Issue Brief
FEDERAL ISSUE BRIEF

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CMS Finalizing Interoperability and Prior Authorization Rule

The Centers for Medicare & Medicaid Services (CMS) are issuing a final rule regarding Interoperability and Prior Authorization.

Through the provisions in the rule, Medicare Advantage (MA) organizations, state Medicaid and Children's Health Insurance Program (CHIP) Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchanges (FFEs), (collectively "impacted payers") are required to implement and maintain certain Health Level 7® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) application programming interfaces (APIs) to improve the electronic exchange of health care data, as well as to streamline prior authorization processes.

To encourage providers to adopt electronic prior authorization processes, the rule also adds a new measure for Merit-based Incentive Payment System (MIPS) eligible clinicians under the Promoting Interoperability performance category of MIPS, as well as for eligible hospitals and critical access hospitals (CAHs), under the Medicare Promoting Interoperability Program.

The final rule is at the ***Federal Register*** office for publication on February 8. A copy of the 728-page document is available at: https://public-inspection.federalregister.gov/2024-00895.pdf.

Comments

CMS posted a version of the rule on January 17 on its website. That version was 822 pages. We are using the ***Federal Register*** copy of 728 pages for the material that follows.

The rule is both complex and intense. It includes what was proposed, comments received, responses and final action sections. To understand the final action sections, one needs to first understand what was proposed and second the changes CMS is making in this final rule.

According to CMS, most of the rule relates to payers.

We are taking a different approach in analyzing the rule. We are providing a section-by-section table of contents. This should help in deciding which material maybe applicable to you.

Page numbers of the rule are provided in red.

Medicare Fee-for-Service Implementation of Final Policies (Page 20)

Although these requirements do not directly pertain to Medicare FFS, CMS says "it wants to ensure that people with Medicare can benefit from the policies in this rule, regardless of their coverage or delivery system. CMS intends for the Medicare FFS program to be a market leader on data exchange, including through the Provider Access, Payer-to-Payer, and Prior Authorization APIs."

"Providers can use the Prior Authorization API to determine whether a specific payer requires prior authorization for a certain item or service, thereby easing one of the major points of administrative burden in the existing prior authorization process."

Effective Dates

For the Provider Access API policy, CMS is finalizing compliance dates in 2027 (by January 1, 2027, for MA organizations and state Medicaid and CHIP FFS programs; by the rating period beginning on or after January 1, 2027 for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027 for QHP issuers on the FFEs).

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Summary of Major Provisions

The material that follows is basically from CMS' fact sheet on this rule.

Patient Access API

CMS is requiring impacted payers to add information about prior authorizations (excluding those for drugs) to the data available via that Patient Access API. This requirement must be implemented by January 1, 2027.

To assess Patient Access API usage, beginning January 1, 2026, CMS is requiring impacted payers to report annual metrics to CMS about Patient Access API usage.

Provider Access API

To facilitate care coordination and support movement toward value-based payment models, CMS is requiring that impacted payers implement and maintain a Provider Access API to share patient data with in-network providers with whom the patient has a treatment relationship. Impacted payers will be required to make the following data available via the Provider Access API: individual claims and encounter data (without provider remittances and enrollee cost-sharing information); data classes and data elements in the United States Core Data for Interoperability (USCDI); and specified prior authorization information (excluding those for drugs).

CMS is also requiring impacted payers to maintain an attribution process to associate patients with in-network or enrolled providers with whom they have a treatment relationship and to allow patients to opt-out of having their data available to providers under these requirements. Impacted payers will be required to provide plain language information to patients about the benefits of API data exchange with their providers and their ability to opt out.

These requirements must be implemented by January 1, 2027.

Payer-to-Payer API

To support care continuity, CMS is requiring that impacted payers implement and maintain a Payer-to-Payer API to make available claims and encounter data (excluding provider remittances and enrollee cost-sharing information), data classes and data elements in the USCDI and information about certain prior authorizations (excluding those for drugs). Impacted payers are only required to share patient data with a date of service within five years of the request for data.

CMS is also finalizing an opt-in process for patients to provide permission under these requirements. Impacted payers are required to provide plain-language educational resources to patients that explain the benefits of the Payer-to-Payer API data exchange and their ability to opt-in.

These requirements must be implemented by January 1, 2027.

