Repository with a FHIR data model at its core	Smile CDR provides payers with the ability to implement both a facade (Hybrid Persistence) model as well as a full featured clinical data repository that is based on the FHIR data model. Data will be indexed and stored according to the FHIR data model to keep it consistent with Blue Button and USCDI requirements. This data can then be exported either via FHIR APIs without further translations or via other standards such as the HL7 v2 messaging format, as documents conforming to CDA, or via custom ETL.
Flexible and comprehensive FHIR APIs	Support for the full FHIR specification means that payers can interact with just about any RESTful API call from any SMART on FHIR application. Likewise, your APIs will be ready to interact with third parties including external clients at providers and other payers at all levels of complexity and customization afforded by FHIR.
Ability to ingest ADT data from providers	Payers can leverage available HL7 v2 to FHIR adaptors that transform the incoming Admit, Discharge and Transfer (ADT) data into FHIR resources and store this data to the repository. Outbound data from FHIR to HL7 v2 is also available to allow for bi-directional interaction with clinical workflows, and for enabling providers who have not yet implemented FHIR APIs to accept ADT messages.
Ability to merge incoming clinical data with claims and EOBs	Tooling to provide mapping and transformation of data from existing systems such as claims databases. This valuable utility provides payers with the ability to consolidate data scattered across several systems for seamless interaction. This in turn generates accurate, comprehensive and timely data for consumption and exchange with patients, providers and other payers.

Smile is Your Platform Partner *continued*

Capabilities	Description
Repository with a FHIR data model at its core	Smile CDR supports the use of OAUTH 2 / OpenID Connect protocols through an internal service and/or via integration with existing enterprise identity management solutions such as OKTA, ForgeRock, RedHat Keycloak, MitreID Connect, Microsoft Identity Platform and others. Smile includes granular and programmatic roles and consent controls for constructing finely-tuned security models. The security model is further supported via rules, scopes, encryption, detailed logging and a security-by-design development philosophy.
Robust and scalable data exchange	Smile integrates with industrial strength REST APIs and file gateways to scale with increasing members and applications. Raw EDI data can translate to FHIR and subsequently be retrieved and consumed in multiple applications via CMS Final Rule data standards. Patients can use payer applications to access their claim, encounter, costs, and health records – allowing payers to better engage and streamline their business. Accurate matching of patient clinical data to claims data helps prevent exposure to potential HIPAA violations.
Integrated Analytics and Empowering Big Data Analytics and AI	Powerful event triggered streaming capabilities using FHIR subscriptions and Kafka enable big data strategies for business intelligence, predictive and other analytics, as well as dynamically generating training data sets for machine learning.
Deployed and Used Globally	Smile is implemented by Global 1000s and governments in 10 countries including the US, Canada, Mexico, Costa Rica, the UK, the Netherlands, Germany, Norway, Australia, and New Zealand. Smile is also used by two of the ten largest payers in the US—with more to come.

Conclusion

Payers need an enterprise-class FHIR server and services platform capable of meeting today's compliance needs and tomorrow's growth objectives.

Firstly, payers must act quickly to meet CMS & ONC timelines. To meet the 2021 requirements, payers should prepare to go into production by Q4 2020.

This will require a proven solution with built-in tooling and a vendor with implementation experience to realize timely and successful compliance.

Looking further ahead, payers will need a FHIR platform with the flexibility to grow with their needs as both compliance requirements and data standards continue to evolve.

Accelerate Time-to-Compliance with Smile

Smile CDR's powerful capabilities enable payers to implement CMS and ONC final rules in an efficient and effective manner.

Find out how you can save time, reduce costs and increase revenue by leveraging Smile's tooling and expertise.

Contact us to learn about our flexible engagement models. Leveraging our expertise in HL7 FHIR and payer implementations, we'll work together with your team's go-to-market plan to realize the promise of "Fast" in FHIR.

As a first step, we'll perform a needs assessment to determine where solution gaps exist.

From there, we can scope out a low-cost Proof of Technology (PoT) where we work with your organization to architect and deliver the best customized infrastructure to meet both the rules and your health plan's immediate needs, all while being a catalyst for your mid-to-long term data strategy.

Together with your team we'll cover:

- Requirements definition and scoping Architectural design and solutioning
- Implementation of PoT in your sandbox that will include sample apps for testing and conformance
- Testing and validation of your APIs Knowledge transfer
- From here you'll have a proven business case and will be ready to graduate to production.

We take a phased and measured approach that minimizes impact to existing systems and mitigates risk as you invest in this endeavor.

About Smile CDR Inc.

Smile CDR specializes in enterprise-grade FHIR implementations (scale, performance).

Smile CDR Inc. helps organizations such as payers, regional and national governments, regional health exchanges, researchers, health systems, providers and app developers build connected health solutions and products by leveraging our core expertise in health data and the new global health data standard for interoperability, HL7 FHIR.

As a founding member of the **FHIR Business Alliance (FHIRBall)** and the leading enterprise-class FHIR server based on HAPI FHIR (the open source reference implementation of HL7 FHIR in Java), Smile CDR has been deployed in 10 countries and is committed to #BetterGlobalHealth.

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