CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule Fact Sheet

The Centers for Medicare and Medicaid Services (CMS) published its Interoperability Standards and Prior Authorization for Drugs Proposed Rule on April 14, 2026, with comments due on June 15, 2026. CMS published a fact sheet on the proposed rule.

Background

CMS continues its effort to reshape prior authorization within healthcare by extending many of the provisions contained in the 2020 CMS Interoperability and Patient Access Final Rule and the 2024 CMS Interoperability and Prior Authorization Final Rule to the prescribing for and payment for prescription drugs. Included in the proposed rule are also proposals to modify existing HIPAA Administrative Simplification standards for dental, professional, and institutional transactions, as well as updates to previously finalized prior authorization application programming interfaces (APIs).

Impacted payers under this proposed rule include 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).

Key Provisions of the Proposed Rule

Electronic Prior Authorization for Drugs

CMS proposes requiring impacted payers to incorporate coverage and documentation requirements into the Prior Authorization API which was finalized under the 2024 prior authorization final rule. The proposed deadline for drugs to be included in the Prior Authorization API is October 1, 2027 with some impacted payers also being required to support the National Council for Prescription Drug Programs (NCPDP) standards at that time.

HIPAA Administrative Simplification: Adoption of the FHIR Standards for Prior Authorization Related Transactions

HHS also proposes to adopt the HL7® Fast Healthcare Interoperability Resource (FHIR®) standard and certain FHIR implementation guides (IGs), such as the standards for the "referral certification and authorization" and the "eligibility for a health plan" transactions related to prior authorization. HHS also proposes to adopt the HL7 FHIR Da Vinci Clinical Data Exchange (CDex) IG as the standard for attachments accompanying prior authorization transactions.

CMS proposes that HIPAA covered entities that engage in applicable electronic transactions will be required to comply with these proposals no later than 24 months after the final rule's effective date, while small health plans will have 36 months.

Payer Reporting of API Endpoints and Associated Information

CMS is proposing requiring impacted payers to report their API endpoints for each of the interoperability APIs to CMS so they can be published in a centralized location. CMS is also proposing to require payers to submit to CMS a direct URL to the interoperability API's FHIR capability statements and required technology documentation. Impacted payers would need to report this information to CMS no later than 60 days after the effective date of a final rule, or 60 days prior to an impacted payer beginning to cover patients.

Adoption of Updated Health IT Standards and Specifications/Updates to Standards and IGs for Interoperability APIs

Included in the proposed rule are a series of proposals from the Office of the National Coordinator for Health Information Technology (ONC) to adopt updated versions of health IT standards and specifications related to interoperability APIs. The current version of the proposed standards expires on January 1, 2028. Additionally, CMS proposes to cross-reference the previously updated prior authorization health IT standards and specifications required by ONC, and require impacted payers to use a set of recommended IGs for the interoperability APIs. CMS proposes that conformance with the IGs will be required by October 1, 2027.

CMS also requests comments on several FHIR® At Scale Taskforce (FAST) and Da Vinci IGs for future rulemaking.

Improving Communications and Decision Timeframes for Prior Authorizations

CMS proposes that impacted payers will be required to provide notice to the prescriber of drug-related prior authorization decisions within specific timeframes. The proposed timeframes are as follows:

- No later than 24 hours after receiving a request for outpatient drugs;
- Seven days for standard items and services requests, 72 hours for expedited requests;
- 24 hours after receiving a prior authorization request for CHIP and FFS programs. This will only apply to prior authorization requests for drugs when Federal Financial Participation (FFP) funds are available; and
- For QHP issuers and FFEs, notice of a prior authorization decision to a requesting provider must be provided as expeditiously as the enrollee's health condition requires, but no later than 72 hours after standard prior authorization requests and no later than 24 hours for expedited prior authorization requests for all drugs.

Compliance with these timelines would begin October 1, 2027.

Expanding Communication of Prior Authorization Denials for Drugs

CMS proposes that beginning October 1, 2027, impacted payers will be required to give providers a specific reason for denying prior authorization requests for any drug.

Prior Authorization Metrics

The 2024 final rule required impacted payers to annually report prior authorization metrics for non-drug items and services on their public websites. CMS proposes to require impacted payers to report additional data for existing metrics and prior authorization metrics on non-drug items and services. CMS also proposes that Medicaid managed care plans and CHIP managed care entities must report prior authorization metrics for non-drug items and services finalized in the 2024 final rule, as well as prior authorization metrics for non-drug items and services in the proposed rule. Additionally, CMS proposes to require impacted payers to annually report prior authorization metrics for drugs on their public websites. Compliance dates for reporting vary based on type of reporting and the type of payer impacted by the proposal.

API Usage Metrics

CMS updates the 2024 final rule API usage metric requirements, proposing that impacted payers annually report Provider Access, Payer-to-Payer, and Prior Authorization API usage metrics to CMS. Impacted payers would begin reporting the metrics in 2028. Additionally, CMS proposes new reporting levels and deadlines for when metrics from the previous year should be submitted. These new requirements vary by payer type in both reporting level and deadline.

Updates to the Patient Access, Provider Access, and Payer-to-Payer APIs

CMS also proposes for impacted payers to provide detailed information about prior authorization requests and decisions for all drugs available through the Patient Access, Provider Access, and Payer-to-Payer APIs. Information required to be transmitted by the APIs includes:

- Prior authorization status;
- Date of prior authorization approval or denial;
    - For the Payer-to-Payer API, only approvals must be included.
- Date or circumstance under which the authorization ends;
- The drug, or drugs approved, including dosages;
- For the Patient Access and Provider Access APIs, a specific reason the request was denied; and
- Related structured administrative and clinical documentation submitted by a provider.

Proposed compliance with these changes would begin October 1, 2027 for impacted payers.

Requests for Information (RFIs)

CMS also includes a number of RFIs within the rule, including:

- Electronic event notification for value-based care and care coordination;
- Increasing healthcare resiliency;
- Improving implementation of payer API technology;
- Step therapy; and
- Laboratory tests and durable medical equipment, prosthetics, orthotics, and supplies items.

If you have any questions about the contents of this proposed rule, please contact us at advocacy@ahima.org.