







Summary

The much-anticipated release of the CMS Interoperability and Patient Access Final Rule (CMS-9115-F) on March 9, 2020, which included the Payer-to-Payer Data Exchange, was designed to advance interoperability and begin to address the silozation of healthcare data. Instead, the Payer-to-Payer Data Exchange ruling created confusion within the industry by not providing clear guidance on the format required for data exchange. The subsequent removal of the enforcement dates from the Payer-to-Payer mandate has resulted in many Payers pausing or abandoning work towards compliance, which experts have warned could have unfortunate consequences.

With additional federal mandates pointing to the HL7® FHIR® standard for data exchange, proactive Payers will consider the evolving situation around the enforcement of the rules as an opportunity to prepare their infrastructure to best handle a liberated flow of data around the FHIR standard. Choosing a trusted and experienced vendor is essential in managing the influx of data and maintaining a competitive advantage in the rapidly-evolving healthcare industry.



Introduction

Achieving functional interoperability throughout the US healthcare system has been hindered by disconnected organizational structures and ineffective standards for exchanging data. To remedy this, the Centers for Medicare & Medicaid Services1 (CMS), the US federal agency responsible for administering Medicare, Medicaid and other government qualified health plans, chose to tackle the data exchange limitations affecting Payers by issuing a number of rules and policies related to healthcare interoperability and patient access.

Released on March 9, 2020, the *CMS Interoperability and Patient Access Final Rule* (CMS-9115-F) included three policies: *Patient Access API, Provider Directory API* and *Payer-to-Payer Data Exchange*. These policies apply to all Payers administering CMS-regulated health plans, including:

- Medicare Advantage (MA) organizations
- Medicaid Fee-for-Service (FFS) programs
- Medicaid-managed care plans
- CHIP FFS programs
- · CHIP-managed care entities, and
- Qualified Health Plan (QHP) issuers on Federally-Facilitated Exchanges (FFEs).

Concurrently, the Office of the National Coordinator for Health Information Technology2 (ONC) issued its *Cures Act Final Rule* for the Patient Access API and Provider Directory API, which required that HL7 FHIR R4 be used.

The CMS rules are a critical early step towards creating a full-scale FHIR-based data exchange network and clear sign that end-to-end data interoperability is considered a priority of the utmost importance within the healthcare sector. FHIR-based networks are a prerequisite to holistic data exchange, with the Payer-to-Payer legislation being one of the first steps toward the inevitable paradigm shift.

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From a Payer's perspective, the Payer-to-Payer (P2P) data exchange is an opportunity to develop the processes and infrastructure required to address mandated data exchanges with their counterparts. A decision that will inevitably pay great dividends when supporting more complex exchanges with Providers and other organizations. Proactive Payers are taking this opportunity to architect the infrastructure ahead of time to safely handle the complex issues surrounding such exchanges, like data quality assurance, consent, storage of data and much more.

This paper explores the evolution of the Payer-to-Payer Data Exchange regulation, its large-scale implications and advises Payers on the benefits of leveraging FHIR sooner rather than later to maximize efficacy.



Solution: CMS Payer-to-Payer Data Exchange

The Payer-to-Payer release mandate via the three-pronged CMS Interoperability and Patient Access Final Rule (CMS-9115-F) on March 9, 2020, was designed to advance interoperability and support the creation of a longitudinal health record—improving patient, Provider and Payer access to pertinent medical information.

The rule initially attempted to achieve this vision by requiring that Payers send the last five years of clinical data—excluding claims and explanation of benefits (EOB) information—to a member's current insurer at their request. While timely and much needed in terms of addressing many of the issues raised by industry leaders, the Payer-to-Payer rule fell short of providing clear guidance regarding the format required for data exchange. The lack of a specified data format, along with the exclusion of claims and EOBs from the exchange mandate, elicited significant confusion from Payers and detracted from its initial vision of interoperability.

To address this growing concern, on December 10, 2020, the CMS Interoperability and Patient Access Proposed Rule (CMS-9123-P), also known as the FHIR only rule was introduced. The new mandate enforceable January 2023—was meant to enhance the data exchange policies of the Patient Access Final Rule by requiring all data exchange be conducted via a FHIR-based Payer-to-Payer API. While clarifying certain vagueness surrounding data format requirements and expanding the data exchange to all new members upon enrollment—not just those who have requested it—the two rules caused additional confusion. Many Payers, who attempted to prepare for compliance amidst fluidly evolving requirements, raised concerns that the relatively short period of time—10 months—to comply with the new rules would create an unnecessary burden on the already strained industry.

