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Understanding the CMS "Interop & Prior Authorization for Drugs" Proposed Rule (CMS-0062-P):

Impacts, Implications, and Considerations for Industry Comments

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PARTNERS | HEALTH IT MANAGEMENT CONSULTANTS

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Agenda

- Rule Overview
- Current State Legislative Outlook
- Perspectives NCPDP and HL7 DaVinci
- Panel Discussion

CMS-0062-P – Who, What and When

- **Primary Purpose:** Improve interoperability, reduce administrative burden, improve the speed and reliability of drug Prior Authorization (PA), align drug and medical ecosystem with *CMS Interoperability and Prior Authorization final rule (CMS-0057-F)*.
  - **Comments are due June 15, 2026.**
- **What it does?** Extends interoperability requirements in addition to electronic PA requirements to all drugs requiring PA (medical and pharmacy benefits).
- **Who is Impacted?:**
  - Medicare Advantage organizations
  - State Medicaid FFS programs
  - State CHIP FFS programs
  - Medicaid managed care plans
  - CHIP managed care entities
  - QHP issuers on the Federally-Facilitated Exchanges
  - Newly added: small-group market Qualified Health Plans (QHP) issuers on ***Federally-Facilitated Small Business Health Options Programs*** **(FF-SHOPs)**
  - This rule brings small group ACA plans into the same interoperability regime as MA and Medicaid for the first time.
- **Operational Deadlines:**
  - **October 1, 2027:** Main system-build and operational readiness for electronic drug PA and applied Program Interfaces (API) updates.
  - **January 1, 2028:** Compliance for small-group QHPs to small businesses through the Federally-Facilitated Small Business Health Options Program (FF-SHOP).

Key Proposals CMS-0062-P

- Extends interoperability requirements for the PA of non-drug items and services to include drug PA
- Mandates certain HL7® FHIR® implementation guides (IGs) currently recommended and introduces several new recommended IGs
- Adopting certain HL7® FHIR® standards and implementation specifications for transactions related to PA under Health Insurance Portability and Accountability Act (HIPAA)
- Impacted payers required to report their application programming interfaces (API) endpoints and related information for the Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization APIs to CMS
- Collecting additional API usage metrics
- Applying the existing interoperability requirements to small group market QHP issuers on FF-SHOPs

The Strategic Pivot - Unifying the Clinical & Pharmacy Ecosystem

1. Creates a single regulatory framework for all drug PA
   - CMS has created **a unified policy architecture** for drug PA across programs
2. Standards alignment across clinical and pharmacy systems.
   - **Medical-benefit drugs →HL7® FHIR® APIs** (expanding the 2024 Prior Authorization API)
   - **Pharmacy-benefit drugs → NCPDP SCRIPT, Formulary & Benefit, and Real-Time Prescription Benefit standards**
3. Shared operational rules and timelines
   - CMS is imposing **aligned decision timelines** across drug types and payer programs, including:
     - **24-hour decisions for urgent Medicaid outpatient drugs**
     - **72-hour decisions for standard exchange plan requests**

4. Integrated workflows between EHRs, pharmacy systems, and payers

5. Transparency and performance reporting across both ecosystems. CMS requires payers to publicly report:
   - PA volumes
   - Approval/denial rates
   - Turnaround times
   - API usage metrics.

6. Unified Compliance Timeline
   - Most operational requirements—including full ePA support for all drugs—take effect **October 1, 2027**, with reporting requirements beginning in 2028.

CMS-0062P Named & Recommended Standards

Required APIs (Expanding use from CMS-0057):

Prior Authorization API • Patient Access API • Provider Access API • Payer to Payer API

Named Technical Standards

(Pharmacy Benefit Drugs):

Mandates three specific **NCPDP standards**: **SCRIPT (v2023011)**, **Formulary & Benefit (F&B) (v6.0)**, and **Real-Time Prescription Benefit (RTPB) (v13)**

(Medical Benefit)

HL7 Da Vinci: Coverage Requirements Discovery (CRD), Documentation Templates & Rules (DTR), Prior Authorization Support (PAS)

Recommended Technical Standards (Medical Benefit):

- **Member Attribution (ATR)) List IG -** provides specific technical guidance for payers and providers to exchange Member Attribution Lists.
- **Clinical Data Exchange (CDex) IG:** provides detailed guidance that helps implementers use FHIR-based interactions to support specific clinical data exchange including PAS requests and supports multiple payload formats (such as C-CDA, PDFs, text files).

