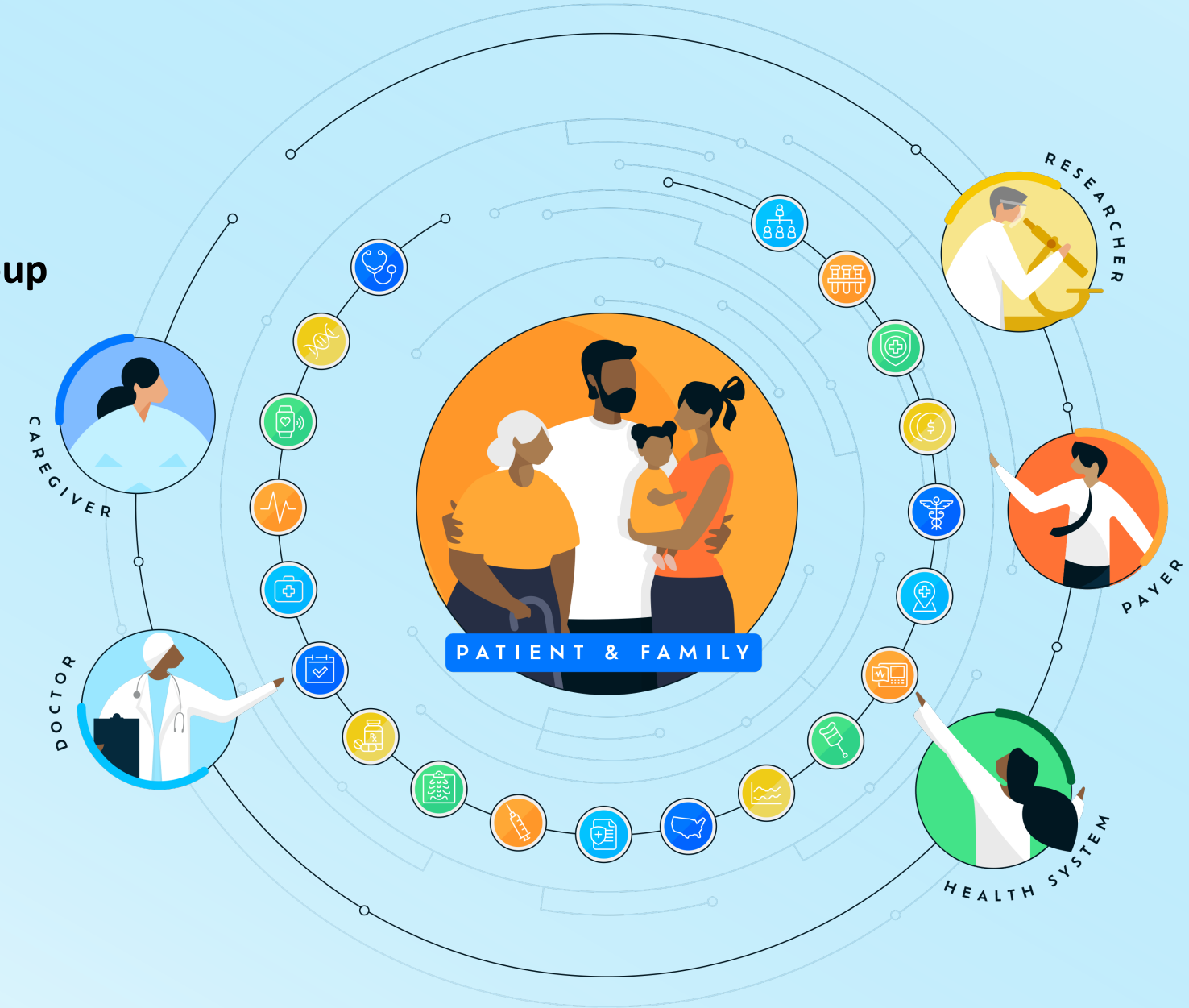
Overview of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P)

Who We Are

Office of Healthcare Experience and Interoperability
Health Informatics and Interoperability Group

Mission: Promote the secure exchange, access, and use of electronic health information to support better informed decision-making and a more efficient health care system.

Vision: A secure, connected health care system that empowers patients and their providers to access and use electronic health information to make better informed and more efficient decisions.



Setting the Stage

- In 2020, CMS finalized the **CMS Interoperability and Patient Access** final rule (CMS-9115-F) ("2020 final rule"). This rule required, among various provisions, implementation of a Patient Access and Provider Directory API.

- In 2024, CMS finalized the **CMS Interoperability and Prior Authorization** final rule (CMS-0057-F) ("2024 final rule"). This rule:
    - Required payers to implement Provider Access, Payer to Payer and Prior Authorization APIs to improve the electronic exchange of health care data and streamline prior authorization processes.
    - Added new measures for eligible hospitals and critical access hospitals under the Medicare Promoting Interoperability Program and eligible clinicians under the Merit-based Incentive Payment Systems (MIPS) Promoting Interoperability performance category.

