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Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-P)

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Summary

On December 6, 2022, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule (hereinafter "Proposed Rule") that aims to improve data sharing and streamline the prior authorization process 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). The Proposed Rule also adds a new measure to the Medicare Promoting Interoperability (PI) Program and Merit-based Incentive Payment System (MIPS) PI performance category.

While the Proposed Rule does not directly apply to Medicare FFS, CMS indicates throughout the Proposed Rule that if several proposals are finalized, it plans to implement these provisions for Medicare FFS. Additionally, on December 14, CMS issued another proposed rule regarding Part D and MA plans where the agency proposes additional reforms regarding prior authorization. A summary of that proposed rule's will be forthcoming.

In the Proposed Rule, CMS also provides six requests for information (RFIs) on a range of topics, including the adoption of standards related to social risk factor data, improving the electronic exchange of information, and improving prior authorization processes for maternal health, among others.

While comments are due by **March 13, 2023,** there is no expected deadline for the release of the final rule. However, if finalized as proposed, the regulations would go into effect January 1, 2026. Vizient looks forward to working with members to help inform our letter to the agency.

Background

In May 2020, CMS published the CMS Interoperability and Patient Access final rule to help increase interoperability and patient access to their health care data by, among other provisions, requiring payers to share, via Fast Healthcare Interoperability Resources Images (FHIR) application programming interfaces[1] (APIs), certain information including patient claims, encounter data, and a subset of clinical data that patients can access via health applications (apps). Building from this final rule, in December 2020, CMS and the Office of the National Coordinator for Health Information Technology (ONC) issued a proposed rule that would impose new requirements on state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to improve the electronic exchange of health care data and streamline processes related to prior authorization, while advancing interoperability. However, the December 2020 proposed rule was not finalized due to various stakeholder concerns, including a short implementation timeline. In this Proposed Rule, CMS withdraws the December 2020 proposed rule,

[1] An API is a set of commands, functions, protocols, or tools published by one software developer ("A") that enables other software developers to create programs (applications or "apps") that can interact with A's software without needed to know the internal workings of A's software, while maintaining data security and patient privacy, if properly implemented.

but re-proposes several policies and incorporates prior feedback received into the new Proposed Rule.

Patient Access API

In the CMS Interoperability and Patient Access final rule, CMS required impacted payers to share certain health information (e.g., patient claims, encounter data, and a subset of clinical data) with patients.[2] More specifically, CMS required such sharing to occur via FHIR APIs, with the data available via the Patient Access API no later than 1 business day after a claim is adjudicated or encounter or clinical data are received. In the Proposed Rule, CMS seeks to expand the Patient Access API to include prior authorization information by January 1, 2026. The Patient Access API is important to providers due to the ability for patients to share information with their healthcare providers. For example, as described by CMS, during a visit with a provider, a patient could share specific diagnoses, procedures and tests accessed through the Patient Access API and stored on a smart phone and this information could help inform a discussion with their provider about their health status.

While Medicare FFS is not currently an impacted payer, CMS does seek comment on applying these requirements to Medicare FFS. CMS also proposes a specific CHIP-related regulatory framework that would align separate CHIP managed care API requirements with the Medicaid managed care API requirements (rather than with CHIP FFS API requirements). Table 1 of the Proposed Rule (pg. 14) outlined the proposed regulatory changes by impacted payer.

Also, in the Proposed Rule, CMS would require that impacted payers report patient access API metrics to CMS on an annual basis (in the December 2020 proposed rule, this was to be done on a quarterly basis). Metrics that would need to be annually reported are the total number of unique patients whose data is transferred via the Patient Access API to a health app designated by the patient; and the total number of unique patients whose data is transferred more than once via the Patient Access API to a health app designated by the patient. While such data would help facilitate CMS oversight, the agency does plan to publicly report these metrics at the state, plan or issuer level. **CMS seeks comments on this aspect of the proposal and other potential Patient Access API metrics.**