Recommended Infrastructure Standards (The "FAST" Framework):

- **HL7® FAST National Directory of Healthcare Providers & Services (NDH) IG:** CMS recommends the NDH IG to help payers report API endpoints in a standardized, compliant profile that supports national-scale discovery.
- **Scalability Guidance:** CMS encourages the use of **FAST** (FHIR at Scale Taskforce) initiatives to address industry-wide barriers such as identity matching and endpoint security without mandating a specific version yet.

Suggested & Required Standards (CMS-0057F vs CMS-0062P)

API / Feature	CMS-0057F (2024 Final Rule)	CMS-0062P (2026 Proposed Rule)
Prior Authorization (PA) Primary Requirement	Required for non-drug items and services	Required for all drugs requiring PA (Medical + Pharmacy)
HIPAA Transaction Standard	Historically X12 278	Proposes retiring X12 278; mandates HL7 FHIR for all HIPAA entities
Medical Drug PA Workflow	Out of scope (excluded drugs)	Mandatory: HL7 FHIR Da Vinci CRD, DTR, and PAS IGs.
Pharmacy Drug PA Workflow	Out of scope	Mandatory: NCPDP SCRIPT, Formulary & Benefit (F&B), and Real-Time Prescription Benefit (RTPB)
Patient Access API (Claims/Clinical)	Recommended: CARIN Blue Button and Da Vinci Pdex	Mandatory: CARIN Blue Button, Da Vinci PDex, and PDex US Drug Formulary.
Provider Access API	Recommended: Da Vinci PDex and Plan Net	Mandatory: Da Vinci PDex and Da Vinci PDex Plan Net.
Payer-to-Payer API	Recommended: Da Vinci PDex and Bulk Data Access	Mandatory: Da Vinci PDex and FHIR Bulk Data Access.
Provider Directory API	Recommended standards	Mandatory: HL7 FHIR Da Vinci PDex Plan Net.

Retiring HIPAA X12 278 and Adopt HL7® FHIR®

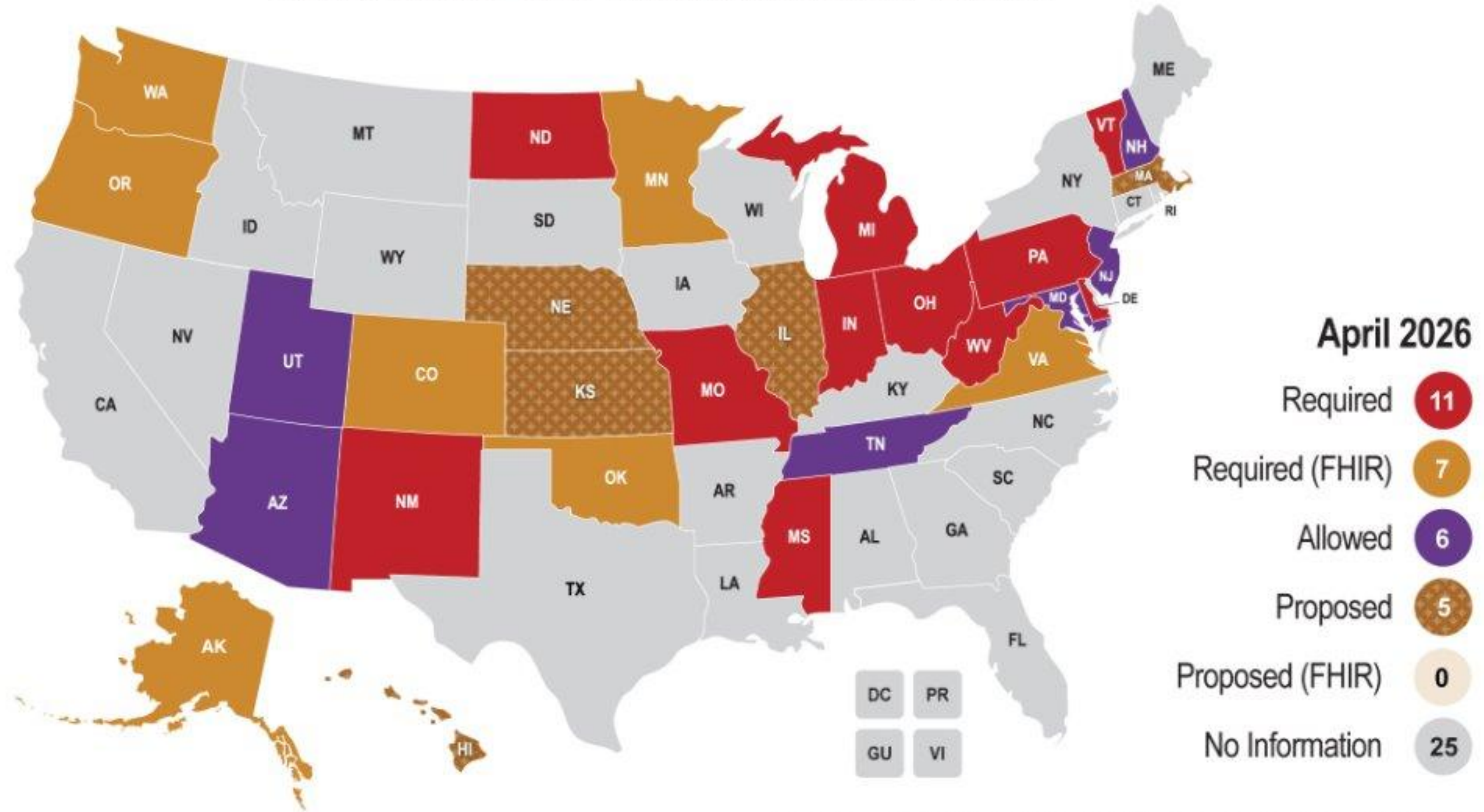
- **Rule Proposes:**
  - **Retiring X12 278** legacy X12N 278 PA transaction standard.
  - **Adoption:** of the **HL7®** **FHIR®** standards for medical PA-related transactions.
- **Impact:** This shift affects **all HIPAA-covered entities** (providers, plans, and clearinghouses), not just those regulated by CMS programs.

