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FAQs about the CMS Interoperability & Patient Access Rule

The Interoperability and Patient Access final rule became final on March 9, 2020. This rule is designed to make health information more easily available to patients by implementing industry-wide standards like APIs and FHIR technology and by deterring information blocking. Because of the complexities and nuances of the rule language, we have compiled a list of Frequently Asked Questions to help the healthcare industry navigate the road to implementation.

Q. I read some of the documents on the CMS website, but I'm still not sure I understand. Can you summarize the rule for me?

A. To improve beneficiaries' access to personal health data, benefits and provider network information, payers will be required to do the following:

- Implement, test, and maintain a secure, standards-based Patient Access API using HL7 FHIR Release 4.0.1
- Make standardized information about provider networks available via a FHIR-based API using HL7 FHIR Release 4.0.1
- Engage in standards-based, electronic Payer-to-Payer Data Exchange using USCDI v1, enabling beneficiaries to import historical health information from previous insurers into their patient profile.* Payers are only obligated, at a minimum, to send data received from another payer under this policy in the electronic form and format it was received.

Payers are NOT required to participate in a trusted exchange network at this time.

Q. The final rule refers to "CMS-regulated payers" — what does this mean?

A. The final rule defines CMS-regulated payers as follows:

CMS-Regulated Payers	Not Applicable
• Medicare Advantage organizations	• Stand-alone dental plans (SADPs)
• Medicaid FFS programs	• Federally-facilitated Small Business Health Options Program (FF-SHOP) plans
• Medicaid managed care plans	
• CHIP FFS programs	
• CHIP managed care entities	
• Qualified Health Plans (QHPs) on the Federally Facilitated Exchanges (FFEs)	

*This requirement does not apply to State Medicaid FFS and CHIP FFS programs

Q. Which parts of the final rule apply to my organization?

A. The Interoperability Rule has seven main components, some of which pertain to healthcare providers, others to CMS-regulated payers, and one specifically to State Medicaid Agencies:

How the Final Rule Impacts Healthcare Organizations

Providers	All CMS-Regulated Payers	State Medicaid Agencies Only
• Provide Admission, Discharge, and Transfer Event Notifications • CMS will publicly report providers: 1) suspected of Information Blocking 2) who do not maintain Digital Contact Information in the NPPES	• Implement a Patient Access API • Implement a Provider Directory API • Support Payer-to-Payer Data Exchange*	• Increase the Frequency of Federal-State Data Reporting Exchanges from Monthly to Daily

* State Medicaid FFS and CHIP FFS programs are exempt from this requirement.

Q. When is the deadline to implement the requirements of the final rule?

A. There are multiple deadlines ranging from late 2020 to April 2022. The following is a complete timeline of applicable dates within the final rule and their applicable parties (Blue = Providers, Green = Payers).

Final Rule Component	Applicable to	Applicable Date
Admission, Discharge, and Transfer Event Notifications	• Hospitals • Psychiatric hospitals • Specialized providers (CAHs)	Late 2020
Public Reporting and Information Blocking	• Eligible clinicians, hospitals and CAHs in the Promoting Interoperability Program	CMS reporting goes live late 2020
Digital Contact Information	• All individual health care providers, facilities, or practices	CMS reporting goes live late 2020
Patient Access API	• MA organizations • State Medicaid FFS programs • Medicaid managed care plans • CHIP FFS programs • CHIP managed care entities • QHP issuers on the FFEs*	January 1, 2021
Provider Directory API	• MA organizations • State Medicaid FFS programs • Medicaid managed care plans • CHIP FFS programs • CHIP managed care entities • QHPs issuers on the FFEs*	January 1, 2021
Payer-to-Payer Data Exchange	• MA organizations • Medicaid managed care plans • CHIP managed care entities • QHP issuers on the FFEs	January 1, 2022
Improving the Dually-Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges	• State Medicaid Agencies	April 1, 2022

* QHP issuers on the FFEs are already required to make provider directory and drug formulary information available in a specified, machine-readable format.

