Summary of Proposed Provisions in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P)

This proposed rule builds on the 2020 CMS Interoperability and Patient Access final rule (CMS-9115-F) and the 2024 CMS Interoperability and Prior Authorization final rule (CMS-0057-F), which require 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") to implement Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization Application Programming Interfaces (APIs) (collectively "interoperability APIs"). In this rule, CMS is proposing to add QHP issuers offering plans on the FF-SHOP as an impacted payer subject to the interoperability requirements of the previous rules and these proposals. In addition, we propose to amend the requirement in 45 CFR 156.223(c) to publicly report prior authorization metrics to apply it to small group market QHP issuers on the FF-SHOPs beginning in 2028.

While the prior authorization requirements in the 2024 final rule focused on non-drug items and services, the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (CMS-0062-P), extends many of those requirements to cover prior authorizations for drugs. Specifically, CMS now proposes to require impacted payers to support electronic prior authorization, to make decisions on requests within shorter timeframes that align CMS programs, and to increase transparency for the prior authorization of drugs. In addition, CMS is proposing to require impacted payers to update health information technology (health IT) standards and to report interoperability API endpoints and API usage metrics to CMS.

Furthermore, under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Department of Health and Human Services (HHS) is proposing to adopt certain Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) standards and implementation specifications for transactions related to prior authorizations. These HHS proposals would apply to all HIPAA covered entities (health care providers, health plans, and health care clearinghouses) that electronically exchange prior authorization information for items and services.

The proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (CMS-0062-P), described in the table below, would enhance transparency of prior authorization requirements allowing for faster and more informed care decisions.

KEY PROVISIONS	CURRENT POLICY	PROPOSED POLICY
Electronic Prior Authorization for Drugs	Requires impacted payers to support electronic prior authorization for non-drug items and services via the Prior Authorization API (the 2024 final rule).	Would require impacted payers to incorporate coverage and documentation requirements for drugs covered under a medical benefit into the Prior Authorization API.

KEY PROVISIONS	CURRENT POLICY	PROPOSED POLICY
		Would require impacted payers to support electronic prior authorization for drugs covered under a pharmacy benefit using certain National Council for Prescription Drug Programs (NCPDP) standards.
Adopt FHIR for Prior Authorization-Related Transactions Under the Administrative Simplification Provisions of HIPAA	The X12N 278 and X12N 270/271 transaction standards are adopted under HIPAA.	Propose to adopt the FHIR standard and certain associated implementation guides (IGs) in place of the X12N 278 and X12N 270/271 transaction standards for transactions related to prior authorization.
Require Payers to Submit API Endpoints and Associated Information to CMS	N/A	Impacted payers would report API endpoints for each of the interoperability APIs and required information to CMS annually or within 7 days of any changes to the required information.
Require Additional Standards for Implementation	Requires impacted payers to use certain standards and specifications to implement APIs and recommends certain standards and specifications (the 2024 final rule).	Would require impacted payers to use standards and specifications that were recommended in the 2024 final rule to implement APIs.
Office of the National Coordinator for Health Information Technology (ONC) Rider to Adopt Updated Versions of Health IT Standards	Currently adopted versions of standards and specifications codified in 45 Code of Federal Regulations (CFR) 170.215 ("Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization" final rule [HTI-4 final rule]).	Propose to adopt updated versions of required health IT standards and specifications in 45 CFR 170.215(j), (k), (m), and (n) for interoperability APIs.

KEY PROVISIONS	CURRENT POLICY	PROPOSED POLICY
Prior Authorization Timeframes	Requires MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care programs, and CHIP managed care entities to make prior authorization decisions on non-drug items and services within 7 calendar days for standard requests and 72 hours for expedited requests (the 2024 final rule). QHP issuers on the FFEs are not subject to the timeframes established in the 2024 final rule; rather they must provide patients with notice on prior authorization decisions regarding non-drug items and services within certain established timeframes in 45 CFR 147.136(b)(3)(i).	Would require that QHP issuers on the FFEs to provide notice to the requesting provider of prior authorization decisions on non-drug items and services as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after receiving a standard request and no later than 72 hours after receiving an expedited request. Would require that impacted payers make prior authorization decisions on all drugs within certain timeframes.
Require a Specific Reason for Denying a Prior Authorization Request for Drugs	Requires impacted payers to include a specific reason for denying a prior authorization request for non-drug items and services (the 2024 final rule).	Would require impacted payers to include a specific reason to providers for denying a prior authorization request for all drugs.
Publicly Report Prior Authorization Metrics	Requires impacted payers to publicly report certain prior authorization metrics on non-drug items and services (the 2024 final rule).	Would require impacted payers to publicly report additional prior authorization metrics on non-drug items and services. Would require impacted payers to publicly report certain prior authorization metrics on all drugs (excluding covered Part D drugs for Medicare Advantage-Prescription Drugs [MA-PDs]).
Report API Usage Metrics	Requires impacted payers to report certain metrics regarding the use of the Patient Access API to CMS.	Would revise reporting deadline and reporting level for certain payers' Patient Access API usage metrics. Would require impacted payers to also report annual usage metrics regarding use of the Provider Access, Payer-to-Payer, and Prior Authorization APIs.

KEY PROVISIONS	CURRENT POLICY	PROPOSED POLICY
Increase Transparency and Access to Drug Prior Authorization Information	Requires impacted payers to include information about prior authorizations for non-drug items and services via Patient Access, Provider Access, and Payer-to-Payer APIs (the 2024 final rule).	Would require impacted payers to include information about prior authorizations for all drugs via the Patient Access, Provider Access, and Payer-to-Payer APIs.
Open Payments Policy	The existing Open Payment program (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests final rule [Open Payments final rule]) does not currently define "failure to report."	Would define "failure to report" which would be foundational to enabling CMS to impose a civil monetary penalty (CMP) upon a reporting entity that failed to provide records pursuant to a CMS audit.