CMS has stated moving to the FHIR standard would allow:

- Real-time coverage checks
- Automated documentation retrieval
- Embedded clinical decision support
- Instant approvals for low-risk requests
- Pre-population of PA forms
- Reduction of provider burden
- Faster patient access to medications

Pragmatic Reality – Data Quality and Trust

- **Improving Data Reliability:** The mandate for Real Time Pharmacy Benefit (**RTPB)** and Formulary and Benefit (**F&B)** standards is an opportunity to improve data accuracy at the point of prescribing.
- **Streamlining Workflow:** Real-time data exchange (RTPB) reduces the "Trust Gap" by providing patient-specific cost and alternatives, which can decrease downstream PA friction.
- **Beyond Compliance:** Leveraging these APIs allows plans and PBMs to shift from static files to dynamic data exchange, supporting care coordination and reducing provider burden.


Medical ePrior Authorization Laws
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April 2026
Required 11
Required (FHIR) 7
Allowed 6
Proposed 5
Proposed (FHIR) 0
No Information 25
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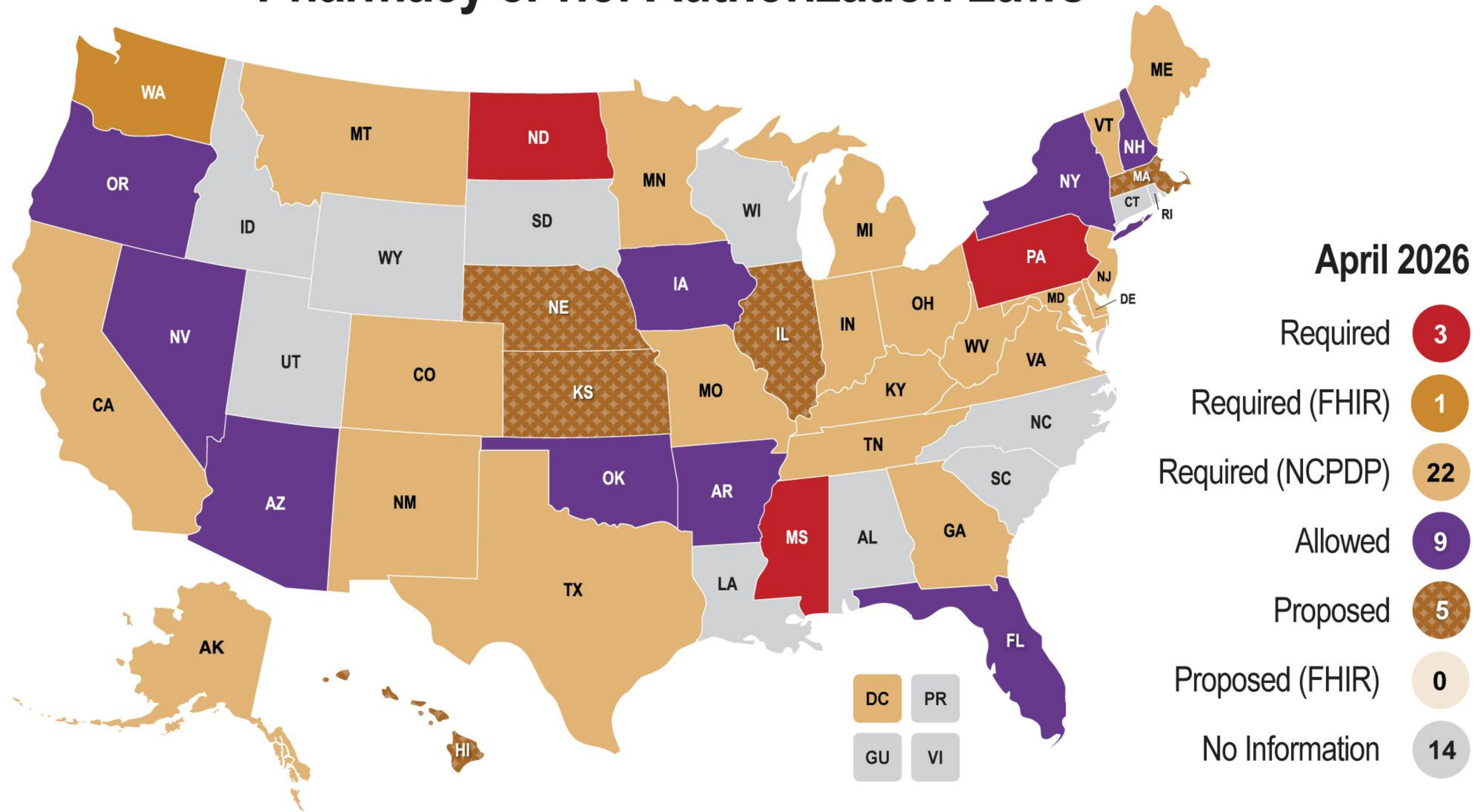
Pharmacy ePrior Authorization Laws



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Da Vinci Perspective

- The **HL7 Da Vinci Project** has been a key contributor to the **2026 Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P)**, which CMS and ONC jointly published on April 10, 2026.
- Da Vinci's role is to advance payer and provider information exchange and value-based care data needs. The **HL7 FHIR® Da Vinci "burden reduction" (CRD-DTR-PAS) implementation guides (IGs)** proposed to become part of HIPAA standards for prior authorization, and related eligibility, transactions.
- Leverages HIPAA Exception pilot results and December 2025 NSG listening session with Designated Standards Maintenance Organizations ("DSMO") and WEDI.

- Proposed rule underscores **paradigm shift** related to intersection of clinical and administrative data and creating more predictability impacting:
