CMS Proposed Rule and Request for Information: *Interoperability Standards and Prior Authorization for Drugs*

In April 2026, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule, *Interoperability Standards and Prior Authorization for Drugs* (CMS-0062-P), that is intended to improve the electronic exchange of health care data and streamline processes related to prior authorization by increasing the interoperability of systems used across the health care industry. Building on the 2020 Interoperability and Patient Access final rule and the 2024 Interoperability and Prior Authorization final rule, this proposed rule closes a major gap in the prior regulatory framework by extending electronic prior authorization (ePA) requirements to drugs, a category deliberately left out of the 2024 rule. The proposed rule also mandates FHIR implementation guides that were previously only recommended, proposes a landmark shift in HIPAA transaction standards for prior authorization, and includes five Requests for Information (RFIs) on topics ranging from electronic event notifications to cybersecurity resiliency. The comment deadline is June 15, 2026. Civitas intends to submit formal comments and is actively seeking written member input to inform our response.

What the Rule Proposes

A. Electronic Prior Authorization for Drugs

The 2024 CMS Interoperability Rule finalized a Prior Authorization API and process requirements for non-drug items and services, but explicitly excluded drugs, noting that drug PA workflows and standards differ meaningfully from other services. This proposed rule addresses that gap, with CMS proposing two parallel standards frameworks, depending on how the drug is covered:

- Drugs under a medical benefit would be incorporated into the existing FHIR-based Prior Authorization API, using the Da Vinci Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS) implementation guides.
- Drugs under a pharmacy benefit would use three NCPDP standards: the NCPDP SCRIPT standard for electronic PA transactions, the NCPDP Formulary & Benefit (F&B) standard for formulary and coverage information, and the NCPDP Real-Time Prescription Benefit (RTPB) standard for point-of-prescribing eligibility and cost-sharing data.

These two frameworks are mutually exclusive by design and together cover the full universe of drugs requiring prior authorization. Medicare Advantage organizations are already subject to NCPDP SCRIPT requirements; this proposal extends all three NCPDP standards to Medicaid FFS, Medicaid managed care, CHIP, and issuers of Qualified Health Plans (QHPs) on Federally-Facilitated Exchanges. The proposed compliance date for all drug ePA requirements is October 1, 2027.

B. Mandatory FHIR Implementation Guides

The 2024 rule required FHIR APIs but treated several key implementation guides (IGs) as *recommended* rather than required. This proposed rule elevates six IGs to *mandatory* status across the five payer APIs: CARIN Blue Button, Da Vinci PDex US Drug Formulary, Da Vinci Plan Net, FHIR Bulk Data Access, and Da Vinci CRD/DTR/PAS. Making these IGs required

means payers will face conformance testing and enforcement, not just encouragement. CMS also proposes to use testing tools to verify conformance and to allow payers to voluntarily adopt updated versions of required standards as they are released.

C. Prior Authorization Process: Denial Reasons, Timeframes, and Reporting

On the process side, the rule proposes three improvements specifically for drug PA:

- **Specific denial reasons:** Payers must provide a substantive, specific reason when denying a drug PA request, not a generic or administrative response.
- **Decision timeframes:** Exchange QHP issuers, previously excluded from the 2024 timeframe requirements, would be subject to the same standards as other impacted payers: 7 calendar days for standard requests and 72 hours for expedited requests.
- **Public reporting:** The public reporting requirements for PA metrics – approvals, denials, and timeframes – would be extended to drugs, enabling CMS and the public to track payer performance on drug PA for the first time.

D. API Endpoint Reporting and Usage Metrics

CMS proposes to require all impacted payers to report their API endpoints and documentation for all five required APIs (Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization) to CMS for public publication. This would create a centralized, publicly accessible directory of payer API endpoints, a meaningful development for any organization trying to systematically connect to or audit payer systems. Doing so would allow policymakers, researchers, and oversight bodies to assess whether payers are maintaining functional APIs and would give organizations like HIEs and HDUs a systematic way to identify connection opportunities and validate payer compliance. CMS also proposes to collect API usage metrics from payers to assess actual adoption and utilization, moving beyond attestation alone. The rule also proposes, for the first time, to extend interoperability requirements to small group market QHP issuers on the FF-SHOP exchanges, aligning them with requirements that apply to individual market QHP issuers on the federal exchanges.