To improve the Patient Access API, CMS proposes to add information about prior authorizations to the categories of data required to be made available to patients through the Patient Access API. For example, CMS proposes to require that impacted payers make information about prior authorization requests and decisions (and related administrative and clinical documentation) for items and services (excluding drugs) available to patients no later than 1 business day after the payer receives the prior authorization request, or if there is another type of status change for the prior authorization. Also, the documentation that would be shared includes any materials that the provider sends to the payer to support a decision. Examples of this data include structured or unstructured clinical data including laboratory results, scores or assessments, past medications or procedures, progress notes, or diagnostic reports. CMS proposes that information regarding prior authorizations be available via the patient access API for as long as the authorization is active and at least one year after the last status change. If a prior authorization is denied, payers would have to provide a specific reason for the denial via the Patient Access API.

[2] CMS also proposes two minor terminology changes regarding the use of the Patient Access API. CMS proposes to revise the description of the clinical data to be made available via the Patient Access API and to revise the language previously finalized for denial or discontinuation of a health app's access to the API.

CMS seeks comments on these proposals. Also, while the proposals do not apply to drugs, CMS requests comments on whether it should consider policies to require impacted payers to include information about prior authorizations for drugs, when the payer covers drugs, via the Patient Access API and the Pay-to-Payer API.

In the Proposed Rule, CMS also responds to prior comments regarding the interaction between the Patient Access API and HIPAA Privacy Rule requirements for individual access and privacy policies. CMS requests comments on how it can help give patients the tools they need to understand the privacy and security implications of using a health app within the scope of CMS's regulatory authority.

Provider Access API

CMS proposes to require impacted payers to implement and maintain a FHIR API to exchange data with providers (Provider Access API). Like the Patient Access API, CMS seeks comment on how each of the agency's proposals for the Provider Access API could be implemented for the Medicare FFS program. CMS proposes to establish the Provider Access API compliance date of January 1, 2026.

CMS expects that the Provider Access API would enable current patients' information to be exchanged from payers to providers that are in that payer's network, at the provider's request. A provider in the payer's network would be any provider or healthcare facility that is part of a specific health plan's network of providers with which it has a contract.[3] **However, CMS seeks comment on potentially imposing a requirement to share patient data with out-of-network providers and how providers currently request such information for consideration in future rulemaking.**

The proposed Provider Access API would allow a provider to initiate a request and it would also facilitate FHIR-based exchange of claims and encounter data, in addition to certain data classes and data elements (e.g., USCDI). In addition, the Provider Access API would require payers to share information related to prior authorization requests and decisions, consistent with the Patient Access API. CMS also proposes that impacted payers make available any of the applicable patient data with a date of service on or after January 1, 2016. CMS notes that this timeframe for data to be included aligns with the already-finalized requirements of the Patient Access API.

In the Proposed Rule, CMS notes that unlike the Patient Access API proposals, the Provider Access API involves the provider requesting and receiving access to the patient's information through the electronic health record (EHR), practice management system, or other technology solution for treatment purposes, including care coordination (all via a FHIR API). CMS believes this provider access framework would allow the provider to incorporate patient data into their records. Payers would be required to share the requested data no later than one business day after the provider initiates the request. Notably, the provider would only be able to request the additional data from the patient's payer if the patient has not opted out. Also, CMS proposes that the Provider Access API would not include provider payments and enrollee cost sharing information.

While the proposed requirements for payers regarding the Provider Access API generally align with the Patient Access API, CMS does propose additional requirements for payers for the Provider Access API regarding attribution (identifying a patient-provider treatment relationship), patient opt

[3] In the case of Medicaid and CHIP FFS programs, it would be any providers or healthcare facilities that are enrolled with the state as Medicaid or CHIP providers.

out process, patient resources and provider resources (e.g., non-technical and easy-to-understand education resources for providers about the Provider Access API). **CMS requests comment regarding whether it should develop guidance regarding, or address in future rulemaking, the specific content of the educational materials about the Provider Access API.**

CMS also indicates that disclosures from payers to healthcare providers would be permitted under the HIPAA Privacy Rule as disclosures for treatment purposes, as well as disclosures required by law (which the proposed rule would be establishing if finalized).

