BREAKING NEWS: CMS Releases Interoperability and Prior Authorization for Drugs Proposed Rule

Friday afternoon, CMS released the display copy of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (CMS-0062-P), which is set to be published in the Federal Register on Tuesday April 14. This is a significant rule for the health care industry as it builds on the 2020 CMS Interoperability and Patient Access (CMS-9115-F) final rule and 2024 CMS Interoperability and Prior Authorization (CMS-0057-F) final rule and includes additional proposals for data exchange standards, electronic prior authorization (ePA) attachments, and prior authorization performance tracking, as well as requests for information (RFIs) for potential future work.

Look to WEDI in the coming days and weeks as we break down these proposals and assist the industry with understanding the details and preparing comments for submission. WEDI will be holding a virtual Member Position Advisory event in the coming weeks to gather input from our members for the development of WEDI's comments on this proposed rule.

The following is a brief overview of the components of this proposed rule.

Impacted Payers

Impacted payers are limited to the following:

- 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
- Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs)
    - New: Add small group market QHP issuers offering plans on the Federally-facilitated Small Business Health Options Program (FF-SHOP) as additional impacted payers.

ePA for Drugs Under Medical Benefits

- Require impacted payers to implement the coverage and documentation requirements in the CMS-0057-F for drugs covered under a medical benefit.
    - Compliance date for supporting drug ePA for medical benefits: October 1, 2027
- Require the following Health Level Seven (HL7) Fast Healthcare Interoperability Resources® (FHIR®) Da Vinci implementation guides (IGs):
    - HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) IG, Version 2.0.1—STU 2*, proposed to expire on January 1, 2028, or Version 2.2.1—STU 2.2*
    - HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) IG, Version 2.0.1—STU 2*, proposed to expire on January 1, 2028, or Version 2.2.0—STU 2.2*
    - HL7 FHIR Da Vinci—Prior Authorization Support (PAS) IG, Version 2.0.1—STU 2*, proposed to expire on January 1, 2028, or Version 2.2.1—STU 2.2*
    - Compliance date for these IGs: October 1, 2027

ePA for Drugs Under Pharmacy Benefits

- Require state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to support ePA for drugs covered under a pharmacy benefit in alignment with existing requirements for Medicare Part D sponsors.
    - Compliance date for supporting drug ePA for pharmacy benefits: October 1, 2027
- Require the following National Council for Prescription Drug Programs (NCPDP) standards:
    - NCPDP SCRIPT Standard
    - NCPDP Real-Time Prescription Benefit (RTPB) Standard
    - NCPDP Formulary & Benefit (F&B) Standard

ePA Transaction Standard

- Modify the current Health Insurance Portability and Accountability Act (HIPAA) ePA standard requirement for "referral certification and authorization" and "eligibility for a health plan" transactions related to prior authorization.
- Require the following FHIR IGs:
    - Retail pharmacy drugs:
        - NCPDP Telecommunication Standard Implementation Guide Version F6, January 2020
        - NCPDP Batch Standard Implementation Guide, Version 15, October 2017
    - Dental, professional, and institutional health care eligibility benefit inquiry and response:
        - HL7 FHIR Release 4.0.1
        - HL7 FHIR US Core Implementation Guide STU 6.1.0
        - HL7 SMART App Launch Implementation Guide Release 2.0.0
        - HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.2.1—STU 2.2
    - For all other transactions, the X12 Standard Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279

Attachments for ePA

- Adopt the HL7 FHIR Da Vinci Clinical Data Exchange (CDex) IG as the standard for ePA to exchange files in various formats, such as Consolidated Clinical Document Architecture (C-CDA) documents, PDF, and text files.
    - Compliance date: 24 months after the final rule's effective date with small health plans having 36 months

Payer Reporting of API Endpoints and Associated Information

- Require impacted payers to report their application programming interface (API) endpoints for each of the interoperability APIs for CMS to publish in a centralized location.
    - Impacted payers would submit to CMS:
        - URL to their interoperability APIs' FHIR capability statements

        - URL(s) with required technical documentation about authorization, authentication protocol, implementation details, and API registration information for each interoperability API
    - Impacted payers would be required to:
        - Update information within one week of any changes
        - Verify that the reported information is still correct at least annually
    - Compliance date:
        - No later than 60 days after the effective date of the final rule
        - New impacted payers: No later than 60 days before they begin covering patients under the applicable CMS program

