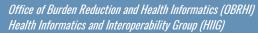


CMS ADVANCING INTEROPERABILITY AND IMPROVING PRIOR AUTHORIZATION PROCESSES PROPOSED RULE

February 8, 2023











PREVIOUS RULES

The proposed and final rules are available on the Federal Register.

CMS INTEROPERABILITY AND PATIENT ACCESS FINAL RULE

CMS-9115-F

The Interoperability and Patient Access final rule puts patients first by giving them access to their health information when they need it most, and in a way they can best use it. This final rule focused on driving interoperability and patient access to health information by liberating patient data using CMS authority to regulate Medicare Advantage (MA), Medicaid, Children's Health Insurance Program (CHIP), and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs). This rule was finalized in May 2020.

CMS DECEMBER 2020 INTEROPERABILITY PROPOSED RULE (WITHDRAWN)

CMS-9123-P

This proposed rule built on the policies finalized in the CMS Interoperability and Patient Access final rule. The provisions emphasized the need to improve health information exchange to achieve appropriate and necessary access to complete health records for patients, healthcare providers, and payers. This proposed rule also focused on efforts to improve prior authorization processes through policies and technology, to help ensure that patients remain at the center of their own care. We are proposing to withdraw this rule with the publication of CMS-0057-P.



CMS-0057-P OVERVIEW

On December 6, 2022, CMS posted the Advancing Interoperability and Improving Prior Authorization Processes proposed rule. The proposed effective date for the provisions in this rule is January 1, 2026.

This rule signals CMS' continued commitment to increasing efficiency by *ensuring that health information is readily available* at the point of care by leveraging FHIR standards.

CMS also includes several proposals intended to reduce payer, provider, and patient burden by *streamlining prior authorization* processes to move the industry toward electronic prior authorization, creating a more efficient and timely process.

Ultimately, reduced provider burden means more time with patients.



PROVISIONS

- Patient Access Application Programming Interface (API)
- Provider Access API
- Payer-to-Payer Data Exchange API
- Prior Authorization Requirements, Documentation & Decision API
- Improving Prior Authorization Processes
- New measures for Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

IMPACTED PAYERS

- Medicare Advantage
- State Medicaid and CHIP agencies
- Medicaid and CHIP Managed Care Plans
- Qualified Health Plans (QHPs) on the Federally-facilitated Exchanges (FFEs)

IMPACTED PROVIDERS

- Eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program
- Eligible clinicians under the Promoting Interoperability performance category of Merit-based Incentive Payment System (MIPS)

REQUESTS FOR INFORMATION (RFI)

- Accelerating the Adoption of Standards Related to Social Risk Factor Data
- Electronic Exchange of Behavioral Health Information
- Improving the Electronic Exchange of Information in Medicare FFS
- Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health
- Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)





PATIENT ACCESS API

CMS proposes to expand the already established Patient Access API to require payers to include information about prior authorization requests and decisions via the FHIR API. The NPRM includes a proposal for payers to report metrics about patient use of the API to CMS on an annual basis.



API DATA REQUIREMENTS

Impacted payers would be required to include information about prior authorization requests and decisions to patients via the Patient Access API, no later than 1 business day after the payer receives the prior authorization request or there is a status change to a prior authorization.



PATIENT ACCESS API USE METRICS

Impacted payers would be required to report metrics in the form of aggregated, de-identified data to CMS on an annual basis about how patients use the Patient Access API.

Impacted payers would annually report:

- (1) The total number of unique patients whose data are transferred via the Patient Access API to a patient's health app; and
- (2) The total number of unique patients whose data are transferred more than once via the Patient Access API to a patient's health app.





PROVIDER ACCESS API

CMS proposed to require impacted payers to implement and maintain a FHIR API to facilitate the exchange of patient data between payers and providers.



PROVIDER ACCESS API

Impacted payers would be required to build and maintain a FHIR API for sharing claims and encounter data (not including cost data), all data classes and data elements included in a content standard adopted at 45 CFR 170.213, and prior authorization requests and decisions for individual patients with providers.