Prior Authorization API

CMS is requiring impacted payers to implement and maintain a Prior Authorization API that is populated with its list of covered items and services, can identify documentation requirements for prior authorization approval, and supports a prior authorization request and response. These Prior Authorization APIs must also communicate whether the payer approves the prior authorization request (and the date or circumstance under which the authorization ends), denies the prior authorization request (and a specific reason for the denial), or requests more information. This requirement must be implemented beginning January 1, 2027.

In response to feedback received on multiple rules, extensive stakeholder outreach, and to further promote efficiency in the prior authorization process, HHS will be announcing the use of enforcement

discretion for the Health Insurance Portability and Accountability Act of 1996 (HIPAA) X12 278 prior authorization transaction standard. Covered entities that implement an all-FHIR-based Prior Authorization API pursuant to the CMS Interoperability and Prior Authorization final rule that do not use the X12 278 standard as part of their API implementation will not be enforced against under HIPAA Administrative Simplification, thus allowing limited flexibility for covered entities to use a FHIR-only or FHIR and X12 combination API to satisfy the requirements of the CMS Interoperability and Prior Authorization final rule. Covered entities may also choose to make available an X12-only prior authorization transaction. HHS will continue to evaluate the HIPAA prior authorization transaction standards for future rulemaking.

Improving Prior Authorization Processes

Prior Authorization Decision Timeframes: CMS is requiring impacted payers (excluding QHP issuers on the FFEs) to send prior authorization decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests.

Provider Notice, Including Denial Reason: Beginning in 2026, impacted payers must provide a specific reason for denied prior authorization decisions, regardless of the method used to send the prior authorization request. Such decisions may be communicated via portal, fax, email, mail, or phone. As with all policies in this final rule, this provision does not apply to prior authorization decisions for drugs. This requirement is intended to both facilitate better communication and transparency between payers, providers, and patients, as well as improve providers' ability to resubmit the prior authorization request, if necessary. Some impacted payers are also subject to existing requirements to provide information about denials to providers, patients, or both through notices. These existing notices are often required in writing, but nothing in this final rule changes these existing requirements.

Prior Authorization Metrics: CMS is requiring impacted payers to publicly report certain prior authorization metrics annually by posting them on their website.

These operational or process-related prior authorization policies are being finalized with a compliance date starting January 1, 2026, and the initial set of metrics must be reported by March 31, 2026.

Electronic Prior Authorization Measure for MIPS Eligible Clinicians and Eligible Hospitals and Critical Access Hospitals (CAHs)

CMS is adding a new measure, titled "Electronic Prior Authorization," to the Health Information Exchange (HIE) objective for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program. MIPS eligible clinicians will report the Electronic Prior Authorization measure beginning with the Calendar Year (CY) 2027 performance period/CY 2029 MIPS payment year and eligible hospitals and CAHs beginning with the CY 2027 EHR reporting period. This will be an attestation measure, for which the MIPS eligible clinician, eligible hospital, or CAH reports a yes/no response or claims an applicable exclusion, rather than the proposed numerator/denominator.

To successfully report the Electronic Prior Authorization measure:

MIPS eligible clinicians must attest "yes" to requesting a prior authorization electronically via a Prior Authorization API using data from certified electronic health record technology (CEHRT) for at least one medical item or service (excluding drugs) ordered during the CY 2027 performance period or (if applicable) report an exclusion.

Eligible hospitals and CAHs must attest "yes" to requesting a prior authorization request electronically via a Prior Authorization API using data from CEHRT for at least one hospital discharge and medical

item or service (excluding drugs) ordered during the 2027 EHR reporting period or (if applicable) report an exclusion.

Required Standards and Recommended Implementation Guides (IGs) for APIs

The required standards and implementation specifications in this final rule include the following:

United States Core Data for Interoperability (USCDI)
HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1
HL7 FHIR US Core Implementation Guide (IG) Standard for Trial Use (STU) 3.1.1
HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0
FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1)
OpenID Connect Core 1.0

For information on which required standards and implementation specifications apply to each API, see Table H3 below.

CMS will allow flexibility for impacted payers to use updated versions of the standards and IGs. Impacted payers may use an updated ONC-approved standard, instead of the standard specified in regulation, if the update does not disrupt end users' ability to access the required data through the API.