Therefore, on September 15, 2021, the CMS issued a clarification in an FAQ3 format, which effectively postponed and omitted enforcement of the Payer-to-Payer exchange rule.

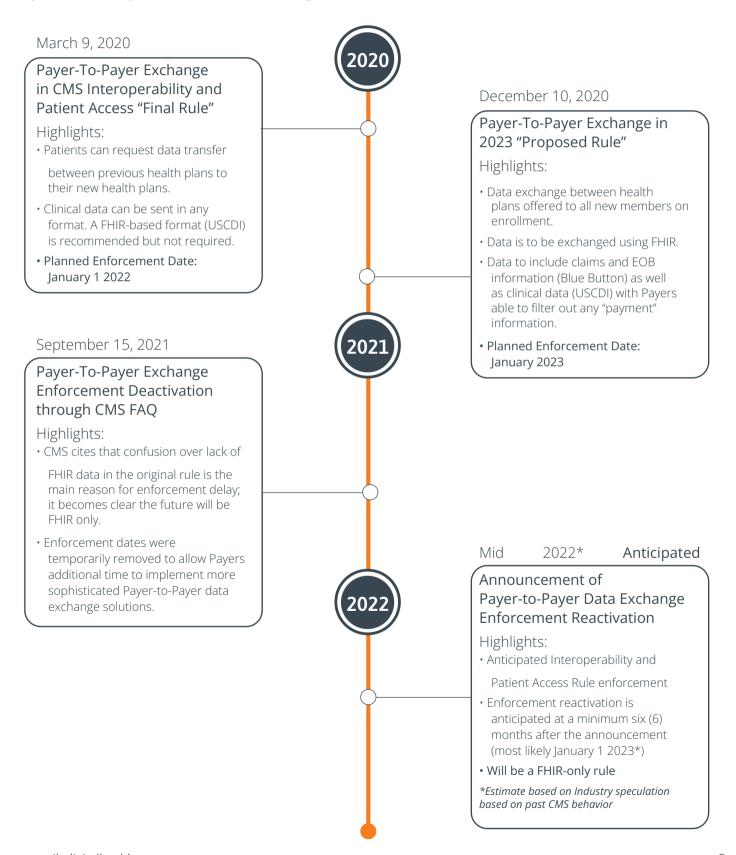
Delaying enforcement provided Payers with the additional time needed to adequately fortify their infrastructure to a FHIR-only Payer-to-Payer data exchange format. Experts maintain that after the amendment process, the Payer-to-Payer mandate will closely resemble what is the 2023 Payer-to-Payer Proposed Rule. The progression of the two rules is shown in Figure 1.

The 2023 Payer-to-Payer Proposed Rule is a FHIR only format rule and, as it includes claims and EOB information, it states that during the data exchange process, Payers will not have to disclose pertinent financial information to other Payers. The inclusion of this condition allows for participation in the Payer-to-Payer data exchange paradigm without sacrificing one's competitive edge through the open disclosure of valuable pricing information. Given the likelihood that Payer-to-Payer data exchange will follow the footsteps of the 2023 Payer-to-Payer Proposed Rule, it will most certainly include this conditional exchange policy. It is one of the many reasons Payers should prepare themselves for a more enforceable and effective Payer-to-Payer mandate compared to its initial predecessor. Informed participants surrounding the Payerto-Payer data exchange mandate estimate that an official confirmation of the rules' similarity to the 2023 Payer-to-Payer Proposed Rule may be provided before mid-2022, along with further information regarding its enforcement. This provides even more justification for Payers to use the CMS amendment window to prepare for the rule's inevitable arrival.



Figure 1. Payer-to-Payer Data Exchange Provision Timeline

Payer-to-Payer Data Exchange Provision Timeline





Additional Data Exchange Mandates

Payers focusing on the Payer-to-Payer policy can garner additional insight on its development through examining the proposal and evolution of similar data exchange mandates that will surely dictate its evolution. One rule, in particular, is the CMS Interoperability and Prior Authorization Rule, which was proposed in December 2020. The rule plans to build around the interoperability of the Patient Access Final Rule, aiming to improve healthcare data exchange between Payers, Providers and patients through streamlining the prior authorization processes. This mandate would require Payers to use the FHIR standard for all data exchanges and demonstrates the resolve of CMS to usher in a FHIR —only framework throughout the healthcare sector. In addition, other new FHIR-based regulations have been recently proposed and should be used by Payers to determine their urgency towards adhering to the much closer Payer-to-Payer policy. The new regulations and legislation, briefly described below (Rules mandating or recommending the use of the FHIR standard), include the following:

- CMS Prior Authorization Rule 4
- No Surprises Act
- CMS Hospital Price Transparency Rule 6
- HEDIS7 / Star Ratings 8 / MIPS 9

Getting ahead of the work on these regulations and legislations will be of enormous benefit to Payers looking to architect for a future of FHIR-based data exchanges. This is further solidified by the multitude of FHIR based mandates that have long signaled the shifting tides of data exchange expectations.