OPT-OUT

Impacted payers would be required to maintain a process for patients to opt-out of having their health information available and shared via the Provider Access API.



EDUCATIONAL RESOURCES

Impacted payers would be required to provide resources to their patients about the benefits of utilizing the Provider Access API requirements, their opt-out rights, and instructions for opting out of the Provider Access API data exchange. Impacted payers would also be required to provide educational resources for communicating with providers, explaining how a provider may make a request to the payer for patient data using the FHIR Provider Access API.



ATTRIBUTION

Impacted payers would be required to develop an attribution process to associate patients with their providers to help ensure that a payer only sends a patient's data to providers who have a treatment relationship with that patient.





PAYER-TO-PAYER API

CMS proposes to rescind the payer-to-payer data exchange finalized in CMS-9115-F and replace it with proposed requirements for impacted payers to implement a standardized, FHIR API to exchange patient information between payers.



FHIR PAYER-TO-PAYER API

The data exchange would be facilitated through a FHIR API that would exchange all data classes and data elements included in a content standard adopted at 45 CFR 170.213, claims and encounter data (excluding provider remittances and enrollee cost-sharing information), and certain prior authorization data.



DATA EXCHANGE

New payers would have to request patient data from the previous payer within one week of the start of coverage. Previous payers would have to provide the data within one day of receiving the request. Patient data must then be incorporated into the new payer's record about the patient.



CONCURRENT COVERAGE

Where a patient has concurrent coverage with two or more payers, the impacted payers would be required to make the patient's data available to the concurrent payer at least quarterly.



OPT-IN

Impacted payers would be required to put in place a process to capture a patient's opt-in preference for the payer-to-payer data exchange prior to the start of coverage. Payers would also be required to share educational materials on an annual basis to inform patients of the benefits of data sharing and their data sharing rights.





IMPROVING PRIOR AUTHORIZATION

CMS proposes requiring impacted payers to implement an API to support functions of electronic prior authorization, standardizing prior authorization decision timeframes, and bringing transparency to prior authorization through metric reporting.



PRIOR AUTHORIZATION REQUIREMENTS, DOCUMENTATION, AND DECISION (PARDD) API

The FHIR PARDD API would be populated with the payer's list of covered items and services for which prior authorization is required, and documentation requirements. The API would also be used to communicate prior authorization decisions.



REASON FOR DENIAL

Impacted payers would be required to include a specific reason for a denial when denying a prior authorization request, regardless of the method used to send the prior authorization decision. Impacted payers would also share whether the payer approves the request, and for how long, or requests more information.



PRIOR AUTHORIZATION DECISION TIMEFRAMES

Certain impacted payers would be required to send standard prior authorization decisions within 7 days and expedited prior authorization decisions within 72 hours.



PRIOR AUTHORIZATION DECISION METRICS

Impacted payers would be required to publicly report aggregated data about their prior authorization process on an annual basis. This would include the percent of prior authorization requests approved, denied, and approved after appeal, and average time between submission and decision.



ELECTRONIC PRIOR AUTHORIZATION MEASURE

CMS proposes to add a new measure, called Electronic Prior Authorization, to the Medicare Promoting Interoperability Program and QPP – MIPS to incentivize clinician and hospital use of the PARDD API starting Calendar Year (CY) 2026.