Q What happened to the Trusted Exchange Networks from the proposed rule?

A. Based on the feedback received during the public comment period, CMS decided not to finalize a rule for Care Coordination through Trusted Exchange Networks at this time.

Q. What is the Improving the Dually-Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges requirement?

A. This requirement is designed to improve payer-provider care coordination for the dual-eligible population (including eligibility, enrollment, benefits, and/or care). Under the final rule state Medicaid agencies are required to increase the frequency of buy-in data exchange and MMA file data submission to CMS from monthly to daily by April 1, 2022. To alleviate any strain this puts on state agencies, CMS will provide federal matching funds and technical assistance, including best practices on upstream data sets necessary to implement daily MMA file submissions.

Q. As a payer, what do I need to know about the PROVIDER REQUIREMENTS and their impact on my business and members?

A. Improving care coordination and interoperability requires effort from both payers and providers. One of the key benefits of mandating provider compliance is the increased amount of patient information that will become digitally available, advancing payer-provider data exchange efforts and improving care quality and other value-based care initiatives. The following components of the final interoperability rule apply to the providers in your networks:

Final Rule Component	Applicable Providers	Details	Applicable Date
Admission, Discharge, & Transfer Event Notifications	Hospitals, psychiatric hospitals, and Critical Access Hospitals (CAHs)	To improve care coordination, hospitals with EHRs will be required to alert providers when their patients are admitted, discharged, transferred or receive any services in the ED.	Late 2020
Public Reporting & Information Blocking	Eligible clinicians, hospitals and CAHs in the Promoting Interoperability Program	To further reduce information blocking, CMS will begin publicizing a list of all providers who submit a "no" response to any of the three Prevention of Information Blocking Attestation statements under the Medicare FFS Promoting Interoperability Program.* Providers will have 30 days to contest prior to publication.	CMS reporting goes live in late 2020, using 2019 report data
Digital Contact Information	All individual health care providers, facilities, or practices	Just as payers need to provide an updated Provider Directory API, providers must maintain digital contact information in the National Plan and Provider Enumeration System (NPPES). CMS will publicly report providers that do not comply with this rule.	CMS reporting goes live in late 2020

* For more information about the attestations, visit: Medicare and Medicaid Promoting Interoperability Programs: Prevention of Information Blocking Attestation Fact Sheet

Q. What data needs to be included in the Patient Access API and the Provider Directory API?

A. Payers must be prepared to expose the following data points via APIs by January 1, 2021:

	Patient Access API Data Points	Provider Directory API Data Points
Included	• Adjudicated claims (including Pharma) • Encounters with capitated providers • Provider remittances • Enrollee cost-sharing • Subset of clinical data, including laboratory results (where maintained by the impacted payer and defined as the classes of data stipulated in USCDI v.1) • Formularies or preferred drug lists* *MA-PD plans must also include:* • Covered drugs, and any tiered formulary structure or utilization management procedure	• Provider names and network status • Addresses • Phone numbers • Specialties *MA-PD plans must also include:* • Pharmacy name • Address • Phone number • Number of pharmacies in network • Type of pharmacy (e.g., "retail pharmacy")
Special Notes		All payers except QHPs on the FFEs must make the Provider Directory API accessible via a public-facing digital endpoint on their website to ensure public discovery and access
Timing	No later than one (1) business day after a claim is adjudicated or encounter data is received by the impacted payer	Within 30 days of receipt of new data or changes to directory data

* Not applicable to QHPs on the FFEs or MA plans that do not cover Part D. Further clarification required to determine minimum compliance required for formulary data.