Impacted Payers

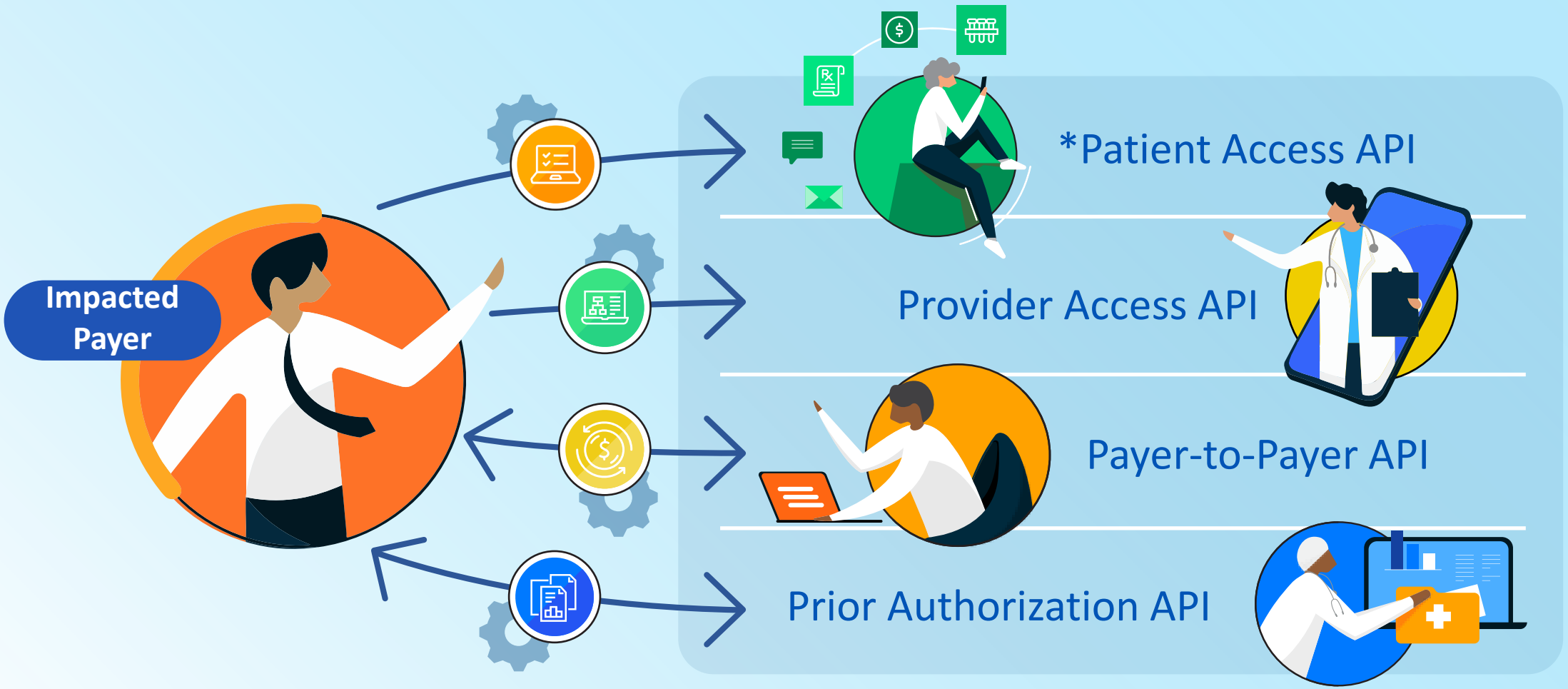
Impacted Payer

- MA organizations
- State Medicaid FFS programs
- State CHIP FFS programs
- Medicaid managed care plans
- CHIP managed care entities
- Individual market QHP issuers on the FFEs

NEW PROPOSAL

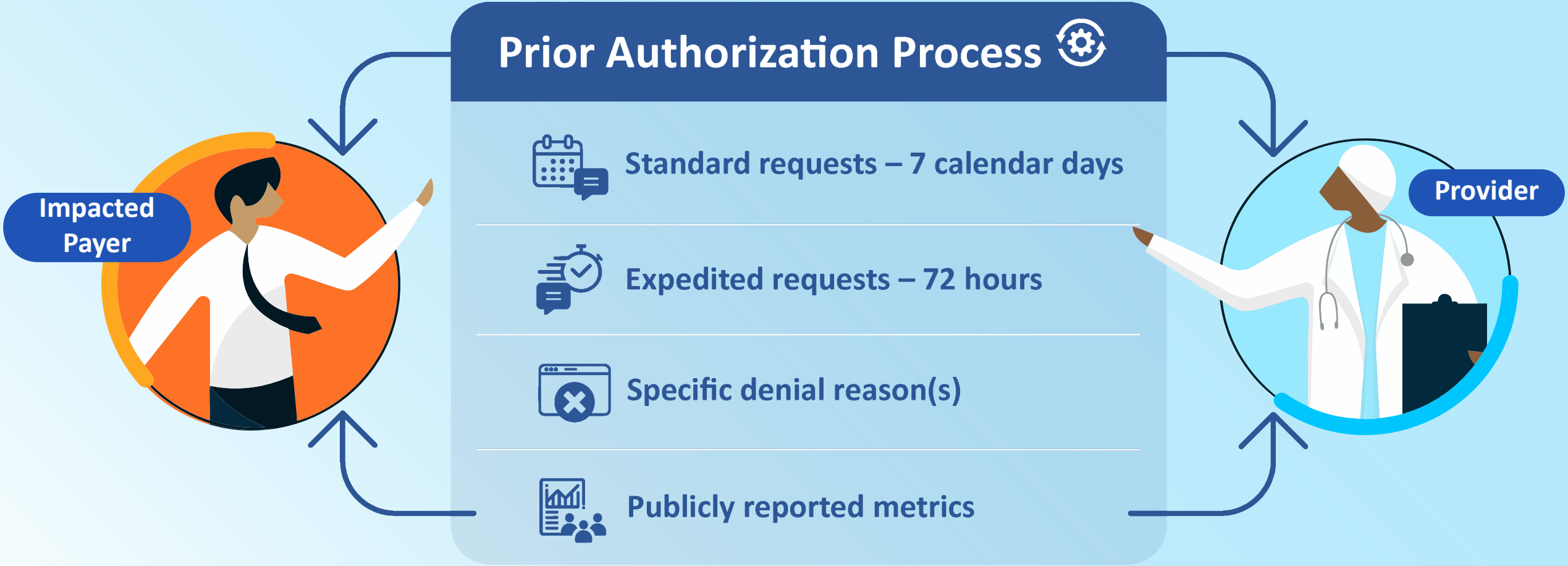
- Small group market QHP issuers on the FF-SHOPs