In the Proposed Rule, CMS further details extensions and exemptions for Medicaid and CHIP FFS Programs and exceptions for QHP Issuers. The agency also further details issues related to Medicaid and CHIP implementation of the Provider Access API. Table 2 of the Proposed Rule (pg. 28) outlines the proposed regulatory changes by impacted payer type.

Payer-to-Payer Data Exchange on FHIR

In prior rulemaking, CMS did not specify an API standard for payer-to-payer data exchange[4], because, at the time, there were a variety of transmission solutions that payers could use to meet the requirement. However, to support consistency and reduce burden, CMS proposes to require impacted payers to implement and maintain a payer-to-payer data exchange using a FHIR API. CMS also proposes to establish a patient opt-in policy for this data exchange for all impacted payers and to require that impacted payers request a patient's data from their previous/concurrent payer no later than one week after the start of coverage. The compliance deadline for the Payer-to-Payer API is January 1, 2026.

Improving Prior Authorization Processes

CMS proposes to require payers to take the following four key steps to improve prior authorization processes by January 1, 2026: implement and maintain and an API to support the prior authorization process; respond to prior authorization requests within specified timeframes; provide a reason for prior authorization denials and public reporting on prior authorization outcomes. Additional information regarding each step is provided below.

Key Requirement 1: Implement and maintain an API to support and streamline the prior authorization process (known as the Prior Authorization Requirements, Documentation and Decisions (PARDD) API)

CMS proposes that payers would be required to implement the PARDD API for all prior authorization rules and requirements for items and services, excluding drugs, by January 1, 2026. Since the anticipated benefits of the PARDD API are, in part, dependent on providers using health IT products that can interact with payers' API, CMS also proposes a new measure for the MIPS Promoting Interoperability performance category for MIPS eligible clinicians and the Medicare Promoting Interoperability Program, as further detailed below.

Key Requirement 2: Respond to prior authorization requests within specified timeframes

CMS proposes to modify the timeframes by which impacted payers must respond to prior authorization requests.[5] Specifically, impacted payers would need to respond to prior authorization

[4] The requirement is that certain impacted payers exchange, at a minimum, all data classes and data elements included in a content standard (e.g., USCDI) at a patient's request. This policy applied to MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. It did not include Medicaid or CHIP FFS programs.

[5] This proposal would not apply to QHP issuers on the FFEs.

requests within 72 hours for expedited (urgent) requests and seven calendar days for standard (non-urgent) requests, unless a shorter minimum time frame is established under state law**. CMS seeks comment on alternative timeframes, such as 48 hours for expedited requests and five calendar days for standard requests. Also, CMS seeks comment on operational or procedural changes payers or providers would need to make in their workflows or systems to reduce decision timeframes from 14 days to 7 calendar days (for standard prior authorization requests) and from 72 hours to 1 day or 24 hours (for expedited prior authorization requests).**

CMS clarifies that it is not proposing to require that impacted payers approve a request for prior authorization should that payer not meet the required standard or expedited decision timeframe. CMS suggests that if a payer fails to meet the timeline for approval or other decision, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete processing of the authorization or if there are other reasons for the delay in a decision. However, the agency also notes that some programs, such as Medicare Advantage, have regulations which include provisions for the failure to provide timely notice of a determination, which constitutes an adverse decision that may be appealed.

Key Requirement 3: Provide a clear reason for prior authorization denials

CMS proposes that, beginning January 1, 2026, impacted payers would be required to provide a specific reason for denied prior authorization decisions[6], regardless of the method used to send the prior authorization request. CMS further clarifies that some payers may also be subject to existing requirements to provide notice to patients or providers with the specific reason for the denial, and that this proposal builds upon those existing policies.

Key Requirement 4: Public Reporting on Prior Authorization Outcomes

CMS proposes to require impacted payers to publicly report[7] on certain metrics annually. For example, the initial set of metrics would be reported by March 31, 2026. CMS proposes that impacted payers make reports available annually on all of the following:

- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations, aggregated for all items and services.