E. HIPAA Standards: FHIR Replaces X12 for Prior Authorization

This may be the most architecturally consequential proposal in the rule. CMS proposes to replace the X12 278 transaction standard, which has governed HIPAA-compliant prior authorization transactions for decades, with FHIR-based standards as the HIPAA-designated transaction standard for *all* prior authorization and related eligibility transactions, not just those for drugs. This means the Da Vinci PAS, CRD, and DTR IGs would become the compliance baseline for every covered entity that conducts these transactions – hospitals, physicians, health plans, and clearinghouses – not just the impacted payers subject to CMS program requirements.

This is a fundamental and significant change. Clearinghouses, EHR vendors, billing systems, and any intermediary that routes or processes prior authorization transactions would need to adapt. CMS proposes a compliance timeline of 24 months after the final rule's effective date for most covered entities, and 36 months for small health plans; the final rule is expected in 2027. CMS is seeking extensive comment on the feasibility and timing of this transition, and it is an area where member experience and perspective will be especially valuable.

F. Open Payments and ONC Standards Adoption

The rule also proposes a technical clarification to the Open Payments program (adding a definition of "failure to report" to support civil monetary penalty enforcement during audits) and uses this joint rulemaking vehicle to allow ONC to adopt updated FHIR standards and implementation specifications under 45 CFR 170 for HHS use, with proposed expiration dates for older versions.

Requests for Information

In addition to the proposed rule provisions, CMS has embedded five RFIs seeking public input on issues it is considering for future action. RFI responses don't directly change the regulation, but they shape what CMS proposes next, making them a high-value opportunity for Civitas members to put operational experience and perspective directly on the record.

RFI A: Electronic Event Notifications for Value-Based Care and Care Coordination

CMS is exploring how electronic event notifications – particularly Admit, Discharge, and Transfer (ADT) alerts – could be better leveraged to support care transitions and value-based care, and whether to strengthen or expand the notification requirements established in the 2020 rule. Key questions include: What event types beyond ADT would be most valuable? What standards should govern notification exchange? What role should intermediary organizations, including HIEs, play in routing and aggregating notifications?

Why it matters: HIEs and HDUs are the primary infrastructure through which ADT notifications flow at scale. Many Civitas members built or significantly expanded ADT capabilities in response to the 2020 rule and now route millions of notifications annually. The Patient-Centered Data Home (PCDH) framework is proof of concept for HIE-driven, cross-state event notification at national scale. This RFI is a direct invitation for Civitas and our members to tell CMS what has been built, what gaps remain, and what federal policy could do to strengthen and sustain this infrastructure as a long-term national asset.

RFI B: Increasing Health Care Resiliency (Cybersecurity)

In the wake of the 2024 Change Healthcare cyberattack, CMS is asking how to improve the cybersecurity posture of interoperability infrastructure, ensuring that expanding API connectivity does not expand the attack surface in ways that create systemic risk. CMS asks about minimum security standards for API access, the role of third-party app developers, and how to support organizations with limited cybersecurity resources.

Why it matters: HIEs and HDUs have built exchange infrastructure with security, auditability, and governance as foundational principles. Trusted participation frameworks, enforceable use agreements, attribution-based query models, and documented audit trails are security mechanisms as much as they are governance tools. There is also a continuity dimension: when major systems fail – as they did during the Change Healthcare attack - HIE networks have served as emergency backup infrastructure, providing providers with access to patient records and a channel for clinical data routing when primary systems were unavailable. QIOs and RHICs also play a critical role, as technical assistance and quality improvement partners to providers, they are often the organizations helping practices assess and strengthen their cybersecurity posture, build operational resilience, and prepare for exactly the kind of systemic

disruption this RFI contemplates. This RFI is an opportunity to share what governed, community-accountable infrastructure has learned about securing health data at scale and sustaining continuity when other systems go down.

RFI C: Improving Implementation of Payer API Technology
CMS acknowledges that real-world adoption and utility of the payer APIs has been uneven despite the 2020 and 2024 requirements. This RFI asks: What is working and what is not? What barriers prevent providers from using the Provider Access API? Are payers meeting the spirit as well as the letter of the requirements? What role should intermediaries – including HIEs and HDUs – play in facilitating API adoption for providers who cannot connect directly?

Why it matters: HIEs and HDUs operate in the exact space between payers and providers that CMS is asking about. Members have direct, first-hand experience with where payer APIs return incomplete or inconsistent data, where smaller providers lack the technical capacity to connect without an intermediary, and where the absence of HIE infrastructure from the original design creates friction that CMS may not be aware of. This RFI is the opportunity to put that experience on the record, with specific examples, operational realities, and concrete recommendations for how HIE and HDU networks can more effectively support payer API adoption at the provider and community level.