2024 Final Rule: Application Programming Interfaces (APIs)



*Required under the 2020 CMS Interoperability and Patient Access final rule

2024 Final Rule: Improving Prior Authorization Processes for Non-Drug Items and Services



Overview of the CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule

Overview of New Proposed Rule

While the prior authorization requirements in the 2024 final rule focused on non-drug items and services, this 2026 proposed rule includes proposals to:

- Expand requirements for electronic prior authorization (ePA) to drugs,
- Extend prior authorization process requirements to include drugs,
- Align shorter timeframes for making prior authorization decisions across programs,
- Updated health information technology standards,
- Report interoperability API* endpoints and associated information to CMS,
- Increase transparency into prior authorization decision making, and
- Gather additional API usage metrics to monitor impact.

**The Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization APIs are collectively referred to as "the interoperability APIs."*

What is CMS Proposing?
A Deeper Dive

An Overview: Prior Authorization API Today

PRIOR AUTHORIZATION API

Provider

1. Includes the list of covered items/services that require prior authorization

2. Identifies all documentation required for approval of any items/services that require prior authorization

3. Supports prior authorization requests and responses and communicates status information

Impacted Payer

Incorporating Coverage and Documentation Requirements to Prior Authorization API for Drugs

Proposed Compliance Date: October 1, 2027

PRIOR AUTHORIZATION API

Provider

Impacted Payer

- CRD IG Δ
- DTR IG *
- PAS IG +

Δ Orders or plans treatment

Δ Receives treatment check

ΔChecks if prior authorization is required

Δ Coverage rules/ document templates identified

ΔResponds with coverage rules & documentation requirements (if required)

Δ Receives impacted payer's response

*Prepares prior authorization request using rules/templates & collects documentation

+Request & documentation bundled, then sent to impacted payer

+Receives request & makes prior authorization determination

+Receives determination

NEW!

Proposal to incorporate policies and documentation requirements into the API to support electronic prior authorization for **drugs covered under a medical benefit**.

Support the NCPDP Standards for ePA for Drugs Covered Under Pharmacy Benefits

Proposed Compliance Date: October 1, 2027

PRIOR AUTHORIZATION CHECK

+ Prescriber recommends drug, checks formulary/benefits rules

RTPB

*Impacted payer confirms benefits and prior authorization requirements

Formulary & Benefits (file published by payer and loaded into health IT)

+ Prescriber's health IT

Prescriber

PRIOR AUTHORIZATION REQUEST & RESPONSE

+ If required, prescriber prepares & submits prior authorization request *(SCRIPT)*

* Impacted payer makes prior authorization determination & responds *(SCRIPT)*

*Prescriber can **cancel** prior authorization request (SCRIPT)*

Impacted Payer

+ Prescriber receives prior authorization determination notification

+ If approved, drug prescribed

+ If denied, prescriber can appeal *(SCRIPT)*

- Impacted Payer*
- Prescriber +

NCPDP F&B Versus RTPB Standards: A Comparison

	Formulary & Benefit (F&B)	Real-Time Prescription Benefit (RTPB)
Implementation	• IG + supported through Surescripts network • Part of EHR certification criteria	• Requires specific software/tailored configuration • No federally defined/mandated certification
Performance	• **Flat file loaded into EHR**	• **Queries payer/pharmacy benefit manager systems**
Accuracy	• Up to **group specific**	• **Patient coverage specific**
Usage/ Functionality	• Broad view of patient's prescription drug benefit — formulary, **copay design (estimated plan costs), benefit coverage restrictions** (ePA support, specialty support)	• Drug specific price and coverage check • **Actual patient copay**

HIPAA: Dental, Professional, and Institutional Transactions Related to Prior Authorization

How is HHS Proposing to Define Prior Authorization?

- Transmissions described in 45 CFR 162.1301(a) used by health care providers to obtain authorization for health care, and
- Transmissions described in 45 CFR 162.1301(c) by health plans to respond to such requests.

**Note: Asterisks indicate alternative proposals*

Referral Certification and Authorization (45 CFR 162.1301)

Primary

- Inquiry from health care provider to health plan to obtain authorization for care.
- Response from health plan to health care provider about authorization requests.

Alternative

- *Inquiry from health care provider to health plan to obtain certification for referring an individual to another health care provider.
- *Response from health plan to health care provider about referral certification requests.

