T (202) 354-2600 vizientinc.com



Vizient Office of Public Policy and Government Relations

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

January 26, 2024

Key Takeaways

On January 17, the Centers for Medicare & Medicaid Services (CMS) issued a <u>Final Rule</u> to improve the electronic exchange of health care data and streamline prior authorization (PA) processes by providing new requirements for Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs) (collectively "impacted payers"). Several of these new requirements for impacted payers involve the implementation and maintenance of certain application programming interfaces (APIs).¹ In addition, the Final Rule adds new measures under the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) and under the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS).

While the regulations in the Final Rule are effective 60 days after publication in the Federal Register, key deadlines for several new requirements are January 1, 2026, and January 1, 2027.²

Major Proposals Finalized & Key Changes from the Proposed Rule

Prior Authorization API and Improving the Prior Authorization Processes

In the Proposed Rule, CMS outlined several new requirements for payers to implement and maintain a new Prior Authorization API, respond to PA requests within certain timeframes, provide a specific reason for PA denials and publicly report on PA approvals, denials and appeals. CMS also proposed a January 1, 2026, compliance date for the Prior Authorization API.

In the Final Rule, CMS acknowledges several commenters' concerns regarding the compliance date (too soon or too late), PA decision timeframes (too short or too long) and reporting metrics (too little or too much). CMS extended the compliance date for the Prior Authorization API for all impacted

¹ Table H1 (pg. 670) of the <u>Final Rule</u> outlines the use of interoperability standards for required APIs; Table H2 (pg. 670) outlines use of updated standards for the required APIs; and Table H3 (pg. 672-673) outlines the required standards and recommended implementation guides to support API implementation.

² In the Final Rule, CMS indicates January 1, 2026 and January 1, 2027 as compliance dates but the compliance date may be later for certain impacted payers. For example, the Final Rule describes the compliance date as January 1, 2027 for MA organizations and state Medicaid and CHIP FFS programs; by the rating period beginning on or after January 1, 2027 for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027 for QHP issuers on the FFEs. Similar clarification is provided for the compliance date of January 1, 2026. As a result, some impacted payers may need to comply after January 1, 2026 or January 1, 2027, depending on that start of the rating period or plan year. For purposes of brevity in this summary, the compliance date referenced is the earliest potential compliance date.

payers by one year to January 1, 2027, which is consistent with the compliance date for other API requirements in the Final Rule.

Regarding decision timeframes, unless state law is more stringent, CMS notes that, generally, a decision should occur as expeditiously as a beneficiary's health condition requires and that this timeframe may not exceed either 7 calendar days (standard request) or 72 hours (expedited request) after receiving the request. Notably, QHP issuers on the FFEs are required to provide notification of a plan's benefit determination within 15 days for standard authorization decisions and within 72 hours for expedited requests. Table E1 (pg. 459) of the Final Rule provides the final requirements for PA decision timeframes that will apply to each payer beginning in 2026. Table E2 (pg. 476) of the Final Rule outlines the PA notification requirements for impacted payers.

Also, CMS clarifies that the January 1, 2026, compliance date, which is consistent with the Proposed Rule, is for PA requests for items and services covered by the Final Rule. However, for all other items and services (e.g., drugs), existing timeframes under the regulations for other preservice requests would continue to apply. Further, CMS clarifies that the Final Rule does not change existing federal timeframes for expedited and standard determinations on requests for Part B drugs for MA organizations and applicable integrated plans.

CMS is also finalizing the proposal that for each metric listed, data would be reported in the aggregate for all items and services. Examples of metrics and information to report include: a list of all items and services that require PA; the percentage of standard PA requests required that were approved, the percentage of standard PA requests that were denied, the average and median time elapsed between the submission of a request, and a decision by the payer, plan or issuers for expedited PAs. CMS notes that it may consider additional reporting options in the future. CMS also finalized a policy to publicly report aggregated metrics.