PARTICIPATING PROGRAMS

QPP – MIPS Program (Promoting Interoperability performance category – HIE objective)

Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (under the HIE objective)



SCORING METHODOLOGY

CY 2026: Required, but unscored measure

CY 2027+: CMS to propose a scoring methodology for future program years in subsequent rulemaking



MEASURE DESCRIPTION

MIPS eligible clinicians, eligible hospitals, and CAHs report the following numerator/denominator or claim an exclusion:

NUMERATOR: Number of unique prior authorizations that are requested from a PARDD API using data from CEHRT

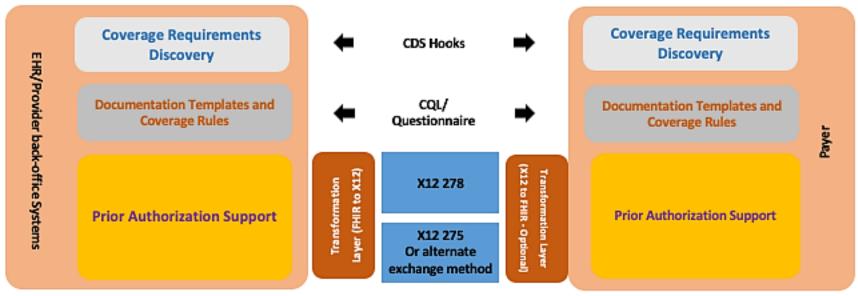
DENOMINATOR: Number of unique prior authorizations requested for items/services (excluding drugs) ordered by the MIPS eligible clinician/ordered for patients discharged from the eligible hospital or CAH inpatient or emergency department during the applicable performance period/EHR reporting period.

EXCLUSION: Did not order any item/service 1) requiring prior authorization or 2) requiring prior authorization from a payer that does not offer an API consistent with the PARDD API requirements.





PARDD API DATA FLOW



Improve transparency

Reduce effort for prior authorization

Leverage available clinical content and increase automation

Source: HL7 Da Vinci Prior Authorization Support (PAS) FHIR IG





INTEROPERABILITY STANDARDS FOR APIs

CMS proposes specific technical standards with which each API would be required to comply. In addition, CMS proposes to allow flexibility for payers wishing to use updated standards. CMS is strongly encouraging, but not requiring, the use of certain implementation guides (IGs) to support API development.



MODIFICATION TO STANDARDS LANGUAGE

Revise regulatory language to further clarify which standards codified at § 170.215 apply to each required API.



USE OF UPDATED STANDARDS

An impacted payer may use an updated standard, instead of the standard specified in the applicable regulation, as long as it does not disrupt an end user's ability to access the data available through the API.



USE OF IMPLEMENTATION GUIDES

Withdraw the December 2020 CMS Interoperability proposed rule's requirement to use IGs and, instead, strongly recommend the use of certain IGs.





PROPOSED STANDARDS BY API

STANDARDS	PATIENT ACCESS API	PROVIDER ACCESS API	PROVIDER DIRECTORY API	PAYER-TO- PAYER API	PARDD API
USCDI, at 45 CFR 170.213 (currently V1)					
FHIR Release 4.0.1					
HL7 FHIR U.S. Core IG STU 3.1.1					
HL7 SMART APP Launch Framework IG 1.0.0					
HL7 FHIR Bulk Access (Flat FHIR) IG v 1.0.0 STU 1	\bigotimes		\times		\bigotimes
OpenID Connect Core 1.0	\bigcirc				

Note: The Patient Access and Provider Directory API were finalized in the CMS Interoperability and Patient Access final rule.





RECOMMENDED IGS BY API

IMPLEMENTATION GUIDE	PATIENT ACCESS API	PROVIDER ACCESS API	PROVIDER DIRECTORY API	PAYER-TO- PAYER API	PARDD API
CARIN for Blue Button IG Version STU 1.1.0			$\overline{\times}$		\bigotimes
Da Vinci PDex IG Version STU 1.0.0			\bigotimes		\bigotimes
Da Vinci PDex U.S. Drug Formulary IG Version STU 1.1.0			\bigotimes		\bigotimes
Da Vinci PDex Plan Net IG Version STU 1.1.0	\bigotimes	\bigotimes		\times	\bigotimes
Da Vinci Payer Coverage Decision Exchange (PCDE) IG Version STU 1.0.0	\times	\bigotimes	\bigotimes		\bigotimes
Da Vinci Prior Authorization Support (PAS) IG Version STU 1.1.0	\bigotimes	\bigotimes	\bigotimes	\bigotimes	
Da Vinci Coverage Requirements Discovery (CRD) IG Version STU 1.0.0	\otimes	\times	\bigotimes	\bigotimes	
Da Vinci Documentation Templates/Rules (DTR) IG Version STU 1.0.0	\bigotimes	$\overline{\times}$	\bigotimes	\bigotimes	

Note: The Patient Access and Provider Directory API were finalized in the CMS Interoperability and Patient Access final rule.