Box 1. Rules mandating or recommending the FHIR standard

Rules mandating or recommending the FHIR standard

- CMS Prior Authorization Rule Prior authorization (PA) is a cost-control process requiring healthcare providers to obtain approval before services are delivered to patients qualifying for payment coverage. The PA Rule requires Payers to provide a clear understanding of the process, verifying that third-party applications adhere to privacy policy provisions and submit quarterly metrics reports determining the API's impact on patients.
- The No Surprises Act Unexpected medical bills occur when patients unknowingly receive treatments by out-of-network providers or facilities. The federal legislation is meant to protect patients from bills that arise after receiving emergency care, undergoing elective procedures or being transported by air ambulance. The continuous data exchange provides patients with pricing transparency.
- CMS Hospital Price Transparency Rule Hospitals maintain a public list of charges for
 their items and services. Providers either
 present pricing by a machine-readable file or
 consumer-intuitive layout. FHIR has accurate,
 individualized costs enabling Payers and
 Providers to comply with mandates that help
 patients avoid surprise bills and potentially
 financial tribulations.
- HEDIS / Star Ratings / MIPS These
 performance evaluators determine the efficacy
 of Payers and Providers. Each system's scores
 are integral to the assessment process,
 determining if Payers and Providers receive
 positive or punitive reinforcement from
 governing organizations. As massive amounts
 of data are needed for each system's collection
 process, FHIR ensures the metrics are not
 misrepresented.



How Payers Can Benefit

Assessing the Payer-centric ramifications of these policies can be challenging. Nonetheless, Payers should avoid prolonging their data exchange participation to align with the rule's inevitable enforcement. Instead, Payers should capitalize on this additional time to preemptively adhere to regulatory consequences and create well-planned infrastructure, administration and processes for these significant FHIR-based data exchanges.

Ultimately, there are several substantial benefits for Payers to reap through early adoption of the new data exchange mandates (summarized on page 7, Key benefits of adopting FHIR standards.)

- Updating their call centers and administrative infrastructure. The proposed 2023 Payer-to-Payer rule requires Payers to offer data exchange activation to members during enrollment, including phone and in-person registration. This option for members to opt-in to P2P on enrollment will certainly create greater member participation of Payer-to-Payer. As a result, Payer's call centers and administrative infrastructure will need to create business processes and workflows to administer P2P opt-ins. Payers can set themselves up for success by preemptively creating the administrative systems to better handle the new Payer-to-Payer option into the enrollment process.
- Sharing and receiving members' health data.

The Payer-to-Payer data exchange means that Payers will share their members' information while also receiving historical health data. In a world where data is the new currency, the healthcare sector is no different—as those who collect and process more data possess an advantage over their competitors. Payers' visibility into members' clinical history can provide additional benefits including clinical risk mitigation, analytics, statistics and improved administration. Simply put, more data can help ensure Payers' participation in the

broader economy of health data and increase the overall revenue of their business. The systems Payers put in place now will prepare them for what comes next.

- Increasing member satisfaction. Providing departing members with a comprehensive record of their health history fosters member satisfaction and general organizational goodwill that is beneficial to Payers. For the most part, members often leave their insurance plan for reasons Payers cannot control, such as job, residence or financial changes. Having members' data follow them when they change plans provides Payers with an additional source of information to analyze—they will know where their members went and why.
- Encouraging cost-efficient care. One of the most compelling reasons for Payers to invest in data sharing today is that the Payer-to-Payer data exchange will inevitably be followed by increased exchanges of data between Payers and Providers. Payers will definitely be motivated to send and receive health data to and from Providers, as it will reduce risk, improve value-based quality care and ensure that their members are being cared for in the most cost-effective fashion.
- Promoting the infrastructure required for future data exchange. Mandates and legislation like Prior Authorization, HEDIS and the *No Surprises Act* that eventually generate full-scale Payer adherence to FHIR will ultimately translate to the amendment of provider network contracts. The incentives that Payers will likely offer in their provider network contracts to garner FHIR formatted data will be a critical step towards the widespread use of FHIR within the healthcare sector. Therefore, it greatly benefits Payers to preemptively set up the infrastructure and security architecture capable of handling the inevitable influx of data that comes from the holistic adoption of FHIR. For example, getting a



step ahead on the data security work needed to begin critical architecture on Quality Assurance structures (receiving/sending repositories, QA repositories, separate repository instances, multitenancy, master data management, etc.) will be essential to Payer success. By leveraging the additional time before data exchange enforcement, Payers will be provided with the much-needed runway to establish this infrastructure.