Patient Access API

In the <u>Proposed Rule</u>, CMS provided policy expanding the current Patient Access API requirements (as provided in the <u>CMS Interoperability and Patient Access Final Rule</u>) to include PA information by January 1, 2026. The Final Rule delays this requirement by one year to January 1, 2027, when impacted payers must include information about certain prior authorizations in the data that are available through the Patient Access API (e.g., PA status, items and services approved, specific denial reason, date or circumstance under which the PA ends). CMS also proposed that impacted payers make information about PA available no later than one business day after any status change.

CMS clarifies, in the Final Rule, that the policies related to PA do not include standards or policies for any drugs, including covered outpatient drugs under Medicaid, and Medicare Part B or Part D drugs covered by an MA (including an MA-PD) plan.

However, beginning January 1, 2026, CMS will require impacted payers to annually report to CMS certain metrics about patient data requests made through the Patient Access API (e.g., total number of unique patients whose data are transferred via the Patient Access API to a health app designated by the patient and the total number of unique patients whose data are transferred more than once via the Patient Access API to a health app designated by the patient). While CMS acknowledged stakeholder comments regarding the value of publicly reporting this information, CMS indicated that this would not occur until it is confident that the data can be presented in an easy-to-understand and meaningful way. If publicly reported, the data would be aggregated and de-identified data and will not include names of specific state agencies, plans or issuers unless additional rulemaking occurs.

Also, CMS broadens the scope of clinical data to be made available via the Patient Access API. Specifically, rather than "clinical data, including laboratory results", all data classes and data elements included in a content standard are to be made available. This requirement is effective as of the effective date of the Final Rule, 60 days after its publication in the Federal Register.

Provider Access API

In the Proposed Rule, CMS proposed to require impacted payers to implement and maintain an API that makes patient data available to providers who have a contractual relationship with the payer and a treatment relationship with the patient. More specifically, impacted payers would have been required to implement and maintain a Provider Access API to make current patients' information (e.g., claims and encounter data) available to in-network or enrolled (as applicable) providers, at the provider's request. Under the proposal, an in-network provider is any provider or health care facility that is part of a specific health plan's network of providers with which it has a contract to furnish covered items or services. In the case of state Medicaid and CHIP FFS programs, that means any providers or health care facilities that are enrolled with the state as Medicaid or CHIP providers. Also, payers would be required to make information related to PA requests and decisions for items and services (excluding drugs) through the Providers Access API. CMS proposed January 1, 2026, to be the compliance date for Provider Access API requirements.

In the Final Rule, CMS finalized most policies as proposed, such as the requirement that impacted payers make available to providers, via the Provider Access API, claims and encounter data (without provider remittances and patient cost-sharing information), all data classes and data elements included in a content standard, and certain information about PAs (excluding those for drugs). However, unlike the Proposed Rule, CMS is not requiring payers to share the quantity of items or services used under a PA or unstructured documentation related to a PA. Also, CMS finalized a later compliance date of January 1, 2027.

In addition, CMS clarifies that under the Final Rule, impacted payers must send the requested data no later than one business day after the payer receives a request and three conditions are met. The three conditions that must be met are: (1) the payer authenticates the identity of the provider and attributes the patient to that provider; (2) the patient has not opted out; and (3) disclosure of the requested information is not prohibited by law. CMS also indicates that payers are not required to establish that these conditions are met in one business day; rather, data must be made available through the Provider Access API no later than one business day after these conditions are met. To minimize provider burden, CMS strongly encourages payers to complete the attribution process in a reasonable amount of time with minimal involvement from the provider.

Payer-to-Payer API

In the Proposed Rule, to support continuity of care as patients transition between payers, CMS provided regulations that would require impacted payers to implement and maintain a Fast Healthcare Interoperability Resources (FHIR) API to facilitate payer-to-payer data exchange.³ This