Eligibility for a Health Plan (45 CFR 162.1201)

- Applicable **ONLY** when used to determine whether prior authorization is required.
- Inquiries from health care provider to health plan to obtain benefit information, including:
  - Eligibility to receive care
  - Coverage of care
  - Copays/deductibles
- Response from health plan to health care provider (or another health plan) about eligibility inquiry.

HIPAA Administrative Simplification: Adoption of FHIR® Standards for Dental, Professional, and Institutional Prior Authorization Transactions

Affected Entities: HIPAA covered entities (health care providers, health plans, health care clearinghouses)

Proposed Compliance Date: 24 months from final rule effective date for HIPAA covered entities; 36 months for small health plans

Referral and Authorization Transaction

Current: X12N 278 transaction standard

NEW Proposed: Adopt the following FHIR standards and specifications for dental, professional, and institutional **electronic prior authorization** transactions:*

- HL7® FHIR®
- US Core IG
- SMART App Launch IG
- CRD IG
- DTR IG
- PAS IG

Eligibility for a Health Plan Transaction

Current: X12N 270/271 transaction standard

NEW Proposed: Adopt the following FHIR standards and specifications for dental, professional, and institutional health care eligibility inquiry and response, when used to determine whether a **prior authorization** is required:*

- HL7® FHIR®
- US Core IG
- SMART App Launch IG
- CRD IG

Referral and Authorization Attachments

Current: None

NEW Proposed: Adopt the following FHIR standard for exchanging attachments related to **prior authorizations:**

- CDex IG

*Alternatively, we propose to expand our proposals to also include referral certifications.

Health IT Standards for Interoperability APIs

Use Updated Versions of Required Health IT Standards

Proposed Compliance Date: Effective upon publication of the final rule

Per the 2024 final rule, impacted payers must use specific versions of certain FHIR IGs to implement and maintain their APIs.

What would change?

- CMS is proposing to require certain FHIR IGs adopted by ONC in 45 CFR 170.215.
- As new versions are adopted and older versions expired at 170.215 through ONC rulemaking, impacted payers will be required to use **any unexpired versions of the required standards**.

Proposed Additional Health IT Standards for Interoperability APIs

Proposed Compliance Date: October 1, 2027

Per the 2024 final rule, the following IGs are recommended to implement and maintain the required interoperability APIs.

What would change?

CMS is proposing to require impacted payers to use updated **versions of the following standards adopted in 45 CFR 170.215**:

- CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®)
- PDex IG
- PDex Plan Net IG
- PDex US Drug Formulary IG
- CRD IG
- DTR IG
- PAS IG

Note: See Appendix for additional information about these IGs.

HHS/ONC Adoption of Updated Health IT Standards and Specifications

IG Name	CFR Citation	IG Versions Finalized in HTI-4 Final Rule	IG Versions Proposed in CMS-0062-P
CARIN IG for Blue Button®	45 CFR 170.215(k)(1)	Version 2.0.0 – STU 2 US*	Version 2.2.0—STU 2.2 US
PDex IG	45 CFR 170.215(k)(2)	Version 2.1.0 – STU 2.1	N/A
PDex Plan Net IG	45 CFR 170.215(n)	Version 1.1.0 – STU 1.1 US*	Version 1.2.0—STU 1.2 US
PDex US Drug Formulary IG	45 CFR 170.215(m)	Version 2.0.1 – STU 2*	Version 2.1.0—STU 2.1
CRD IG	45 CFR 170.215(j)(1)	Version 2.0.1 – STU 2*	Version 2.2.1—STU 2.2
DTR IG	45 CFR 170.215(j)(2)	Version 2.0.1 – STU 2*	Version 2.2.0—STU 2.2
PAS IG	45 CFR 170.215(j)(3)	Version 2.0.1 – STU 2*	Version 2.2.1—STU 2.2

Note: If these newer versions are adopted as proposed, the versions of the standards and specifications currently identified in 45 CFR 170.215(j)(1)-(3), (k)(1), (m), and (n) would expire January 1, 2028. Indicated by an asterisk (*) in the table.