Box 2. Key benefits of adopting FHIR standards

Key benefits of adopting FHIR standards

- Increased volume of data processed (input and output).
- Efficient administrative system for the enrollment of new members.
- · Increased members' satisfaction.
- Cost savings fueled by reduced risks and improved value-based care.
- · Infrastructure readiness.

The crucial message to understand is that the best method to take advantage of data exchange is to prepare for the future of FHIR now. Putting full-scale efforts into developing FHIR-based solutions to facilitate the ingestion and management needed for the inevitable data increase will provide Payers with the tools necessary to participate in this economy. By looking beyond today and understanding the true ramifications of these mandates tomorrow, Payers will be able to adapt their business model for success instead of frantically scrambling for compliance.

Selecting a FHIR Vendor

When choosing a trusted FHIR vendor, one should review their flexible integration abilities as one of many requirements. Smile Digital Health is an enterprise FHIR-native data platform built by the developers of the open source library HAPI FHIR. Designed around the HL7® FHIR® standard, Smile Digital Health can ingest different data formats from disparate sources, in whatever format is convenient (for example, HL7 v2, CDA, flat file, etc.). Smile Digital Health's solution is designed for flexible integration with enterprise architectures, which means it can be modified to meet the bespoke needs of IT organizations.

When it comes to securely protecting and uniquely identifying received data to be matched to the correct member, taking the time to create the right processes and architecture for your organization is not something that should be rushed. Beginning this effort in a thoughtful and unhurried approach is one of the critical reasons Payers should start work on the complexities of the Payer-to-Payer exchange and all the future mandated data exchanges today. Most importantly, utilizing the proven expertise of Smile Digital Health to handle this process will be a smart step for any Payer looking to maximize their efficacy.



Conclusion

The CMS Interoperability and Patient Access Final Rule and the CMS Interoperability and Prior Authorization Proposed Rule have huge implications for health data interoperability. They signal a fundamental shift in healthcare, leading to greater availability and access to longitudinal patient data. As a result, Payers will need to receive and manage massive amounts of data—effectively requiring their current IT systems to become FHIR data exchange hubs.

Payers need to be thinking about the strategic advantages of data sharing and start building their strategy now for the coming digital transformation. The best way to capitalize on this paradigm shift is to leverage the advantages made available through liberated data and reap the benefits of acting as pioneers and not late adopters to a FHIR-only framework that is not an if, but when.



References

- ¹ Center for Medicare Services. (n.d). https://www.cms.gov/
- ² The Office of the National Coordinator for Health Information Technology. (n.d). A**bout ONC**. https://www.healthit.gov/topic/about-onc
- ³ Center for Medicare Services. (n.d). *FAQs*. https://www.cms.gov/about-cms/obrhi/faqs#122
- ⁴ Center for Medicare Services. (n.d). *CMS Interoperability and Prior Authorization Proposed Rule*. https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index#CMS-Interoperability-and-Prior-Authorization-Proposed-Rule
- ⁴ Center for Medicare Services. (n.d). *Ending Surprise Medical Bills*. <u>https://www.cms.gov/nosurprises</u>
- ⁵ Center for Medicare Services. (n.d). Hospital Price Transparency Rule. https://www.cms.gov/hospital-price-transparency
- ⁶ Center for Medicare Services. (n.d). *Healthcare Effectiveness Data and Information Set (HEDIS)*. https://www.cms.gov/Medicare/Health-Plans/SpecialNeedsPlans/SNP-HEDIS
- ⁷ Center for Medicare Services. (n.d.). *Star Ratings*. https://www.cms.gov/newsroom/press-releases/cms-releases-2022-medicare-advantage-and-part-d-star-ratings-help-medicare-beneficiaries-compare
- ⁸ Quality Payment Program. (n.d). Merit-Based Incentive Payment System. https://qpp.cms.gov/mips/promoting-interoperability



Do you have questions about the legislative evolution of incoming data exchange mandates and how it could affect your enterprise's operational performance? Speak with a Smile Digital Health representative.

We're HAPI to help.

Smile CDR Inc (doing business as Smile Digital Health).

622 College Street, Suite 401 Toronto, Ontario M6G 1B4, Canada info@SmileDigitalHealth.com 1 (877) 537-3343

www.smiledigitalhealth.com

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