Q. I still have concerns about security breaches. How do I know I'm not at risk for HIPAA violations?

A. CMS made the following provisions in the final rule to ensure payers feel safe exchanging and exposing data via APIs and USCDI data sets:

- A payer may deny a 3rd-party application access to the Patient Access API if the payer reasonably determines that doing so would present an unacceptable level of risk to the security of PHI on the payer's systems based on objective and verifiable criteria.
- Payers must provide enrollees with resources explaining risk factors, including practical strategies to safeguard their privacy and security, and how to submit complaints to OCR or FTC.
- Payers may request that 3rd-party apps attest to having certain information included in their privacy policy, and inform patients about this attestation, to help ensure patients are aware of the privacy risks associated with their choices.
- Payers are NOT responsible for breaches of PHI, nor breach notification requirements, when the breach of PHI is caused by a third party or by the patient to whom the PHI has been released by the Payer. The rule also clarifies that privacy issues outside the scope of HIPAA are governed by the FTC under section 5 of the FTC Act (15 U.S.C. Sec. 45(a)) and the FTC Health Breach Notification Rule.

Payers are encouraged to review the OCR website for resources on the individual access standard to ensure they understand their responsibilities.

Q. Are there IMPLEMENTATION GUIDES payers can refer to when developing Patient Access and Provider Directory APIs?

A. CMS has provided the following implementation guides (IGs) for the specific data elements required for the Patient Access and Provider Directory APIs. While use of these IGs is not required, it is highly recommended that payers leverage them when developing their APIs to avoid duplicative efforts. CMS has been working with HL7 and other industry partners to ensure these resources are freely available to payers. For a complete list of additional resources (e.g., reference models, sample data, testing tools and code, and hosted reference implementations), please visit the final rule page on the CMS website.

Data Element	Implementation Guide
Claims and Encounters	CARIN Alliance Blue Button® Framework and Common Payer Consumer Data Set (CPCDS) IG
Clinical Data (in USCDI v1)	HL7 FHIR® US Core IG STU 3.1.0
Plan Coverage and Formularies	Da Vinci Payer Data Exchange US Drug Formulary IG
Provider Directory	Da Vinci PDEX Plan Net IG

Q. What are the TECHNICAL STANDARDS payers need to follow?

A. There are three main technical standards in the ONC's 21st Century Cures Act final rule for payers and developers to use to meet the requirements of the CMS Interoperability final rule:

Use	Standard	Version Date	Summary
Data Exchange	HL7 FHIR®	Version 4.0.1 10/30/2019	Provides the first set of normative FHIR resources, which means future changes will be "backward compatible." These resources define the content and structure of core health data, which can be used by developers to build standardized applications.
Authorization Guide	SMART IG / OAuth 2.0	Release 1.0.0 11/13/2018	Provides reliable, secure authorization for a variety of app architectures via the OAuth 2.0 standard. Supports the four use cases defined for Phase 1 of the Argonaut Project. Enables 3rd-party apps to request authorization to access a FHIR resource and retrieve a resource.
Authentication Guide	OpenID Connect	Core 1.0 Incorporating Errata Set 1 11/8/2014	Simple identity layer built on top of the OAuth 2.0 protocol to enable clients to verify end-user identity and obtain basic profile information from claims data in an interoperable and REST-like manner.

Q. What are the CONTENT & VOCABULARY STANDARDS payers need to follow?

A. The ONC's 21st Century Cures Act final rule also delineates content and vocabulary standards for payers and developers to use to meet the requirements of the CMS Interoperability final rule:

Use	Standard	Version Date	Summary
Health Data Sets	USCDI	Version 1 February 2020	Standardized set of health data classes and component data elements for nationwide, interoperable health information exchange. CMS has required that payers share the USCDI data they maintain with patients via the Patient Access API, and with other payers via the Payer-to-Payer Data Exchange

Q. What are some BEST PRACTICES for payers and developers sharing and receiving patient data via FHIR-based APIs?

A. CMS created a Best Practices for Payers and App Developers document, which provides links to useful information and best practices to help you build and maintain a FHIR-based API, as well as best practices for payers and third-party app developers.

Q. Where can payers find guidance on producing tailored PATIENT EDUCATION RESOURCES?

A. To support payers as they produce patient resources tailored to their patient population, CMS created a Patient Privacy and Security Resources document, which summarizes the required information that must be included in a payer's patient resource document, as well as some content payers may choose to use to help meet this requirement.

Why Edifecs?

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