Reporting API Endpoints

Denial Reasons for Drugs

Shorter Decision Timeframes for Prior Authorization

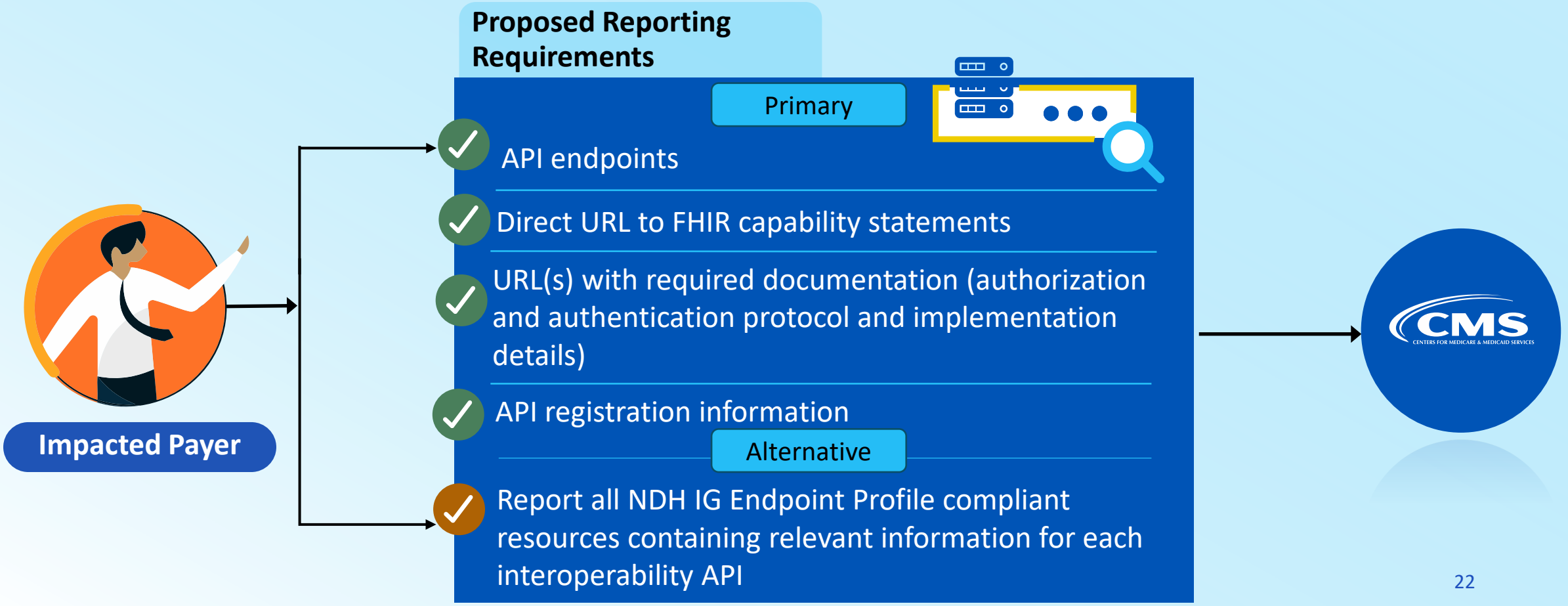
New/Updated Prior Authorization Metrics

New API Metrics and Updates

Payer Reporting of API Endpoints and Associated Information

Proposed Compliance Date for Existing Impacted Payers: No later than 60 days after the effective date of the final rule. Update information within one week of any changes and verify at least annually.

New Impacted Payers: No later than 60 days before the payer begins covering patients under the applicable CMS program.

