STRATEGIC HEALTH CARE

Executive Summary: CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule

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Bottom line for executives

- This proposal is CMS's next major interoperability rule. It extends prior authorization interoperability requirements beyond non-drug items and services to drugs, using different standards depending on whether the drug is covered under a medical or pharmacy benefit.
- The practical effect is to push health plans, PBMs, provider technology vendors, and providers toward a more end-to-end electronic prior authorization workflow, with clearer denial reasons, tighter and more standardized response timelines, more public performance reporting, and more standardized API discovery.
- For most impacted payers, the main operational deadline is October 1, 2027. New reporting and public posting requirements generally begin in 2028. Small-group QHP issuers on the FF-SHOP would be brought into the interoperability framework starting with plan years beginning on or after January 1, 2028.
- The proposed rule is strategically important because it reaches beyond CMS program policy into HIPAA transaction standards. HHS is proposing HL7 FHIR-based standards for prior-authorization-related HIPAA transactions, which would affect all HIPAA covered entities, not only the payers directly regulated elsewhere in the rule.

1. What the rule does

The proposal applies to Medicare Advantage organizations, state Medicaid fee-for-service programs, state CHIP fee-for-service programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan issuers on the federally facilitated exchanges. CMS also proposes to include issuers offering small-group QHPs on the FF-SHOP within the same overall interoperability framework.

The central policy move is to require impacted payers to support electronic prior authorization for all drugs that require prior authorization. For drugs covered under the medical benefit, payers would expand the Prior Authorization API finalized in the 2024 interoperability rule. For drugs covered under the pharmacy benefit, payers would use the NCPDP SCRIPT, Formulary & Benefit, and Real-Time Prescription Benefit standards.

CMS and ONC are also using this proposal to harden the technical architecture around payer APIs by moving certain implementation guides from recommended to required status, collecting API endpoint information for centralized publication, and expanding API usage reporting so CMS can monitor whether these policies are actually being used in practice.

2. Why this matters strategically

This is not a narrow IT rule. It is a major administrative simplification and operating-model rule for plans, providers, EHR vendors, pharmacy benefit workflows, and utilization management teams. CMS is signaling that prior authorization should become a digital, standards-based workflow rather than a fragmented mix of portals, faxes, phone calls, and payer-specific rules.

For health systems and physician groups, the most important benefit is potential reduction in friction around drug prior authorization, especially for therapies administered under the medical benefit and for drugs that generate repeated documentation requests, denials for missing information, and appeals. For payers, the proposal creates new build, governance, testing, and compliance obligations, but also sets up the prospect of fewer manual touches, clearer intake requirements, and more scalable data exchange.

The broader policy signal is equally important: HHS is proposing FHIR-based HIPAA transaction standards for prior-authorization-related transactions. That is a meaningful shift because it starts to pull HIPAA administrative simplification toward modern API-based exchange rather than older transaction paradigms.

3. Major policy proposals

Electronic prior authorization for drugs. CMS proposes that impacted payers support electronic prior authorization for all drugs. The rule distinguishes between drugs under the medical benefit and drugs under the pharmacy benefit. Medical-benefit drugs would flow through the Prior Authorization API built on the HL7 FHIR Da Vinci CRD, DTR, and PAS implementation guides. Pharmacy-benefit drugs would flow through applicable NCPDP standards. This is the single biggest policy change in the rule.

Clearer communications and response timeframes. CMS proposes that impacted payers provide a specific reason for denying prior authorization requests for drugs. It also proposes drug-specific decision-timeframe requirements or alignment with existing drug decision-timeframe requirements. For QHP issuers on the FFEs, the proposal would tighten and standardize provider notification timelines, including 7 calendar days for standard non-drug requests, 72 hours for standard drug requests, and 24 hours for expedited drug requests.

Expanded transparency and performance reporting. Impacted payers would have to report additional prior authorization metrics and publicly post a set of metrics for drug prior authorizations, with numeric counts in addition to percentages for certain measures. CMS is clearly moving toward more visible payer performance measurement in prior authorization.

API endpoint reporting and discoverability. Payers would report API endpoints and related public URLs for documentation, protocols, and, where applicable, registration information so CMS can publish a centralized source for API discovery. This addresses a practical market problem: even when APIs exist, they are hard to find and integrate.

API usage metrics. CMS proposes to collect usage metrics not just for Patient Access APIs, but also for Provider Access, Payer-to-Payer, and Prior Authorization APIs. This is a compliance and market-adoption signal: CMS wants evidence that the APIs are not merely implemented, but actually used.

Extension of requirements to small-group FF-SHOP issuers. CMS proposes to apply existing and new interoperability requirements to small-group market QHP issuers on the FF-SHOP, generally beginning with plan years on or after January 1, 2028. CMS argues the burden should be manageable because current FF-SHOP issuers also operate in the individual FFE market and already support similar capabilities there.