³ For the Payer-to-Payer API, impacted payers must use the following standards: HL7 FHIR Release 4.0.1 at 45 CFR 170.215(a)(1), US Core IG STU 3.1.1 at 45 CFR 170.215(b)(1)(i), and Bulk Data Access IG v1.0.0: STU 1 at 45 CFR 170.215(d)(1). CMS further clarifies impacted payers are permitted to use updated standards, specifications, or IGs that are not yet adopted in regulation for the APIs required in the Final Rule, should certain conditions be met. For the standards at 45 CFR 170.215, updated versions available for use under our policy include, but are not limited to, US Core IG STU 6.1.0 and the Bulk Data Access IG v2.0.0: STU 2, which have been approved for the ONC Health IT Certification Program. CMS recommends payers use the CARIN IG for Blue Button STU 2.0.0, PDex IG STU 2.0.0, and SMART

Payer-to-Payer API would facilitate patient data exchange of certain information (e.g., claims and encounter data, data classes and elements in the USCDI and information about certain prior authorizations) at the start of coverage with a new payer and would apply to concurrent payers (i.e., two or more payers providing coverage at the same time). CMS also proposed that patients must opt in for this data exchange to occur (but payers still must meet the functionality requirements – even if patients do not choose to opt-in to the data exchange). In the Final Rule, CMS finalized most policies as proposed with several exceptions. For example, CMS will require impacted payers to exchange data with a date of service within 5 years of the exchange request rather than exchanging and maintaining a patient's entire health history dating to January 1, 2016, as proposed. In addition, unlike the Proposed Rule, which included compliance dates in 2026, CMS finalized a compliance date of January 1, 2027.

Medicare Fee-for-Service

In the Final Rule, CMS indicates that while the policies finalized do not directly pertain to Medicare fee-for-service (FFS), the agency intends for the Medicare FFS program to exchange data, including through the Provider Access, Payer-to-Payer and Prior Authorizations APIs. CMS did not finalize policies regarding this effort but may provide policies in the future.

Extensions, Exemptions and Exceptions

Table F1 (pg. 535) of the <u>Final Rule</u> outlines which impacted payers are eligible to apply for extensions, exemptions, or exceptions by the API type.

Electronic Prior Authorization Measures for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

CMS finalized new Electronic Prior Authorization measures, with some differences from the proposed measures. More specifically, the new measures are structured as an attestation (yes/no) measure, instead of a numerator and denominator measure as originally proposed, for both MIPS eligible clinicians and eligible hospitals and CAHs. CMS clarifies that the measures will not be scored (i.e., not assigned points for completion or failure), but if a MIPS eligible clinician, eligible hospital, or CAH fails to report the measure as specified, they would not meet the minimum reporting requirements, not be considered a meaningful EHR user, and fail the Medicare Promoting Interoperability Program or the MIPS Promoting Interoperability performance category.

In addition, CMS finalized that MIPS eligible clinicians report the Electronic Prior Authorization measure beginning with the CY 2027 performance period/2029 MIPS payment year (rather than the CY 2026 performance period/2028 MIPS payment year), and that eligible hospitals and CAHs report the Electronic Prior Authorization measure beginning with the CY 2027 EHR reporting period (rather than the CY 2026 EHR reporting period).

"Gold-Carding" Programs for Prior Authorization

In the Proposed Rule, CMS requested comments on the potential for gold-carding or PA exemption programs and how they might reduce provider and payer burden and improve services to patients.

App Launch IG Release 2.0.0 to support Backend Services Authorization. Also, unlike the proposed rule, CMS is not requiring the SMART App Launch IG at 45 CFR 170.215(c) and OpenID Connect Core at 45 CFR 170.215(e)(1).

While CMS acknowledges that several comments on this topic were received, no specific policies were proposed. As a result, CMS did not finalize policies on this topic and will consider comments for possible future rulemaking.

Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

In the Proposed Rule, CMS requested information regarding the adoption of standards related to social risk factor data. In the Final Rule, CMS did not directly address stakeholder comments in response to this request.

What's Next?

While most provisions in the Final Rule have January 1, 2026 and January 1, 2027, compliance dates, there are opportunities for exceptions, exemptions and extensions. Vizient's Office of Public Policy and Government Relations is happy to answer any questions you may have about provisions in this Final Rule. Please reach out to <u>Jenna Stern</u>, Associate Vice President, Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.