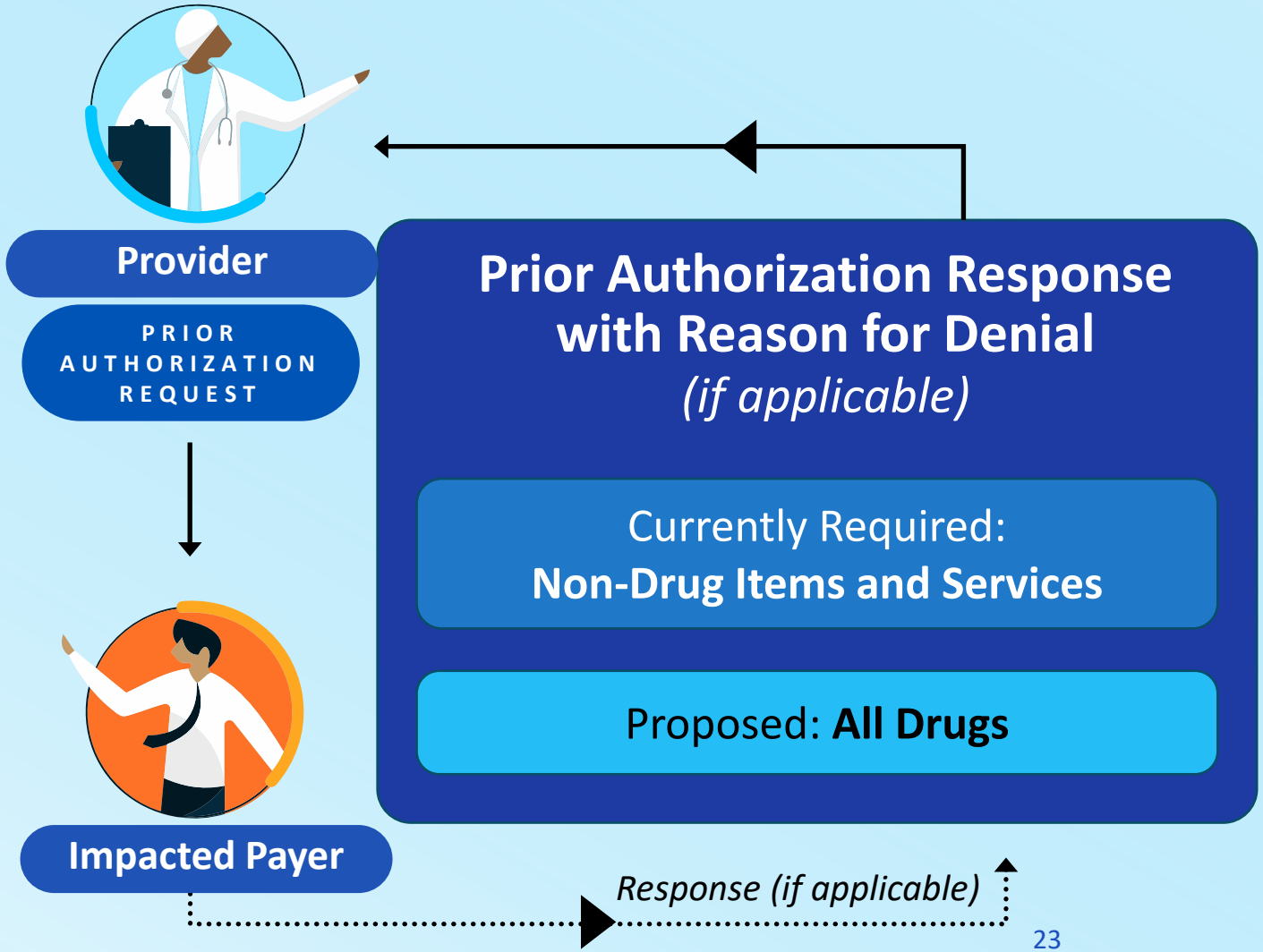


Expanding Communication of Prior Authorization Denials for Drugs

Proposed Compliance Date: October 1, 2027

What would change?

- CMS is proposing impacted payers **provide a specific reason for denying prior authorization requests for all drugs.**



Improving Communications and Decision Timeframes for Prior Authorizations of Non-Drug Items and Services

Proposed Compliance Date: October 1, 2027

What would change?

- CMS is proposing that QHP issuers on the FFEs provide notice of prior authorization decisions for **non-drug items and services** to the provider no later than 7 calendar days after receiving a standard request and no later than 72 hours after receiving an expedited request. This would:
  - Align prior authorization timeframe requirements for QHP issuers on the FFEs with other impacted payers; and
  - Establish consistent expectations for prior authorization decisions across impacted payers, mitigating administrative burden.

Improving Communications and Decision Timeframes for Prior Authorizations of Drugs

Proposed Compliance Date: October 1, 2027

What would change?

- CMS is proposing that certain **payers provide notice of prior authorization decisions for drugs** within specific timeframes.

Payer Type	Drug Category	Proposed Notification Timeframe
State Medicaid FFS	Prescribed drugs for which FFP is available that are not currently subject to an existing timeframe	No later than 24 hours from receipt of request
Medicaid Managed Care Plans		
CHIP Managed Care Entities		
State CHIP FFS	Prescription drugs for which FFP is available	No later than 24 hours from receipt of request
QHP Issuers on the FFEs	All drugs	Standard requests: No later than 72 hours from receipt of request Expedited requests: No later than 24 hours from receipt of request

Proposed Updates to Current Prior Authorization Metrics for Non-Drug Items and Services

Proposed Compliance Date: Effective date of final rule. *Reporting deadlines vary by payer type*.

- **What would change?**
- CMS is proposing that impacted payers publicly report **numeric counts of prior authorization requests in addition to percentages** for non-drug items and services and **new prior authorization metrics on their websites.**

Standard Requests	
Revised	The **total number** and % of standard requests that were approved
Revised	The **total number** and % of standard requests that were denied
Revised	The **total number** and % of standard requests that were approved after appeal
NEW	Total number and % of standard requests that remain denied after appeal
Revised	The **total number** and % of standard requests for which the timeframe for review was extended, and the request was approved
NEW	Total number and % of standard requests for which the timeframe for review was extended, and the request was denied

Expedited Requests	
Revised	The **total number** and % of expedited requests that were approved
Revised	The **total number** and % of expedited requests that were denied
NEW	Total number and % of expedited requests that were approved after appeal
NEW	Total number and % of expedited requests that remain denied after appeal
NEW	Total number and % of expedited requests for which the timeframe for review was extended, and the request was approved*
NEW	Total number and % of expedited requests for which the timeframe for review was extended, and the request was denied*

**These metrics are not applicable to state Medicaid FFS programs because existing regulations do not allow for expedited prior authorization requests to be extended by these programs.*

Proposed New Prior Authorization Metrics for Drugs

Proposed Compliance Date: Beginning in 2028 for the 2027 reporting period. *Reporting deadlines vary by payer type.*

What would change? CMS is proposing that impacted payers be required to report prior authorization metrics for drugs.

Proposed New Metrics	MA Organizations	Medicaid and CHIP FFS	Medicaid Managed Care	CHIP Managed Care	QHP Issuers on FFEs
List of drugs that require prior authorization	✓	✓	✓	✓	✓
Total number and % of requests for drugs approved*	✓	✓	✓	✓	✓
Total number and % of requests for drugs denied*	✓	✓	✓	✓	✓
Total number and % of requests for which the timeframe for review was extended, and the request was approved*	✓	x	x	x	✓
Total number and % of requests for which the timeframe for review was extended, and the request was denied*	✓	x	x	x	✓
Total number and % of requests for drugs approved after appeal*	✓	✓	✓	✓	✓
Total number and % of requests for drugs denied after appeal*	✓	✓	✓	✓	✓
Average time that elapsed between submission of requests and decisions for drugs	✓	✓	✓	✓	✓
Median time that elapsed between submission of requests and decisions for drugs	✓	✓	✓	✓	✓

Note: MA organizations would only report these metrics for drugs that require prior authorization and are payable under Medicare Part B. State Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs would report these metrics for all drugs.