Updated Health IT Standards and Specifications

- Adopt updated versions of the health information technology (IT) standards and specifications, per the Office of the National Coordinator for Health Information Technology (ONC), related to the interoperability APIs:
    - Expiration date: Currently adopted versions of the proposed standards would expire on January 1, 2028
- Require use of the following versions of the below IGs that are currently recommended:
    - HL7 FHIR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG, Version 2.0.0—STU 2, or Version 2.2.0—STU 2.2*
    - HL7 FHIR Da Vinci—Payer Data Exchange (PDex) IG, Version 2.1.0—STU 2.1
    - HL7 FHIR Da Vinci—Payer Data Exchange (PDex) US Drug Formulary IG, Version 2.0.1—STU 2*, or Version 2.1.0—STU 2.1*
    - HL7 FHIR Da Vinci—Payer Data Exchange (PDex) Plan Net IG, Version 1.1.0—STU 1.1 US*, or Version 1.2.0—STU 1.2*
    - Compliance date: October 1, 2027
- CMS is also requesting comments on the following IGs for consideration in future rulemaking:
    - HL7 FAST Security for Scalable Registration, Authentication, and Authorization Release (FAST Security IG), Version 2.0.0—STU 2
    - HL7 FHIR Da Vinci Member Attribution (ATR) List IG, Version 2.1.0—STU 2.1
    - HL7 FHIR Da Vinci Clinical Data Exchange (CDex) IG, Version 2.1.0—STU 2.1

Timeframes for Prior Authorization Decisions

- For prior authorizations for drugs, align prior authorization decision processes across different CMS programs as follows:
    - Medicaid and CHIP programs, state Medicaid FFS programs, Medicaid managed care plans, and CHIP managed care entities: No later than 24 hours after receiving a prior authorization request)
    - State CHIP FFS programs: No later than 24 hours after receiving a prior authorization request for any prescription drugs for which Federal Financial Participation (FFP) is available

    - QHP issuers on the FFEs: 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 date: October 1, 2027
- For prior Authorization for non-drug items and services, align QHP issuers on the FFEs with other CMS programs and require notice of prior authorization decisions as expeditiously as the enrollee's health condition requires, but no later than seven calendar days after receiving a standard prior authorization request and no later than 72 hours after receiving an expedited prior authorization request.
    - Compliance date: October 1, 2027

Communication of Prior Authorization Denials for Drugs

- Require state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to provide providers with a specific reason for denying prior authorization requests for any drugs.
    - Compliance date: October 1, 2027

Prior Authorization Metrics

- For non-drug items and services, add requirements for impacted payers to:
    - Report numeric counts in addition to percentages for certain existing metrics
    - Report additional prior authorization metrics on non-drug items and services beginning on the effective date of the final rule.
    - Reporting deadlines:
        - MA organizations, state Medicaid and CHIP FFS programs, and QHP issuers on the FFEs: March 31 of the following year
        - Medicaid managed care plans and CHIP managed care entities: No later than 90 days after the end of each rating period
- Require Medicaid managed care plans and CHIP managed care entities to report prior authorization metrics for non-drug items and services finalized in CMS-0057-F and this proposed rule at both the program and plan levels.
- For drugs, require impacted payers to annually report prior authorization metrics for drugs on their public websites.
    - Compliance dates: 2028 for data from the 2027 reporting period

API Usage Metrics (Provider Access, Payer-to-Payer, and Prior Authorization APIs)

- Require impacted payers annually report certain Provider Access, Payer-to-Payer, and Prior Authorization APIs usage metrics to CMS, in addition to the current requirement for the Patient Access API.
    - Compliance date: 2028 with data from the 2027 reporting period

Access API Usage Metrics

- Require impacted payers make detailed information about prior authorization requests and decisions for all drugs available through the Patient Access, Provider Access, and Payer-to-Payer APIs, including:
    - Status of the prior authorization
    - Date prior authorization was approved or denied
    - Date or circumstance under which the authorization ends
    - Drug(s) approved, including dosage
    - Specific reason the request was denied, if applicable
    - Related structured administrative and clinical documentation submitted by a provider
- For the Payer-to-Payer API, the required information would include:
    - Status of the prior authorization
    - Date the prior authorization was approved
    - Date or circumstance under which the authorization ends
    - Drug(s) approved, including dosage
    - Related structured and unstructured administrative and clinical documentation submitted by a provider, excluding denied prior authorization requests
- Compliance date: October 1, 2027

Open Payments Program Proposal

- Add "Failure to Report" to the Open Payments program to enable imposing of civil monetary penalties on applicable entities for failure to report.
    - Compliance date: Effective date of the final rule.

RFIs

The proposed rule includes five standalone RFIs that CMS plans to use to determine additional steps it can take to improve related issues in the health care industry.

1. **Electronic Event Notifications for Value-Based Care and Care Coordination**
   CMS is seeking comments on ways to improve the electronic event notifications, often referred to as admission, discharge, and transfer, or "ADT" notification.
2. **Increasing Health Care Resiliency**
   CMS is seeking feedback on opportunities to strengthen, protect, and increase the resiliency of our health care system and electronic protected health information in cybersecurity spaces to prevent and better handle future threats.
3. **Improving Implementation of Payer Application Programming Interface Technology**
   CMS is seeking comments on improving oversight of payer APIs, such as through strengthening testing and transparency requirements, and leveraging existing programs, such as the ONC Health Information Technology (IT) Certification Program, to help ensure that API technology used by payers meets the technical requirements CMS establishes.
4. **Step Therapy**

CMS is seeking comments on ways to streamline the step therapy process through technology and data sharing to allow payers access to historical patient information.

5. **Laboratory Tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Items** CMS is seeking feedback on how prior authorization requirements for laboratory tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies items impact patient care and provider burden and what can be done to mitigate that burden.