REQUESTS FOR INFORMATION

CMS issued the following requests for information in the proposed rule.

CMS is gathering information on these topics to support future rulemaking or other initiatives.

ACCELERATING THE ADOPTION OF STANDARDS
RELATED TO SOCIAL RISK FACTOR DATA
We request information on barriers to adopting standards, and
opportunities to accelerate standards adoption related to social risk
data. Given the importance of these data, we look to understand how
to better standardize and liberate these data to address social

ELECTRONIC EXCHANGE OF BEHAVIORAL HEALTH INFORMATION

determinants of health.

We are seeking comment on how CMS might leverage APIs to facilitate electronic data exchange between and with behavioral health care providers and community-based organizations, who have lagged behind other provider types in EHR adoption.





REQUESTS FOR INFORMATION

CMS issued the following requests for information in the proposed rule.

CMS is gathering information on these topics to support future rulemaking or other initiatives.

IMPROVING THE ELECTRONIC EXCHANGE OF INFORMATION IN MEDICARE FFS

We are seeking comment on how Medicare FFS could support improved medical documentation exchange between and among providers, suppliers, and patients. We believe it could enable better care for beneficiaries if covered services are not delayed by administrative inefficiencies.

ADVANCING INTEROPERABILITY AND IMPROVING PRIOR AUTHORIZATION PROCESSES FOR MATERNAL HEALTH

We are seeking comment on how health IT standards, such as FHIR, can be used to promote interoperability with, for instance, human services to improve maternal health outcomes. We are also interested in comment on special considerations for prior authorization in maternal healthcare.

ADVANCING THE TRUSTED EXCHANGE
FRAMEWORK AND COMMON AGREEMENT (TEFCA)
We are seeking comment on how to encourage providers and payers
to enable exchange under the Trusted Exchange Framework and
Common Agreement (TEFCA) to make patient information available to
providers and support the transmission of coverage and prior
authorization requests from providers.





HELPFUL RESOURCES

HIIG INTEROPERABILITY WEBSITE



- CMS Interoperability and Patient Access Final Rule Fact Sheet
- (December 2020) CMS Interoperability and Prior Authorization Proposed Rule Fact Sheet
- CMS Interoperability FAQs

...

TECHNICAL STANDARDS AND IMPLEMENTATION SUPPORT

- Technical Standards: FHIR, SMART IG/OAuth 2.0, OpenID Connect, USCDI
- Implementation Support for APIs: <u>CARIN for Blue Button IG</u>, <u>PDex IG</u>, <u>PDex Formulary IG</u>, <u>PDex Plan Net IG</u>, US Core IG, CRD IG, DTR IG, PAS IG, PCDE IG, Bulk Data Access IG

Visit our <u>website</u> for additional resources and information



POLICY: FEDERAL REGISTER

- (December 2020) CMS Interoperability and Prior Authorization Proposed Rule
- CMS Interoperability and Patient Access Final Rule
- ONC 21st Century Cures Act Final Rule



QUESTIONS?

Contact us at CMSHealthInformaticsandInteroperabilityGroup@cms.hhs.gov





HOW TO COMMENT



ELECTRONICALLY - March 13, 2023

http://www.regulations.gov

REGULAR MAIL - March 13, 2023, 5:00pm ET

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0057-P, P.O. Box 8013, Baltimore, MD 21244-8013



EXPRESS OR OVERNIGHT MAIL

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0057-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850