**** MA organizations and QHP issuers on the FFEs would report separately for standard and expedited requests. State Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities would report in a single metric for all prior authorization requests for all drugs.***

New API Usage Metrics

Proposed Compliance Date: Beginning in 2028 for the 2027 reporting period. *Reporting deadlines vary by payer type.*

Patient Access API

- Total unique patients whose data were transferred via Patient Access API to personal health app
- Total unique patients whose data were transferred more than once via Patient Access API to personal health app

Impacted Payer

NEW! Provider Access API

- **Total unique providers requesting patient data via Provider Access API**
- **Total unique patients whose data were transferred via Provider Access API to provider's health IT system**
- **Total patient data transfers via Provider Access API**

NEW! Payer-to-Payer API

- **% patients opted in to payer to payer data exchange**
- **Total unique patients whose data were sent to other payers**
- **Total unique patients whose data were received from other payers**

NEW! Prior Authorization API

- **Total unique providers who requested prior authorization through Prior Authorization API**
- **Total unique prior authorization requests for items, services, and drugs received through Prior Authorization API**
- **% prior authorization requests received through Prior Authorization API**

Updates to APIs

Proposed Compliance Date: October 1, 2027

Information on Prior Authorization Requests and Decisions for All Drugs

Impacted Payer

- Prior Authorization Status
- Prior Authorization Approval/Denial Date
- Authorization End Date
- Approved Drug(s) (including dosage)
- Denial Reason
- Structured Clinical and Administrative Documentation

→ **Patient Access API**

→ **Provider Access API**

- Prior Authorization Status
- Prior Authorization Approval Date
- Authorization End Date
- Approved Drug(s) (including dosage)
- Structured and Unstructured Clinical and Administrative Documentation

→ **Payer-to-Payer API**

Additional Interoperability Proposals, Information on Exemptions/Exceptions/Extensions, and Helpful Resources

Extensions, Exemptions, and Exceptions

Impacted Payer	Proposal	Description
State Medicaid and CHIP FFS Programs	**Extension**	Permitted to request an extension, until the compliance date for the HIPAA Administrative Simplification proposals, as a part of annual Advance Planning Document for MMIS operations expenditures for: • 2024 final rule requirement to implement and maintain the Prior Authorization API for items and services • Proposal to incorporate drugs covered under a medical benefit into the Prior Authorization API • Proposal to support NCPDP standards for electronic prior authorization of drugs covered under a pharmacy benefit
State Medicaid and CHIP FFS Programs	**Exemption**	To harmonize with HIPAA proposals, remove the policy finalized in the 2024 CMS Interoperability and Prior Authorization final rule allowing states with small FFS populations to request an exemption for non-drug items and services Prior Authorization API requirements.
QHP Issuers on the FFEs	**Exception**	Permitted to apply for an exception by submitting narrative justification as part of QHP application for proposal to support the NCPDP standards for drugs covered under a pharmacy benefit.

Additional Proposals (part 1)

Metrics Reporting and API Revisions

- Revision to 2024 final rule metrics reporting deadlines
  - Aligning Medicaid and CHIP managed care with contract rating periods (aligns with proposals for new usage metrics)
  - Aligning QHP issuers on the FFEs with certification deadlines for Patient Access API usage metrics (aligns with proposals for new usage metrics)
- Removing drug formulary information from Provider Access API and Payer-to-Payer API
- Revise denial or discontinuation of access policy for the Provider Directory API for consistency with the other interoperability APIs

Additional Proposals (part 2)

Addition of Small Group Market QHP Issuers on the FF-SHOPs as Impacted Payers

Proposed Compliance Dates: Specific Compliance Dates Vary by Proposal

The 2020 and the 2024 final rules excluded issuers that offer small group market QHPs on the FF-SHOP Exchanges from its policies.

What would change?

- Apply existing requirements in 45 CFR 156.221, 45 CFR 156.222, and 45 CFR 156.223 to small group market QHP issuers on the FF-SHOPs.

Additional Proposals (part 3)

Open Payments Civil Monetary Penalties

Proposed Compliance Date: Effective date of final rule

The Open Payments final rule requires “applicable manufacturers” and “applicable group purchasing organizations” to annually report certain payments or transfers of value made during the previous calendar year to specified “covered recipients,” such as physicians.

What would change?

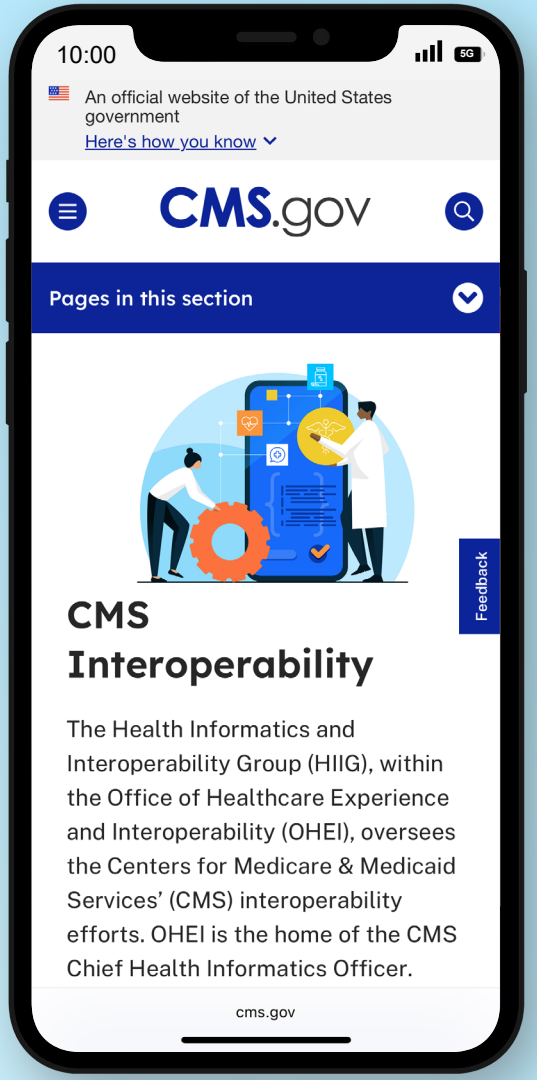
- Add a definition for “Failure to Report” in 42 CFR 403.902.
- Allow the agency to impose a civil monetary penalty on applicable manufacturers or group purchasing organizations if either fail to grant timely access (within 30 calendar days of the audit request) for the purposes of an Open Payments program audit authorized by 42 CFR 402.912(e)(2).