  - technical underpinnings modernization
  - API request/response data exchange models
  - operational workflows redesign
  - transparency of statuses and public metrics reporting
  - standards advancement
- Introduces significant shifts around:
  - **eligibility inquiries** for prior auth
  - **attachments** for prior auth (PAS invokes CDex IG)
  - **IG version** management and upgrade adoption
  - **expired IGs** per federal policy (not same as HL7's use of term)

NCPDP Perspective

- **Standardization:** NCPDP prior authorization transactions are intended to be used for products covered by a patient's pharmacy benefit (e.g., medications and supplies); exchanged in a real-time request and response mode.
- Provides a standard structure for exchanging the PA questions and answers between prescriber and payers, while allowing for payers to customize the wording of the questions
- Supports elements that allow for automation of the collection of data required for PA consideration (i.e., coded references for each question allowing an EHR vendor to systemically pull data from patient's medical record)

- **Workflow Integration:** The proposed 2026 rule, which mirrors many NCPDP goals, aims to require payers to implement NCPDP Formulary and Benefit Standard, Realtime Prescription Benefit Standard and the NCPDP SCRIPT standard – ePA Transactions
- This allows for a provider to know what drugs are covered under the patient's pharmacy benefit, if a PA is required for that drug and how much that drug will cost the patient out of pocket.
- **Implementation and Adoption Progress:** NCPDP is working closely with CMS to ensure that a "prospective" workflow is adopted for pharmacy ePA. Bi-weekly stakeholder meetings are being held by NCPDP and CMS to support this goal.

PANEL DISCUSSION

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Thank You

For additional assistance please contact Brian Dwyer, Business Strategist

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