RFI D: Step Therapy
CMS is seeking input on the prevalence and burden of step therapy ("fail first") requirements across payer types and drug categories, and whether current electronic prior authorization standards can adequately support the documentation and decision-making requirements step therapy entails. Step therapy protocols often require providers to document prior treatment attempts, clinical rationale, and patient-specific circumstances – the exact kind of structured clinical data that interoperability infrastructure is designed to support. HIE and HDU networks are well-positioned to speak to whether and how this kind of structured clinical documentation is being surfaced in prior authorization workflows today and what gaps remain. Civitas welcomes member feedback on experiences with step therapy and its intersection with data exchange and documentation workflows.

RFI E: Laboratory Tests and DME/DMEPOS Items
CMS is exploring whether to extend prior authorization requirements – including the ePA API standards proposed in this rule – to laboratory tests and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Civitas broadly supports standards-based approaches to reducing prior authorization burden across service categories; input from members – particularly those with APCDs, quality improvement programs that include lab data, or connections to community health centers and post-acute care settings – on the implications of extending prior authorization requirements to these categories will be important.

Strategic Implications for Civitas and Members

1. **The payer API architecture is expanding, and HIEs need to be in it.** CMS is building an increasingly comprehensive API-based data exchange architecture centered on payers. Five required FHIR APIs, mandatory implementation guides, endpoint reporting, usage metrics, and now drug PA integration – these all signal significant and growing federal

infrastructure investment. But the architecture as designed treats payer APIs primarily as bilateral connections: payer-to-patient, payer-to-provider, payer-to-payer. HIEs and HDUs, which already serve as the connective tissue between payers, providers, public health, and community partners in many states, are not explicitly positioned in this framework. Many of the "last mile" problems CMS is trying to solve through these API requirements – connecting data to providers who cannot connect directly, routing notifications across care settings, aggregating payer data for population health – are problems that HIE and HDU infrastructure is already built to address. Civitas members have FHIR endpoints, provider directory integration, trusted participation frameworks, and established relationships with thousands of providers. CMS needs to understand this infrastructure exists and what it can do.

2. **The HIPAA/FHIR shift is a system-wide event worth watching closely.** The proposal to replace X12 278 with FHIR-based PA standards as the HIPAA transaction standard is not just a standards update; it is a compliance reset for the entire industry. Every covered entity that processes prior authorization transactions, including clearinghouses and any intermediary that touches these workflows, will need to adapt. For members whose infrastructure intersects with prior authorization transactions – either through clinical system connections or quality measurement programs – this is a transition that warrants close attention. CMS will be seeking detailed comment on feasibility and timelines, and member experience here is directly useful.
3. **Drug PA compliance adds new pressure on Medicaid partners.** The extension of NCPDP SCRIPT, F&B, and RTPB standards to Medicaid FFS and managed care programs by October 2027 will create significant operational demands for state Medicaid systems, particularly at a time when they are already making significant system changes to comply with community engagement and eligibility requirements under HR1. State readiness varies widely; members who serve as technical intermediaries for state Medicaid agencies, or who support Medicaid quality improvement programs, should be thinking now about whether existing system interfaces will need to be updated and what the implications are for current and planned connectivity.
4. **Payer API adoption: implementation meets reality.** CMS's acknowledgement in RFI C that payer API adoption has been slower and more uneven than anticipated reflects a gap between regulatory requirements and operational outcomes that the Civitas network is uniquely positioned to address. HIEs and HDUs working at the intersection of payers and providers have accumulated concrete, on-the-ground knowledge about where the APIs function as intended and where they fall short, i.e., where data is incomplete or inconsistent, where implementation guide conformance varies, and where providers who lack technical capacity are effectively shut out without an intermediary. This is precisely the kind of specific, practical experience CMS is seeking through this RFI, and it is where the Civitas network has the most to contribute.

Next Steps

Civitas will submit formal comments on this proposed rule by the June 15, 2026 deadline. We are seeking member input on any aspect of this rule. Please consider sharing your experience and perspective on:

- **Event notifications (RFI A):** What has your organization built? What gaps remain? What federal policy would help or hinder?

- **Payer API implementation (RFI C):** What friction have you encountered? What should CMS know about the real-world state of payer API adoption?
- **HIPAA/FHIR PA transition:** If your systems touch PA transactions, what would a shift from X12 278 to FHIR-based standards mean operationally?
- **Drug PA and NCPDP standards:** What are the operational implications for your Medicaid or managed care connections?
- **Any other concerns or opportunities:** If any provision of this rule affects your operations or your ability to serve patients and communities, we want to hear about it.

Please send feedback or questions to Karen Ostrowski.