[6] As a reminder, the Proposed Rule's interpretation of "items and services" does not include drugs. Therefore, payers would not need to provide a specific reason for denied prior authorization decisions for drugs as described in this Proposed Rule.

[7] CMS provides that impacted payers would publicly report aggregated metrics by posting them directly on the payer's website or via a publicly accessible hyperlink(s). This proposed reporting would be at the organizational level for MA, the state level for Medicaid and CHIP FFS, the plan level for Medicaid and CHIP managed care, and the issuer level for QHP issuers on the FFEs.

- The average and median time that elapsed between the submission of a request and a decision by the payer, plan or issuer, for expedited prior authorizations, aggregated for all items and services.

CMS clarifies the proposals would apply to any formal decision-making process where an impacted payer renders an approval or denial determination in response to prior authorization requests based on the payer's coverage guidelines and policies before services are rendered or items are provided. However, since the processes and standards for prior authorization applicable to drugs differ from other items and services, the Proposed Rule would not apply to any drugs that could be covered by the impacted payers (e.g., outpatient drugs, drugs that may be prescribed, those that may be administered by a physician, or that may be administered in a pharmacy, or hospital). The implementation date for many of the proposals in this section is January 1, 2026, however, some of the Medicaid FFS fair hearings and notice proposals that CMS provides would take effect before this date if the Proposed Rule is finalized.

Electronic Options for Prior Authorization

Regarding electronic options for prior authorization, CMS proposes to require impacted payers to implement an HL7 FHIR API that would work in combination with the adopted HIPAA transaction standard to conduct the prior authorization process. CMS emphasizes that it is not proposing changes to the requirement for covered entities, such as hospitals, to use the adopted HIPAA transaction standard, but is proposing to require that impacted payers develop and implement an API that works together with that standard and may support greater use of the X12 278 standard.[8]

Potential Application to Medicare FFS

While the Proposed Rule does not apply to Medicare FFS, CMS notes Medicare FFS is evaluating opportunities to improve automation of prior authorization processes and whether the Proposed Rule's policies could be implemented for the FFS program. In the Proposed Rule, CMS further details extensions and exemptions for Medicaid and CHIP FFS Programs and exceptions for QHP Issuers.

Gold-Carding for Prior Authorization

In the Proposed Rule, CMS indicates that it is aware of opportunities for payers to support efficiencies in the prior authorization process, including discretion about when to require prior authorization and basing such decisions on data and provider performance. For example, some payers have implemented ''gold-carding'' or similar programs to relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance. In "gold-carding" or similar programs, providers are relieved of requirements to submit prior authorization requests based on data indicating their adherence to submission requirements, appropriate utilization of items or services, or other evidence-driven criteria. CMS encourages payers to adopt gold-carding approaches that would allow more prior authorization exemptions or more streamlined reviews for certain providers, while reducing provider burden.

CMS seeks comment for consideration for future rulemaking on how to measure whether and how such gold-carding or prior authorization exemption programs could reduce provider and payer burden and improve services to patients. Also, CMS seeks comment on how CMS and other payers could ensure that such programs benefit diverse populations,

[8] ASC X12 Version 5010x217 278 (X12 278) for dental, professional, and institutional requests for review and response. The X12 278 standard was adopted for the prior authorization of medical items and services. Though payers are required to use the X12 278 version 5010 standard for electronic prior authorization transactions and providers are encouraged to conduct the transaction electronically, the X12 278 has not achieved a high adoption rate by covered entities.

including individuals in rural areas, individuals with disabilities, individuals with chronic illnesses, small and minority providers, and providers who disproportionately serve minority and underserved communities. CMS also seeks comment on the potential for adding a gold-carding measure as a factor in quality ratings for MA organizations.

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

In the Proposed Rule, CMS proposes a new measure for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS, as well as for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program, related to electronic prior authorization. CMS intends for the new measure to be titled ‘‘Electronic Prior Authorization”[9]. The proposed new measure would be included in the Health Information Exchange (HIE) objective for the MIPS Promoting Interoperability performance category and in the HIE objective for the Medicare Promoting Interoperability Program.