Open Payments enforcement clarification. Separately, CMS proposes to define ‘failure to report’ for Open Payments audits in a way that would permit civil monetary penalties when manufacturers or GPOs do not timely provide requested audit documents. This is not central to prior authorization, but it is a meaningful enforcement proposal embedded in the rule.

4. Compliance dates and implementation calendar

October 1, 2027 is the key date for most payer operational changes related to electronic prior authorization for drugs, denial-specific communications, and certain related requirements. That date should be viewed as the main system-build and operational-readiness milestone for plans and their vendors.

For small-group QHP issuers on the FF-SHOP, existing interoperability requirements finalized in earlier rules would generally apply for plan years beginning on or after January 1, 2028. CMS also proposes API usage reporting and public posting requirements that generally start in 2028.

ONC would adopt updated versions of certain 45 CFR 170.215 standards and specifications, with some currently adopted versions proposed to expire on January 1, 2028. That means implementation planning should assume version management and transition planning, not just one-time build work.

For QHP issuers on the FFEs, API usage metric reporting would align with the annual QHP certification process rather than a standalone March 31 deadline. For Medicaid managed care plans and CHIP managed care entities, reporting would align with rating periods and generally be due within 90 days after the close of each rating period.

5. Operational implications for health systems, plans, and vendors

For health systems and large medical groups, the near-term question is readiness of EHR and revenue-cycle workflows to consume payer prior authorization APIs for drugs, especially for infusion, specialty, oncology, and other therapies that often sit under the medical benefit. The value proposition is strongest where current workflows are manual, documentation-heavy, and denial-prone.

For health plans and PBM-related operations, the rule requires tighter alignment among medical management, pharmacy management, interoperability teams, compliance, vendor management, and member/provider services. The difficult work will not be limited to API coding; it will include coverage-rule translation, documentation-rule maintenance, denial-reason specificity, endpoint governance, testing, and reporting integrity.

For technology vendors, this rule should accelerate demand for workflow orchestration, standards implementation, endpoint management, directory/discovery services, and analytics that track prior authorization performance. Vendors that already built around the 2024 rule will have an advantage because CMS is largely extending that architecture rather than replacing it.

For CEOs and operating executives, the practical implication is that prior authorization is increasingly becoming an enterprise interoperability issue, not just a utilization-management issue. Organizations will need coordinated governance across clinical operations, digital, compliance, payer contracting, pharmacy, and managed-care administration.

6. Financial and regulatory impact

CMS estimates total 10-year costs of approximately $396.91 million, excluding premium tax credit effects and any savings from prior authorization improvements. The largest cost bucket is adoption of FHIR standards for prior-authorization-related HIPAA-standard transactions, estimated at about $243.67 million over 10 years. The rule's accounting statement shows annualized monetized costs of about $40.68 million at a 7 percent discount rate and $40.06 million at a 3 percent discount rate, while benefits are described as unquantified rather than formally monetized.

CMS explicitly states that it expects meaningful long-term savings and administrative efficiencies from reduced paperwork, faster response times, fewer denials tied to missing information, and fewer appeals. But those benefits are not precisely quantified in the rule. In other words, the business case is directional and operationally plausible, but not yet fully evidenced in formal monetary terms.

For one subset of health plans that may need to newly develop FHIR capability for HIPAA prior-authorization transactions, HHS estimates a one-time development and implementation cost of roughly $327,000 per entity over two years, plus annual maintenance costs of about $78,000 per entity. The federal government's 10-year cost is estimated at about $74.21 million, including Medicare, Medicaid, and premium tax credit effects.

7. Executive assessment

This is a consequential proposed rule with real strategic significance. It expands CMS's 2024 interoperability framework into the drug prior authorization space, tries to solve a persistent industry pain point, and pushes the market toward more standardized digital exchange across payers and providers.

The biggest upside is reduced friction in prior authorization, especially for high-volume or high-acuity drug workflows. The biggest implementation risk is not the API standard itself but operational translation: getting coverage rules, documentation requirements, endpoint discoverability, denial communications, and reporting logic aligned across multiple internal functions and external vendors.

For a health system CEO, the priority is to direct pharmacy, revenue-cycle, physician enterprise, digital, and managed-care leaders to identify where drug prior authorization is creating the most delay, denial, and labor today, then assess whether the organization's core EHR and payer partners are positioned to capitalize on this rule. For a payer CEO, the priority is enterprise readiness for October 2027, including cross-functional ownership, vendor accountability, and a credible plan for public metrics and regulator-facing reporting.

Overall, the proposal is best understood as a major interoperability and administrative simplification rule that could materially improve prior authorization operations over time, but only if plans, providers, and vendors convert the technical standards into reliable frontline workflows.

Source: CMS and ONC proposed rule CMS-0062-P, public inspection document 2026-07205.