Resources

- The full proposed rule is available here for public comment: https://www.federalregister.gov/public-inspection/2026-07205/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-standards
- Proposed rule fact sheet
- Proposed rule website

The proposed rule will be available for public comment until June 15, 2026.

Visit our website for additional resources and information or email CMSInteroperability@cms.hhs.gov!



Currently Required Standards

Implementation Guide	Patient Access API	Provider Access API	Provider Directory API	Payer-To-Payer API	Prior Authorization API
HL7 FHIR, Release 4.0.1	✓	✓	✓	✓	✓
HL7 FHIR US Core IG, STU 3.1.1 and 6.1.0	✓	✓	✓	✓	✓
HL7 SMART Application Launch Framework IG, Release 1.0.0 and 2.0.0	✓	✓	✗	✗	✓
OpenID Connect Core 1.0	✓	✗	✗	✗	✗
FHIR Bulk Data Access IG (v1.0.0: STU 1)	✗	✓	✗	✓	✗

Proposed Required Standards

*Note: Highlighted items marked with a * symbol are contingent on ONC finalizing proposals outlined in this proposed rule.*

Implementation Guide	Patient Access API	Provider Access API	Provider Directory API	Payer-To-Payer API	Prior Authorization API
HL7 FHIR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button) IG, Version 2.0.0—STU 2 and Version 2.2.0—STU 2.2*	✓	✓	✗	✓	✗
HL7 FHIR Da Vinci—PDex IG, Version 2.1.0—STU 2.1	✓	✓	✗	✓	✗
HL7 FHIR Da Vinci—PDex US Drug Formulary IG, Version 2.0.1—STU 2, and Version 2.1.0—STU 2.1*	✓	✗	✗	✗	✗
HL7 FHIR Da Vinci—PDex Plan Net IG, Version 1.1.0—STU 1.1 U.S. and Version 1.2.0—STU 1.2 U.S.*	✗	✗	✓	✗	✗
HL7 FHIR Da Vinci— CRD IG, Version 2.0.1—STU 2 and Version 2.2.1—STU 2.2*	✗	✗	✗	✗	✓
HL7 FHIR Da Vinci—DTR IG, Version 2.0.1—STU 2 and Version 2.2.0—STU 2.2*	✗	✗	✗	✗	✓
HL7 FHIR Da Vinci—PAS IG, Version 2.0.1—STU 2 and Version 2.2.1—STU 2.2*	✗	✗	✗	✗	✓

Recommended Standards

Implementation Guide	Patient Access API	Provider Access API	Provider Directory API	Payer-To-Payer API	Prior Authorization API
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 CDex IG, Version 2.1.0—STU 2.1	✗	✗	✗	✗	✓

Acronyms and Abbreviations List

- Application programming interface (API)
- Office of the National Coordinator for Health Information Technology (ONC)
- Centers for Medicare and Medicaid Services (CMS)
- Children's Health Insurance Program (CHIP)
- Code of Federal Regulation (CFR)
- Coverage Requirements Discovery (CRD)
- Da Vinci Clinical Data Exchange (CDex)
- Department of Health and Human Services (HHS)
- Documentation Templates and Coverage Rules (DTR)
- Electronic health record (EHR)
- Electronic prior authorization (ePA)
- Fast Healthcare Interoperability Resources (FHIR®)
- Federally-facilitated Exchange (FFE)
- Fee-for-service (FFS)
- Federally-facilitated Small Business Health Options Program (FF-SHOPs)
- Formulary and Benefit (F&B)
- Health Insurance Portability and Accountability Act (HIPAA) of 1996
- Health Level Seven (HL7®)
- Health Information Technology for Economic and Clinical Health Act (HITECH Act)
- Health Data, Technology, and Interoperability (HTI)
- Implementation guide (IG)
- Information technology (IT)
- Managed care organization (MCO)
- Merit-based Incentive Payment System (MIPS)
- Medicare Advantage (MA)

Acronyms and Abbreviations List (Cont.)

- Medicaid Management Information System (MMIS)
- National Council for Prescription Drug Programs (NCPDP)
- Office of the National Coordinator (ONC)
- Payer Data Exchange (PDex)
- Prior Authorization Support (PAS)
- Qualified Health Plan (QHP)
- Qualified Health Information Network (QHIN)
- Real-time Prescription Benefit (RTPB)
- Request for Information (RFI)
- Trusted Exchange Framework and Common Agreement (TEFCA)