Recommended Implementation Guides

When implementing the updated Patient Access API, the existing Provider Directory API, and the new APIs (Provider Access, Payer-to-Payer, and the Prior Authorization APIs), CMS strongly encourages impacted payers to use the following IGs, as applicable, to reduce burden and increase interoperability:

- HL7 FHIR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG Version STU 2.0.0
- HL7 SMART App Launch IG Release 2.0.0 to support Backend Services Authorization
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG Version STU 2.0.0
- HL7 FHIR Da Vinci PDex US Drug Formulary IG Version STU 2.0.1
- HL7 FHIR Da Vinci PDex Plan-Net IG Version STU 1.1.0
- HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG Version STU 2.0.1
- HL7 FHIR Da Vinci Documentation Templates and Rules (DTR) IG Version STU 2.0.0
- HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG Version STU 2.0.1

The standards CMS is finalizing, including updated citations are as follows:

- Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1 at 45 CFR 170.215(a)(1) (HL7 FHIR).
- HL7® FHIR® US Core Implementation Guide (IG) Standard for Trial Use (STU) 3.1.1, which expires on January 1, 2026, at 45 CFR 170.215(b)(1)(i) (US Core IG).
- HL7® SMART Application Launch Framework IG Release 1.0.0 which expires on January 1, 2026, at 45 CFR 170.215(c)(1) (SMART App Launch IG).
- FHIR® Bulk Data Access (Flat FHIR) IG v1.0.0: STU 1 at 45 CFR 170.215(d)(1) (Bulk Data Access IG).
- OpenID Connect Core 1.0, incorporating errata set 1 at 45 CFR 170.215(e)(1) (OpenID Connect Core).

TABLE H3: Required Standards and Recommended Implementation Guides To Support API Implementation

API	*Required* Standards*	*Recommended* Implementation Guides
Patient Access API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.*** 45 CFR 170.215(c)(1) HL7 SMART Application Launch Framework IG Release 1.0.0.*** 45 CFR 170.215(e)(1) OpenID Connect Core 1.0, incorporating errata set 1	HL7 FHIR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: http://hl7.org/fhir/us/carin-bb/history.html. HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davinci- pdex/history.html. HL7 FHIR Da Vinci - Payer Data Exchange (PDex) US Drug Formulary IG STU 2.0.1. URL: http://hl7.org/fhir/us/Davinci-drug- formulary/history.html.
Provider Access API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.*** 45 CFR 170.215(c)(1) HL7 SMART Application Launch Framework IG Release 1.0.0.*** 45 CFR 170.215(d)(1) FHIR Bulk Data Access (Flat FHIR) IG (v1.0.0: STU 1)	HL7 FHIR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: http://hl7.org/fhir/us/carin-bb/history.html. HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davinci- pdex/history.html. 45 CFR 170.215(c)(2) HL7 SMART App Launch IG, Release 2.0.0 to support Backend Services Authorization. URL: https://hl7.org/fhir/smart-app-launch/STU2/backend-services.hotml
Provider Directory API**	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.***	HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net IG STU 1.1.0. URL: http://www.hl7.org/fhir/us/davinci-pdex-plan- net/history.html.
Payer-to-Payer API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.*** 45 CFR 170.215(d)(1) FHIR Bulk Data Access (Flat FHIR) IG (v1.0.0: STU 1)	HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: http://hl7.org/fhir/us/carin-bb/history.html. HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davinci- pdex/history.html. 45 CFR 170.215(c)(2) HL7 SMART App Launch IG, Release 2.0.0 to support Backend Services Authorization. URL: https://hl7.org/fhir/smart-app-launch/STU2/backend-services.html
Prior Authorization API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.*** 45 CFR 170.215(c)(1) HL7 SMART Application Launch Framework IG Release 1.0.0.***	HL7 FHIR Da Vinci - Coverage Requirements Discovery (CRD) IG STU 2.0.1. URL: http://hl7.org/fhir/us/davinci-crd/history.html. HL7 FHIR Da Vinci - Documentation Templates and Rules (DTR) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davinci-dtr/history.html. HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG STU 2.0.1. URL: http://hl7.org/fhir/us/davinci- pas/history.html.

Final Thoughts

We have only one basic comment. Once again, CMS has not provided a complete table of contents. This is not helpful at all. If we can make such why can't CMS do so. The agency is always arguing to reduce burden. Yet, they are continuously failing to abide by their own standards.