CMS proposes to require MIPS eligible clinicians to report this measure beginning with the CY 2026 performance period/CY 2028 MIPS payment year and for eligible hospitals and CAHs to report this measure beginning with the CY 2026 EHR reporting period. Although the measure would be reported beginning with the CY 2026 performance period, the agency also proposes that the measure will not be scored in 2026.

CMS seeks comment on a range of issues, including whether it should consider alternatives to the proposed numerator and denominator, and potential challenges providers will face in identifying those payers that have the PARDD API technology so that they can accurately include eligible prior authorization requests in the denominator.

Interoperability Standards for APIs

In the Proposed Rule, Table 8 (pg. 81) provides the interoperability standards for APIs proposed policies, Table 9 (pg. 82) provides the use of updated standards for APIs proposed policies and Table 10 (pg. 83-84) provides standards to support API implementation.

Requests for Information

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

In the Proposed Rule, CMS seeks input on barriers the healthcare industry faces to using industry standards and opportunities to accelerate adoption of data collection standards related to social risk

[9] Electronic Prior Authorization measure description: For at least one hospital discharge and medical item or service (excluding drugs) ordered during the EHR reporting period, the prior authorization is requested electronically from a PARDD API using data from CEHRT. The hospital or CAH would also be required to report the numerator and denominator for the measure or report an exclusion.
Numerator: The number of unique prior authorizations in the denominator that are requested electronically from a PARDD API using data from CEHRT.
Denominator: The number of unique prior authorizations requested for medical items and services (excluding drugs) ordered for patients discharged from the eligible hospital or CAH inpatient or emergency department (place of service (POS) code 21 or 23) during the EHR reporting period, excluding prior authorizations that cannot be requested using the PARDD API because the payer does not offer an API that meets the PARDD API requirements outlined in section II.D.3.a of this proposed rule.
Exclusions: Any eligible hospital or CAH that: (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable EHR reporting period; or (2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the PARDD API requirements outlined in section II.D.3.a of this proposed rule during the applicable EHR reporting period.
Note: The Electronic Prior Authorization measure description for MIPS eligible clinicians under the MIPS Promoting Interoperability Performance Category is available in the Proposed Rule (pg. 76).

factor data, including exchange of information with community-based organizations. For example, CMS seeks input on best practices regarding frequency of collection of social risk and social needs data, best practice regarding workforce training and potential policy levers CMS could use to better incentivize use and interoperability of social risk factor data. A complete list of questions is available in the Proposed Rule (pgs. 85-86).

Request for Information: Electronic Exchange of Behavioral Health Information

In the Proposed Rule, CMS seeks comment on how it might best support electronic data exchange of behavioral health information between and among behavioral health providers, other healthcare providers, and patients. CMS also seeks feedback on how it might best inform and support the movement of health data (and its consistency) to behavioral health providers as data is used to inform care and treatment for individuals with behavioral health needs. A complete list of questions is available in the Proposed Rule (pg. 87).

Request for Information: Improving the Electronic Exchange of Information in Medicare Fee-for-Service

In the Proposed Rule, CMS seeks input on specific changes or improvements in health IT that could assist providers or suppliers in submitting medical documentation to CMS and its contractors so that claims are not denied and/or are not deemed improper payments in Medicare FFS. A complete list of questions is available in the Proposed Rule (pg. 88).

Request for Information: Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health

In the Proposed Rule, CMS outlines various initiatives related to maternal health and seeks input regarding data elements and classes, and efforts to support gaps in standardization and harmonization, as related to maternal health data. The agency also seeks feedback regarding maternal health prior authorization processes and related impacts to care. A complete list of questions is available in the Proposed Rule (pg. 89-90).

Request for Information: Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)

In the Proposed Rule, CMS seeks input TEFCA advancement opportunities, particularly for health plans. A complete list of questions is available in the Proposed Rule (pg. 92).

What's Next?

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. This feedback will help inform our comments to the agency. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, AVP Regulatory Affairs and Public Policy in the Washington, D.C. office.